

1  
2 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3  
4 PROGRESS ON

5 MODERNIZING THE REGULATORY SYSTEM FOR

6 BIOTECHNOLOGY PRODUCTS

7 -- SECOND PUBLIC MEETING --

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11 EPA Region 6 Main Office  
12 1445 Ross Avenue  
Oklahoma Room, 12th Floor  
13 Dallas, Texas 75202

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17  
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1 P R O C E E D I N G S

2 MR. McNALLY: Good morning. Welcome to  
3 this morning's webinar and public meeting.

4 To kick things off, I'd like to  
5 introduce our regional administrator here in  
6 Region 6, Ron Curry. Ron has spent over three  
7 decades working at the federal, state and local  
8 levels. Ron is from New Mexico, and in addition  
9 to working for Governor Bill Richardson, I  
10 understand he's an avid hot air balloonist. So  
11 with that, I'm going to introduce Regional  
12 Administrator Curry.

13 MR. CURRY: Thank you, Bob.

14 Well, welcome you all to Dallas. It's  
15 very nice to have you here, and I really  
16 appreciate the fact that you're having this  
17 meeting and kind of updating what's been going on  
18 since the 1986 Coordinated Framework on the  
19 regulation for biotechnology.

20 Region 6 is made up of five states and  
21 66 tribes, and we often talk about the fact that  
22 on any given day we have between 62 to 68 percent

1 of all the oil and gas production in the United  
2 States, but more importantly, we have about 2.58  
3 million farmers working more than 230 million  
4 total agricultural acres within the region. And  
5 so we like to say that because we're not all oil  
6 and gas all the time, and sometimes the two come  
7 together in one form or another depending on that  
8 particular day.

9 But I just wanted to tell you that I  
10 appreciate the work that you're doing, because as  
11 you've heard the administrator talk about  
12 recently, everything that we do eventually ends up  
13 defining us in the terms of public health, and  
14 there's nothing more important in the  
15 biotechnology work that you all are doing that  
16 really says public health.

17 And one of the more interesting  
18 experiences that I had since I've been regional  
19 administrator here was that I was touring some  
20 agricultural communities in Louisiana and during  
21 the course of that tour, we were going out to see  
22 a large cotton farmer in northern Louisiana, and

1 one of the reasons we were out there to talk with  
2 him was about the Waters of the U.S. Rule and we  
3 were having a meeting in Monroe, Louisiana.

4 But what I found most interesting is  
5 when I got out there and met the guy he was an old  
6 high school classmate of mine from Sandia High  
7 School in Albuquerque, New Mexico, and he'd gone  
8 to the University of New Mexico and gotten his  
9 master's degree in classical art, and now he's a  
10 cotton farmer in northern Louisiana, and he had  
11 actually risen at one point or another to be  
12 president of the National Cotton Farmers  
13 Association.

14 And he told me that one of the reasons  
15 he was able to do that was talking about  
16 biotechnology and how it affected his crop and how  
17 successful he had been in going through and using  
18 the technologies that were available to them and  
19 trying to figure out how best to use the  
20 regulations to go forward with it. So for me,  
21 that was a real life experience coming from an old  
22 friend in high school that taught me the

1 importance of the work that you all do and how we  
2 go forward in looking at the framework of  
3 regulation.

4 So I just want to welcome you here to  
5 Dallas. I appreciate you being here, and I really  
6 appreciate the work that you do. So good luck to  
7 you and thanks for being here.

8 (Applause.)

9 MR. McNALLY: Thank you, Ron.

10 As many of you know, this is our second  
11 of three public meetings. The next one will be  
12 later this month on the West Coast. So I want to  
13 thank everyone for joining us here in Dallas, and  
14 those of you who are joining us from around the  
15 country on the Adobe Connect.

16 I'm going to cover the agenda and some  
17 housekeeping items here in a second, but first I  
18 want to introduce Jeff Morris, who is the deputy  
19 director of the Office of Pollution Prevention and  
20 Toxics, to give some welcoming remarks on behalf  
21 of EPA headquarters. So Jeff Morris.

22 MR. MORRIS: Thanks, Bob.

1           And like Regional Administrator Curry,  
2 I'd like to thank you for coming, both here and  
3 online. But also a career public servant, I'd  
4 like to thank you for your attendance.

5           It's clear now, as we're well into the  
6 21st century, more than ever that the implications  
7 of the work we do are just too important to not  
8 ask for, receive and incorporate in our work the  
9 insights of people like you. And indeed, ensuring  
10 the continued safety of biotechnology is a great  
11 big thing, and it's clear to us that responsible  
12 development can't be taken as a given, it's  
13 something that has to be watched over, evaluated  
14 and updated from time to time, and that's why  
15 we're here, to give the Coordinated Framework for  
16 biotechnology the good government attention that  
17 it deserves.

18           We're going to have a really good  
19 meeting today and we're going to have a good  
20 meeting because of you and your insights. So  
21 again, welcome, and thank you very much.

22           MR. McNALLY: All right. Thank you,

1 Jeff.

2 Let me cover the agenda here relatively  
3 quickly. So really there are three parts of this  
4 agenda I want to call your attention to. First is  
5 going to be a background and progress report to  
6 date that Robbie Barbero is going to do to  
7 highlight where we are in the process, and that's  
8 the first part.

9 The second part, and really the main  
10 part of the agenda, is a discussion of case  
11 studies. Now, as Jeff alluded to, we're looking  
12 for feedback and we're looking for clarifying  
13 questions from the public, so as part of the case  
14 studies we're going to present each case study and  
15 then at the end of each case study we're going to  
16 have about ten minutes for questions and answers.  
17 And if you have a question that comes to mind when  
18 you listen to one of the case studies there are  
19 index cards, so if you didn't pick any up out  
20 front, EPA staff can get you some cards. Just jot  
21 down the question that you have, signal to one of  
22 the EPA staffers, and at the conclusion of the



1 case study we'll come up and read those questions  
2 here from the podium. And put your name on it so  
3 we know who to refer to. And if for some reason  
4 we don't get the question right, don't hesitate to  
5 clarify, but hopefully in the question you write  
6 we can get the gist of what you'd like to hear.

7 Now, for those of you at home, I  
8 understand there's a little Q&A chat box you can  
9 do the same thing. Feel free to make use of that,  
10 send them, put your name on it as well, and then  
11 we'll read those here from the podium. And we  
12 hope to have about ten minutes of questions after  
13 each of the case studies.

14 So that's the second area for public  
15 engagement, but related to that, at the end I  
16 think we have a list of about a dozen people  
17 who've signed up to make public comment, and so  
18 each public commenter will have three minutes to  
19 make their comments at the end of the agenda this  
20 morning. And what we'd like you to do, because of  
21 the Adobe Connect, is come up to the podium here  
22 to make those comments so the people who are

1 tuning in around the country can see and hear you  
2 better.

3 So those are sort of the two  
4 opportunities, as Jeff alluded to, get some public  
5 input, public engagement.

6 And at the end we're going to talk a  
7 little bit about next steps moving forward in  
8 terms of our next meeting.

9 Now, a few housekeeping items. If you  
10 want to get a cup of coffee or something to eat,  
11 I'm told on the 5th floor here there is a food  
12 court, feel free to make use of that.

13 We have a break at around 11:15 and the  
14 good news is there are bathrooms on this floor,  
15 the bad news is you're going to need an EPA  
16 employee to use one of these badges to let you in  
17 the door to get to the restrooms. So the staff  
18 will be out there and the bathrooms are on the  
19 other side of the building, and again, at 11:15  
20 we'll make sure that flows back and forth pretty  
21 smoothly, but if in the interim you need to use  
22 the restroom, just let one of the EPA staff know

1 and they can let you in.

2 So that's an overview of the agenda. So  
3 with that, let me now introduce Dr. Robbie  
4 Barbero. He's going to give you sort of a summary  
5 of our progress to date, when we started last  
6 July, what we've accomplished thus far, what we're  
7 hoping to do today, and later in the morning's  
8 agenda we'll talk a little bit about the next step  
9 and our next meeting.

10 So with that, let me introduce Dr.  
11 Barbero.

12 DR. BARBERO: Thank you very much.

13 So my name is Robbie Barbero. I live in  
14 Washington, D.C. now, I work in the White House in  
15 the Office of Science and Technology Policy,  
16 although I'm originally from Grand Junction,  
17 Colorado, this isn't Grand Junction but it's  
18 closer to Grand Junction than Washington, D.C. is  
19 for sure.

20 So what I will walk through here today  
21 is what we are doing and why we are doing it and  
22 where we are in the process on this. I'll give

1 you a little bit of background and then talk you  
2 through the next steps.

3           So the background in this policy area is  
4 that in 1986 the White House Office of Science and  
5 Technology Policy issued a policy document called  
6 the Coordinated Framework for the Regulation of  
7 Biotechnology, and that was a document that  
8 described how the federal agencies would help to  
9 ensure the safety of the products of biotechnology  
10 using their existing authorities and especially  
11 how they would coordinate together in order to do  
12 so.

13           In 1992 that document was updated and  
14 then in the ensuing years after that, each of the  
15 agencies continued to issue guidance and to update  
16 their processes and also to work together to  
17 ensure the safety of the products of  
18 biotechnology.

19           In 2011 this administration issued an  
20 executive order that was broadly about how to  
21 improve regulation and regulatory review. And  
22 then just last summer, in July of 2015, the

1 Executive Office of the President issued a  
2 memorandum directing the primary agencies that  
3 have oversight responsibility for the products of  
4 biotechnology--the EPA, the FDA, and the USDA--to  
5 do three things, and I'll walk slowly through  
6 these so you can understand how they're related to  
7 each other and why we hope to accomplish these  
8 three things.

9           The first task is to update the Coordinated  
10 Framework for the Regulation of Biotechnology by  
11 clarifying the current roles and responsibilities.  
12 So much like in 1986, the current roles and  
13 responsibilities were articulated in the  
14 Coordinated Framework, the update we  
15 are working on will clarify the current roles and  
16 responsibilities. And in the materials that were  
17 handed out at the door when you came in, and, for  
18 those of you watching the webcast, the materials can be  
19 accessed through the docket, there is a table of  
20 oversight authority. That is just a  
21 draft version, for discussion purposes only, but in  
22 there you can get a sense of the current roles and

1 responsibilities of each of these agencies, vis-a-vis  
2 the products of biotechnology. So that's the  
3 first document that we are working on.

4           The second task then was that we were tasked  
5 with commissioning an expert independent analysis  
6 of the future landscape of biotechnology products.  
7 And so I'll have a little bit more information on  
8 that for you later, but we have asked the National  
9 Academies of Sciences to perform this analysis.

10           The third task then is to develop a  
11 strategic plan or a long-term strategy to ensure  
12 that the federal biotechnology regulatory system  
13 is prepared for these future products of  
14 biotechnology. So this is the document that will  
15 tie how the current system functions into what the  
16 future of biotechnology products looks like.

17           Let me give you a few more  
18 details on the memorandum that was issued in July  
19 of last year. So the goals and guidance were that  
20 the federal agencies that regulate biotechnology  
21 products should continually strive to improve  
22 predictability, increase efficiency and reduce

1 uncertainty in the regulatory process and  
2 requirements. This is consistent with the  
3 executive order from 2011 that I mentioned. And  
4 it is critical these improvements maintain high  
5 standards that are based on the best available  
6 science and deliver appropriate health and  
7 environmental protection, also, that they  
8 establish transparent, coordinated, predictable  
9 and efficient regulatory practices across agencies  
10 with overlapping jurisdictions, and promote public  
11 confidence in the oversight of the products of  
12 biotechnology through clear and transparent public  
13 engagement.

14 Now, the principles that guide the  
15 regulation of biotechnology products -- and these  
16 are drawn largely for the 1986 Coordinated  
17 Framework and the 1992 update -- are listed on  
18 this slide here, and I'll walk through them  
19 because I think that these are important. These  
20 are the guiding principles that our forebears laid  
21 out for us and that continue to help guide the  
22 federal government as it works to help ensure the

1 safety of the products of biotechnology.

2           The first is that the process used to  
3 make a product does not determine the safety of or  
4 risk posed by the product. Rather, it's the  
5 characteristics of the organism, the environment  
6 into which it will be introduced, and the  
7 application or intended use of that organization  
8 that determine the risk or lack thereof. This  
9 risk-based approach to regulation should  
10 distinguish between those organisms that require a  
11 certain level of federal action and those that do  
12 not. And also, a real critical advantage of this  
13 risk-based approach is that it properly protects  
14 public health and the environment against risks  
15 without hindering safe innovations.

16           Each agency was given a principle that  
17 it should use its existing statutory authorities  
18 and regulatory programs to help ensure the safety  
19 of biotechnology products, and these federal  
20 statutes and implementing regulations regulate  
21 products based on the specific uses which has the  
22 advantage of allowing for similar products,



1 whether made through biotechnology or other ways,  
2 to be treated similarly by regulatory agencies.

3 This is where the coordinated part of the  
4 framework comes from: the agency should seek to  
5 operate their programs in an integrated and  
6 coordinated fashion. And although there is some  
7 inconsistency in the statutory nomenclature, so in other  
8 words the laws that are underlying each of the agencies  
9 authorities -- the reviews conducted by each agency  
10 should be of comparable rigor. And also, a  
11 recognition that future scientific developments  
12 would lead to further refinements of federal  
13 policies.

14 The update to the Coordinated  
15 Framework -- and I will not walk through all of  
16 these steps but I put them up here because this is  
17 language that's drawn directly out of the July  
18 2015 memorandum, so I encourage you to look at it  
19 because these are the actual instructions that we  
20 were given -- is focused on clarifying  
21 which biotechnology product areas are within the  
22 authority and responsibility of each agency

1 clarifying the roles that each agency plays  
2 for those different product areas, and also, when  
3 appropriate, clarifying how the agencies  
4 communicate and coordinate among each other, as  
5 well as clarifying a mechanism and timeline for  
6 regularly reviewing and updating the Coordinated  
7 Framework.

8           So the long-term strategy had several  
9 components to it. The group is working on  
10 implementing the tasks they were charged  
11 with considering. This includes identifying  
12 timetables and mechanisms to work with  
13 stakeholders, to identify impediments to  
14 innovation, proactively engaging with the public  
15 to discuss how the federal government uses a risk-  
16 based scientifically sound approach, recognizing  
17 that the complexity of the current  
18 regulatory system makes it very difficult for  
19 small and mid size companies to navigate.

20           We're coordinating to develop the tools  
21 and mechanisms for assisting small businesses. And  
22 then initiating the development of a modernized,

1 user-friendly set of tools for presenting the  
2 regulatory agencies' authorities and practices and  
3 bases for decision-making. Recognizing  
4 that the science that underscores the regulatory  
5 system is critical, we are tasked to work with  
6 other federal agencies, as appropriate, to develop  
7 a coordinated and goal-oriented plan for supporting  
8 the science that informs regulatory activities. And  
9 then looking to the predictability and efficiency  
10 of the system, we have been tasked to conduct  
11 horizon scanning assessments of new biotechnology  
12 products and if any, identifying changes to  
13 authorities, regulations and policies that could  
14 improve agencies' ability to assess the impacts of  
15 future products of biotechnology.

16           And then finally, continuing to ensure  
17 the product evaluations are risk-based and  
18 grounded in the best science available, and when  
19 possible, regularly adjust regulatory activities  
20 based on experience with specific products.

21           So where are we so far? Well, as I've  
22 mentioned several times, in July of last year the

1 memorandum was issued. Shortly thereafter, the  
2 Executive Office of the President, USDA, FDA and  
3 EPA formed an interagency working group. This was  
4 established under an existing Emerging  
5 Technologies Interagency Policy Coordination  
6 Committee, and that group now has been meeting on  
7 a regular basis with a very high level of buy-in and  
8 support across all three of those agencies and the  
9 Executive Office of the President.

10 Last fall the working group issued a  
11 request for information which was really focused  
12 on helping the working group figure out how to  
13 address the tasks in that memorandum. There were  
14 over 900 comments that were submitted.  
15 And then in October of last year, the first of the  
16 public meetings that were committed to was held at  
17 FDA's White Oak campus. And in that one we spent  
18 a lot of time talking about what the memorandum  
19 was describing and the goals of it, and also had  
20 some presentations from each of the agencies about  
21 what they did in their purview in order to ensure  
22 the safety of products of biotechnology.

1           So one of the other things that I  
2 mentioned was that we had asked the National  
3 Academies of Sciences to conduct this landscape  
4 analysis of future products of biotechnology, so  
5 in January of this year, just two months ago, the  
6 Academies officially announced their study.  
7 They're calling it "Future Biotechnology Products  
8 and Opportunities to Enhance Capabilities of the  
9 Biotechnology Regulatory System."

10           I think one thing that's really  
11 important to note about the way that the National  
12 Academies operate is that once they have initiated  
13 a study, it is very much a hands-off approach for  
14 the organizations that are funding that study. So  
15 while the federal agencies that you'll hear from  
16 today are paying for this study and they work with  
17 the Academies to have the Academies understand what  
18 their goals of it are, the study is now in the  
19 hands of the National Academies of Sciences and  
20 they will deliver a product that the working group  
21 here can use in order to understand what the future  
22 landscape of biotechnology products will

1 look like.

2 And I've put in here some key points  
3 that the

4 Academies have written in their  
5 statement of tasks. All of this information is  
6 available on their website. You can see there's a  
7 URL near the bottom end of that slide there:  
8 [www.nas.edu/biotech](http://www.nas.edu/biotech). You can find the full  
9 statement of tasks there, and my understanding is  
10 that they will be announcing the study committee  
11 that will be performing this study in the coming  
12 days, and so when that is announced, you'll be  
13 able to learn from the National Academies about  
14 that committee, as well as when their meetings  
15 will be held. And I encourage all of you to  
16 engage with the Academies and help this body of  
17 experts understand what the future landscape of  
18 biotechnology products will look like.

19 So since the last public meeting, each  
20 of the agencies and the Executive Office of the  
21 President have reviewed all 900 of the responses  
22 to the RFI that were received. A little bit

1 later in this presentation I will give you a very  
2 high level summary of what those comments were so  
3 that if you have not taken the time to read all  
4 900 of them, you will at least be able to get a  
5 high level summary of them. And we are deeply  
6 involved in the actual process of working on this  
7 update to the Coordinated Framework and in  
8 developing a long-term strategy.

9           So we are now on March 9 which is our  
10 second public meeting here in Dallas, and what  
11 you'll hear from us today, after I've finished  
12 talking, I hope will be a much more interesting  
13 session where we will walk through case studies of  
14 a handful of hypothetical products and describe  
15 those products and then describe who would have  
16 oversight authority and why and what the various  
17 responsibilities of the developers and the  
18 regulatory agencies would be for those products.  
19 I think it should be very helpful because once you  
20 start talking about the details of products, you  
21 can get an understanding of what the current roles  
22 and responsibilities are.

1           And then there will be a third public  
2 meeting which has already been announced that will  
3 happen on March 30 in Davis, California. And more  
4 details about that will be posted on the  
5 USDA website and also placed in the docket.

6           And then per the mandate that we were  
7 given from the July 2015 memorandum, the update to  
8 the Coordinated Framework will be made available  
9 this spring/summer, and it will undergo a comment  
10 period before it is finalized. And so the  
11 materials that you received when you walked in  
12 today --the table of oversight and the case  
13 studies -- are available on the  
14 docket to those who are not here in person, the  
15 information that's presented in those documents will be  
16 incorporated into the update to the  
17 Coordinated Framework, and you will have an  
18 opportunity to comment on that before it's  
19 finalized.  
20

21           So you can think of today as us  
22 presenting this to you verbally and having some



1 discussion about them, but to the extent that you  
2 have a strong interest in publicly commenting on  
3 them, you will be able to do so when the draft  
4 document is placed into the Federal Register.

5           Okay. So I'd like to briefly walk  
6 through the summary of the RFI comments. So  
7 written and oral comments were submitted by a wide  
8 variety of organizations, including industry, academia,  
9 trade associations, consumer groups, environmental  
10 advocacy groups, individual consumers, foreign  
11 governments and other organizations. The agencies  
12 received and reviewed slightly more than 900  
13 written comments, and the agencies also received  
14 and reviewed the oral comments that were made at  
15 the October 30 public meeting, and what follows is  
16 a brief summary of those responses.

17           So in the first category of responses  
18 are what I'll call general responses, and there  
19 were comments that favored the use of risk-based,  
20 science-based regulatory systems and a Coordinated  
21 Framework that facilitates or at least does not  
22 stifle innovation and also reduces burden to

1 industry, especially to small businesses. There  
2 were requests for a balance between the level of  
3 regulation and the degree of risk posed by a new  
4 trait or an existing trait in its introduction  
5 into an environment. There were commenters that  
6 noted that the complexities of the current  
7 regulatory system made it difficult for small  
8 companies and academics to navigate. There were  
9 also comments that sought uniform regulation  
10 across products rather than regulation based on  
11 the process of production. There were calls for  
12 funding agencies to support more risk assessment  
13 research for biotechnology products.

14 There were discussions on expanding  
15 exemptions and fast tracking product reviews for  
16 familiar or well known products. There were  
17 recommendations for regulating based on process  
18 using genetic engineering, in and of itself, as  
19 the trigger for mandatory pre-market review of  
20 products with independent testing of ecological  
21 and health risks. Recommendations that agencies  
22 harmonize their regulatory approaches with CODEX

1 guidelines and coordinate with international  
2 regulatory partners.

3           Some commenters noted that the range of  
4 traits in GE products on the market is very small,  
5 and therefore, past safety evaluations may not or  
6 cannot apply to the more diverse technologies and  
7 types of products that are being developed right  
8 now. And there were comments suggesting that  
9 manufacturers publish safety data very early in  
10 the development process so that the public and  
11 others can review the data.

12           In the RFI comments related to public  
13 education awareness and outreach, there were  
14 comments that supported agencies taking action  
15 regarding public education awareness and training  
16 on genetic engineering very generally, as well as  
17 on specific applications. Suggestions for  
18 facilitated coordinated public outreach sessions  
19 with the agencies. Suggestions to develop simple  
20 and easy to understand information about how  
21 agencies regulate products and coordinate their  
22 respective roles and responsibilities and provide

1 information on a single U.S. Government  
2 website.

3           Commenters suggested that sharing  
4 scientific evidence and information underlying  
5 regulatory decisions with the public should happen  
6 more often. Suggestions to develop security  
7 training programs for researchers and hobbyists in  
8 biotechnology products. Suggestions to establish  
9 standards for information sharing and harmonizing  
10 protocols across the agencies. One comment  
11 suggested that by filling regulatory gaps,  
12 clarifying agency roles and responsibilities and  
13 conducting risk assessments for novel products  
14 the Federal Government would build public confidence in  
15 biotechnology products.

16           In the category that I will call  
17 recommendations related to coordination among  
18 regulatory agencies, there were a handful of  
19 comments. There were suggestions that  
20 coordination among regulatory agencies, including  
21 on risk assessments and data collection on  
22 unintended consequences should happen. There was

1 a specific suggestion to create a review board  
2 consisting of representatives from all three  
3 regulatory agencies to review all new genetically  
4 engineered and non-genetically engineered crops.  
5 There was a suggestion to establish a group of  
6 experts under or at the National Academies of  
7 Sciences, with representation from each regulatory  
8 agency, to determine whether a product is exempt  
9 from review and creating and publishing decision  
10 trees for developers to determine whether products  
11 are exempt.

12           There were suggestions to streamline regulatory  
13 process and procedures to expedite reviews or  
14 approvals. Suggestions to coordinate among  
15 relevant agencies such that the burden on industry  
16 with respect to obtaining multiple permits for  
17 conducting trials could be reduced. There were  
18 several comments that suggested that the  
19 establishment of a central coordinating office or  
20 a single window for entry for service of  
21 regulatory submissions for biotechnology products  
22 would be a good idea. There were suggestions about

1 grouping similar products into categories and  
2 appointing a primary agency in charge of oversight  
3 for each product area.

4           And then finally, the final bucket here  
5 is one that I'll just call other recommendations,  
6 and some of these are very specific and some are a  
7 little bit more general. There were comments  
8 around identifying and establishing appropriate  
9 restrictions related to genetically engineered  
10 crop plants, restrictions on where and how  
11 genetically engineered crops are grown so as to  
12 minimize the potential for cross-contamination and/or  
13 restrictions on privately owned genetically  
14 engineered seed stock.

15           There was a suggestion to adopt a U.S. federal  
16 regulatory policy for low level presence of  
17 genetically engineered sources in food, feed and  
18 seed. Suggestion to clarify how products of  
19 genome editing techniques are regulated or will be  
20 regulated. Suggestions to fund risk assessment  
21 research to support creation of regulatory  
22 exemptions. There were several comments

1 indicating that confidential information business  
2 status should be granted less freely. Comments to  
3 exempt DNA from the Toxic Substances Chemical Act  
4 review process. Suggestions to impose more post-  
5 market requirements and lighten pre-market  
6 requirements.

7           Suggestions to assess the risk of  
8 products evolving beyond designed capacity and to  
9 identify the possible interactions between those  
10 products and the environments into which they will  
11 be released or in which they'll be kept.

12           Suggestions around clarifying agency rules on  
13 field trials and dual use products, as well as on  
14 clarifying the regulation of genetically  
15 engineered insects. And then suggestions related  
16 to implementing post-market surveillance programs  
17 to ensure the traceability of genetically  
18 engineered ingredients or components of products.

19           So now that we've walked through the  
20 summary of where we are and why we are doing this,  
21 we will transition into our discussion of the case  
22 studies of hypothetical products. And what we

1 will do is we'll have someone from each of the  
2 agencies come up and talk through this table here.  
3 So this is a table of what we can sort of loosely  
4 call agency protection goals for the regulation of  
5 biotechnology products and these are the primary  
6 statutory authorities that the USDA, EPA and FDA  
7 use to help ensure the safety of the products of  
8 biotechnology. And there is much more detail  
9 available on each of these from the agencies and I  
10 encourage you, to the extent that you're  
11 interested, to really dig in on those. But these  
12 protection goals and statutes should give you a  
13 high level of understanding of the tools that the  
14 agencies have available. And once we have walked  
15 through these, then we'll start to do each of the  
16 case studies and walk through them.

17 Neil, are you ready to go first?

18 MR. HOFFMAN: Sure. Thank you, Robbie.

19 I'm Neil Hoffman, I'm with the USDA, the  
20 Animal Plant Health Inspection Service in the  
21 program Biotechnology Regulatory Services.

22 The USDA typically regulates under two



1 statutes, one is the Animal Health Protection Act.  
2 We have a program in APHIS called Veterinary  
3 Services whose mission is to protect livestock  
4 from animal pest and disease risks. And then the  
5 second statute is the Plant Protection Act, and  
6 the program that I'm in, Biotechnology Regulatory  
7 Services, regulates organisms that are plant pests  
8 and our protection goal is to protect agricultural  
9 plants and agriculturally important natural  
10 resources from damage caused by organisms that  
11 pose plant pest or noxious weed risks.

12 And next I'll turn it over to my  
13 colleague, Mike Mendelsohn from the EPA.

14 MR. MENDELSON: Good morning. I'm Mike  
15 Mendelsohn from the EPA's Office of Pesticide  
16 Programs. I'm in the Biopesticide and Pollution  
17 Prevention Division. I'm going to briefly talk  
18 about protection goals that we have for  
19 pesticides.

20 There are primarily two statutes that we  
21 work under, the Federal Insecticide, Fungicide and  
22 Rodenticide Act, and our protection goals there

1 are to eliminate unreasonable adverse effects upon  
2 man and the environment. For environmental and  
3 occupational risks, this involves comparing  
4 economic, social and environmental risks and  
5 benefits associated with pesticide use, and for  
6 dietary or residential human health effects the  
7 sole standard is the safety of exposure.

8 In addition to FIFRA, or the licensing  
9 of pesticides law EPA administers the Food, Drug and  
10 Cosmetic Act provision for pesticide residues in  
11 food or feed. The protection goal there is to  
12 ensure dietary exposure to pesticide chemical  
13 residues in or on food are safe.

14 Next I'll turn it over to Dr. Mark Segal  
15 for the Toxic Substances Control Act.

16 DR. SEGAL: So I'm Mark Segal from the  
17 Office of Chemical Safety and Pollution  
18 Prevention. This office also  
19 implements the Toxic Substances Control Act, and  
20 that act is a bit of a catchall act. It excludes  
21 from regulation those substances that are used for  
22 food or drugs or cosmetics or pesticide uses.

1 Other substances including microorganisms are  
2 subject to oversight under that act, and within  
3 that act we intend to ensure the manufacture,  
4 processing, distribution and commerce, use or  
5 disposal of chemical substances -- again,  
6 microorganisms are included in that -- or any  
7 combination of such activities with such  
8 substances does not present an unreasonable risk  
9 of injury to health or to the environment.

10 And I guess I will now turn it over to  
11 Ritu.

12 DR. NALUBOLA: Thank you, Mark.

13 So I am Ritu Nalubola. I'm a senior  
14 policy advisor in the Office of Policy in the  
15 Commissioner's Office at FDA.

16 FDA regulates a number of different  
17 products and we derive our authorities primarily  
18 from two different statutes, the Federal Food,  
19 Drug and Cosmetic Act and the Public Health  
20 Service Act. Our mission includes ensuring that  
21 food is safe, sanitary and properly labeled, food  
22 meaning both food for humans as well as for

1 animals, ensuring that human and veterinary drugs  
2 are safe and effective, ensuring there is a  
3 reasonable assurance of safety and effectiveness  
4 of devices intended for human use, ensuring  
5 cosmetics are safe and properly labeled, ensuring  
6 public health and safety are protected from  
7 electronic product radiation, and we also regulate  
8 tobacco products.

9 DR. BARBERO: Okay, great. Thank you.

10 So before we start into the first case  
11 study, let me give you a little bit of an  
12 understanding of what these case studies are and  
13 why they were chosen, and then we'll start to walk  
14 through them. As a reminder, as we walk  
15 through these case studies if you have any  
16 questions, and I think those questions should be  
17 this or that is unclear, please write them down on a  
18 note card and please put your name on it so that  
19 we know who asked that question, and then we will  
20 respond to those questions at the back end of the  
21 case study. And for those of you who are online,  
22 please do the same, please write your name and the

1 question that you have around that specific case.

2           So these case studies are  
3 intended to provide general information to  
4 developers who believe they may have or are  
5 uncertain as to whether they do have a  
6 biotechnology product that is subject to  
7 regulation under one or more of the laws that we  
8 just walked through and that are described in the  
9 Coordinated Framework for Regulation of  
10 Biotechnology. And  
11 we will walk through these case studies as a  
12 means of demonstrating how a developer might  
13 navigate the regulatory framework starting from  
14 research activities in the lab through to full  
15 commercialization of the product. Certain products  
16 may also have post-market and monitoring and  
17 reporting requirements that are not described in  
18 this document, and more information on these  
19 requirements and other requirements is available  
20 in the relevant agency's regulations and guidance.  
21           I'd also like to note once more that the  
22 contents of the document provided,

1 as well as what we will be discussing today, are  
2 still in draft form and under review at the  
3 various agencies, and when they are finalized,  
4 they'll be placed in the update to the Coordinated  
5 Framework and will undergo a formal comment  
6 period.

7 So these case studies were selected  
8 because they cover multiple biotechnology product  
9 areas with different characteristics and intended  
10 uses and because they illustrate how the agencies  
11 coordinate with each other under the Coordinated  
12 Framework. There are other nuances such as  
13 exemptions for certain products within the  
14 regulatory system that could affect the path a  
15 product takes, and these will be touched on in the  
16 case studies as appropriate.

17 The case studies presented here cover  
18 typical relevant milestones from the  
19 identification of a potentially commercializable  
20 biotechnology product to research and  
21 development activities in the laboratory and field  
22 and to commercialization. Recognizing that

1 intricacies do exist in any regulatory system,  
2 FDA, EPA and USDA welcome and encourage developers  
3 of potential biotechnology products to contact  
4 them at the earliest stages so that any questions  
5 about regulatory status, safety and/or  
6 effectiveness, when appropriate, can be identified  
7 and addressed.

8           And finally, the materials and facts and  
9 scenarios that we will be discussing here are  
10 purely hypothetical and presented for discussion  
11 purposes only, so these should not be taken --  
12 this is the part the lawyers make me read --  
13 these should not be taken to reflect the views or  
14 policies of the federal agencies or any official  
15 position on these products.

16           With that, let's start with our first  
17 case study which is a hypothetical genetically  
18 engineered corn with pesticidal properties. So  
19 the way that we'll do this is I will describe the  
20 product and then introduce which agencies have  
21 oversight authority and why, and then we'll have  
22 someone from each of those agencies come up and

1 walk you through the details of their oversight.

2           So in this case study, a field crop  
3 which is used for food for humans and animals is  
4 genetically engineered with a plant pest component  
5 to have pesticidal activity against certain  
6 insects. The corn produces a protein with  
7 pesticidal activity. The gene encoding the  
8 protein is isolated from the bacterium *Bacillus*  
9 *thuringiensis* and is controlled by the cauliflower  
10 mosaic virus derived 35S promoter. The genetic  
11 construct is actually integrated into a binary  
12 vector and is introduced into the corn genome  
13 using *Agrobacterium*- mediated transformation.  
14 Also encoded on that vector, and stably  
15 incorporated in the corn genome, is a gene that  
16 enables selection of transformants during the R&D  
17 process.

18           So which agencies have oversight and  
19 why? Well, the GE corn is engineered with a plant  
20 pest component, so the USDA will have oversight  
21 authority. The DNA codes for a pesticidal trait,  
22 so EPA will have oversight. And the GE corn is



1 going to be used for food for humans and/or  
2 animals, so FDA will also have oversight. So our  
3 first one will be Neil.

4 MR. HOFFMAN: So I'll walk you through  
5 how USDA would regulate through the stages of R&D,  
6 field trials and commercialization.

7 So the USDA does not have the authority  
8 to regulate gene organisms in contained  
9 facilities, so pretty much the only involvement  
10 the USDA would have during the R&D phase would be  
11 in case genetically engineered organisms are moved  
12 from state to state or imported into the U.S., and  
13 for those sorts of movements, an authorization  
14 would be needed, either a notification or a  
15 permit. In this case a corn qualifies for  
16 notification so the GE corn could be moved under  
17 notification.

18 For the small or large scale field  
19 trials, an authorization would be needed in  
20 addition now for environmental release. The USDA  
21 complies with NEPA and NEPA is an environmental  
22 statute to inform decision-making. It does not

1 give us any additional authority. Typically when  
2 we do a permit activity, permits under our NEPA  
3 implementing regulations are categorically  
4 excluded from NEPA. If there are new species or  
5 novel modifications that raise new issues,  
6 then that's an exception to the categorical  
7 exclusion and typically we do  
8 an EA.

9           Prior to commercialization, the  
10 companies can collect information and submit what  
11 we call a petition for non-regulated status. If  
12 we grant non-regulated status, then the developer  
13 no longer needs to get authorization for the  
14 import, interstate movement or environmental  
15 release. And typically when we grant non-  
16 regulated status, we would do either an  
17 environmental assessment or an environmental  
18 impact statement to comply with our NEPA  
19 obligations.

20           And I'll turn it over to Mike.

21           MR. MENDELSON: Okay. I'll talk  
22 shortly here about how EPA oversees a GE corn

1 trait with pesticidal properties. So during the  
2 R&D phase, EPA is largely not involved, small  
3 scale testing the same. Now, prior to large scale  
4 trials, which would be over ten acres, typically  
5 developers submit an experimental use permit  
6 application and that experimental use permit  
7 oversees the field trial.

8 In this case, the case study involves  
9 food or feed, so in order for that food or feed to  
10 get into the food supply, for that pesticide residue,  
11 there has to be a temporary tolerance or tolerance  
12 exemption for the residues of the pesticidal  
13 traits. And what we call these traits in plants,  
14 we call it a plant-incorporated protectant, and  
15 that's a two component item, so it would be both  
16 the genetic material that's necessary for the  
17 production of the trait, as well as the pesticidal  
18 trait itself.

19 Prior to commercialization, that would  
20 require a pesticide registration for the PIP, or  
21 the plant- incorporated protectant, as well as a  
22 tolerance or tolerance exemption for the pesticide

1 residue in food.

2 Now I'll turn it over to Ritu for FDA.

3 DR. NALUBOLA: So where FDA would come  
4 into this case study is because our oversight is  
5 actually on the finished food and its intended  
6 use, and in this case it would be the corn that is  
7 going into the food supply either as a food for  
8 humans or for animals. And under the Food, Drug  
9 and Cosmetic Act, the developer has the  
10 responsibility and legal duty to ensure that the  
11 food they market is safe and lawful, and to help  
12 industry to comply with their responsibility, what  
13 FDA has set up is a voluntary consultation process  
14 whereby a developer may provide relevant  
15 scientific and technical information to FDA for  
16 our consideration and begin the voluntary  
17 consultation process.

18 So in this case, at a point during  
19 either small scale trials or prior to starting the  
20 large scale field trials, we would encourage the  
21 developer to come in and begin the voluntary  
22 consultation process. However, prior to

1 commercialization we do strongly recommend that  
2 the developer complete the voluntary consultation  
3 process with FDA, and we can talk about the  
4 voluntary consultation process either during the  
5 Q&A or a couple more case studies that will also  
6 touch on this.

7 But essentially, during this  
8 consultation process, FDA would review all of the  
9 information that is submitted by the developer.  
10 We use a multi-disciplinary comparative approach  
11 to assess the safety of the food from the GE  
12 plants. The approach involves comparing key  
13 aspects of the new food to one that has been  
14 historically safely consumed.

15 And under this consultation process,  
16 the FDA evaluates all of the data and the  
17 information. Once we have addressed all of the  
18 safety and regulatory issues and those are  
19 resolved and the data and information support the  
20 conclusion that the food from this new variety is  
21 safe or is as safe as food from the conventional  
22 varieties, we would then conclude the

1 consultation. And once we complete the  
2 consultation, a letter would be sent to the  
3 developer indicating that FDA has no further  
4 questions, and also reminding the developer that  
5 it is their responsibility and a legal obligation  
6 is still upon them to ensure the safety of the  
7 food.

8 At the end of this consultation process,  
9 FDA also makes information available to the public  
10 by posting on the internet our response letter and  
11 a note to the file which provides a summary of the  
12 relevant information.

13 DR. BARBERO: Thank you very much. We  
14 will do the second case study that's in this  
15 category of food for humans and animals, and then  
16 do Q&A if anybody has questions.

17 So the second product is a hypothetical  
18 genetically engineered herbicide-tolerant canola.  
19 This is a field crop used as food for humans  
20 and/or animals and it is genetically engineered  
21 with a plant pest component to tolerate an already  
22 registered herbicide. This particular herbicide

1 has not previously been used on plants for food  
2 for humans and/or animals.

3 If you're following along in the case  
4 study handbook, we are on case study #3. Sorry  
5 about the confusion. That's why I was also  
6 flipping pages. So we're on case study #3. We're  
7 not going to do case study #2 today.

8 So this hypothetical genetically  
9 engineered herbicide-tolerant canola is a field  
10 crop used as food for humans and/or animals. It's  
11 genetically engineered with a plant pest component  
12 to tolerate an already registered herbicide, but  
13 this particular herbicide has not previously been  
14 used on plants used for food for animals.

15 The product is a domesticated canola, genetically  
16 engineered to tolerate an herbicide by increasing  
17 the expression of a gene found in the canola  
18 genome using a constitutive 35S cauliflower mosaic  
19 promoter. Extracted canola oils will be  
20 used for biodiesel production and the remaining  
21 biomass will be processed into meal for food for  
22 animals and the animal or products of the animal

1 may subsequently be consumed by humans. The 35S  
2 cauliflower mosaic virus promoter and the canola  
3 gene are both introduced into the plant using a  
4 biolistic approach.

5           Because the canola gene confers  
6 resistance to an herbicide, no additional  
7 selectable marker is required. This particular  
8 herbicide, which we will call Herbicide X, is  
9 already registered by the EPA but is not yet  
10 approved for use on animal food crops. In this  
11 scenario, a single developer produces both the  
12 herbicide resistant canola and the herbicide.

13           So which agencies have oversight and  
14 why? The herbicide-tolerant plant is genetically  
15 engineered with plant pest components, therefore,  
16 USDA will have oversight. EPA regulates the new  
17 use of the herbicide itself, because remember that  
18 the herbicide had not previously been used on  
19 plants used for food for animals, but not the  
20 genetic material used to engineer the plant. And  
21 FDA will have oversight because the GE canola will  
22 be used for food for humans and/or animals.



1           MR. HOFFMAN: So our oversight is very  
2 similar to the previous example that we discussed.  
3 During the R&D phase notifications would be needed  
4 for interstate movement or import. We would not  
5 be regulating in the greenhouse. For  
6 environmental release, a notification would be  
7 required. This herbicide-tolerant canola is  
8 not a new species or a novel modification that  
9 raises new issues, so the notification for the  
10 release into the environment would be categorically  
11 excluded from NEPA. If we recieved a petition for  
12 non-regulated status, then we would most likely do  
13 an EA associated with that petition analysis.

14

15           MR. MENDELSON: I'm going to talk about  
16 for the herbicide-tolerant canola; the part EPA  
17 plays, and as was mentioned earlier, this is not a  
18 PIP or a plant- incorporated protectant, we focus  
19 on the actual herbicide itself. So at small  
20 scale field testing, it's not applicable unless  
21 the Herbicide X treated canola enters the  
22 food supply. Regarding large scale field trials,

1 if the company was going to go ahead and test it  
2 on greater than ten acres, this is an herbicide,  
3 they would have to get an experimental use permit  
4 for, and if the canola was going to enter the food  
5 or feed supply, there would have to be a temporary  
6 tolerance exemption. In practice this doesn't  
7 happen very often at all. Usually the developers  
8 test the herbicide-tolerant crops at small scale  
9 and don't come into EPA until they are seeking a  
10 registration or amendment.

11 So before they can commercialize the  
12 herbicide for that use, it allows it to be used on  
13 the herbicide-resistant crop. And you might ask  
14 yourself why would they need to do this. Because  
15 the use rates and the timing are often different  
16 for the herbicide for use on the herbicide-  
17 tolerant crop, that would require either an  
18 amendment to a registration, or more likely what  
19 happens is the company comes in with a new product  
20 to amend the use of that particular herbicide, and  
21 as well, they come in with a petition to amend the  
22 tolerance to allow for that residue to be in the

1 food or feed.

2 So primarily where EPA focuses for the  
3 herbicide-tolerant crops is on the herbicide  
4 itself and that would be for amending the use of  
5 that herbicide for use on the crop for the timing  
6 and rate, and then also to amend the tolerance to  
7 allow for residues of that herbicide on the crop.

8 DR. NALUBOLA: So even in this case, as  
9 in the previous one, our oversight would be on the  
10 finished food that's intended for humans or for  
11 animals, and as I mentioned in the previous case,  
12 we do have a voluntary consultation process that  
13 is intended for industry to come in and consult  
14 with us so any food safety or other regulatory  
15 issues can be resolved. And as an example, one of  
16 the questions that the food safety or other  
17 regulatory issues that may come up may include the  
18 presence of an unapproved food additive in the  
19 resulting food product, in which case that would  
20 trigger a pre-market approval process.

21 An important point that I should also  
22 note in this case, as I did in the past, is that

1 although the consultation with FDA is voluntary,  
2 compliance with the relevant statutory provisions  
3 is not. The compliance with law is mandatory, the  
4 consultation process is voluntary and intended to  
5 help industry to meet their legal obligations.

6 Just to elaborate a little bit on the  
7 consultation process, we do have guidance that  
8 talks about these procedures, and during the  
9 initial consultation phase, the GE developers may  
10 meet with FDA and explain their product to us, we  
11 may provide feedback about the kinds of data  
12 and information and testing that may be needed for  
13 a complete safety assessment. And during these  
14 initial consultations is also where FDA would  
15 provide feedback to the firm on the specific plant  
16 variety, the types of safety testing, legal  
17 questions that need to be addressed.

18 The final consultation process begins  
19 once the GE plant developer completes its safety  
20 assessment and submits a summary of the assessment  
21 to FDA, and this is where, as I mentioned in the  
22 previous case study, we would do a multi-

1 disciplinary comparative approach to look at the  
2 safety of the product.

3           Some of the questions that we may  
4 consider and that may be evaluated by FDA include, for  
5 example, uses of the food, including in humans  
6 and in animals, the purpose or intended technical  
7 effect of the modification, as well as the  
8 expected effect on composition and  
9 characteristics, and then a comparison of this  
10 composition and characteristics with other  
11 commonly consumed varieties or the parental  
12 variety with a specific focus, for example, on  
13 nutrients or anti-nutrients or toxicants that may  
14 be naturally present in the plant and food, as  
15 well as whether the genetic modification altered  
16 in any way at all the potential for the food to  
17 induce an allergic response. These are just  
18 examples of some of the things that we would  
19 consider.

20           And as I mentioned in the previous case,  
21 once all of the safety and regulatory issues are  
22 resolved and the data and information logically

1 support the conclusion that the food from the GE  
2 plant is as safe as from a conventionally bred  
3 variety, we would then conclude the consultation  
4 and information about the completed consultation  
5 and our no questions letter to the developer are also  
6 provided on our website.

7 So let me stop there.

8 DR. BARBERO: Have we gotten any  
9 questions from this group? So both of these  
10 questions are from Judith McGeary. Did I get that  
11 right? Okay, great.

12 So the first question is do any of the  
13 agencies have specific standards that the  
14 developer's data must meet such as  
15 one, sample sizes or statistical power, or two,  
16 scope of effects studied and what results are  
17 measured. Did I get that question right?

18 Anybody want to take a stab at answering  
19 that first?

20 DR. HOFFMAN: So yes, the USDA provides some  
21 guidance about the number of field trials that  
22 need to be done. I'm sorry, it's been a while so

1 I don't actually remember, but for example, there  
2 needs to be field trials done in different  
3 geographies where that crop will be used, it needs  
4 to be replicated a certain number of times.

5 DR. BARBERO: Sample sizes, statistical  
6 power, scope of effects studied, what results are  
7 measured.

8 DR. HOFFMAN: So statistical power,  
9 that's really not -- that would probably be more  
10 for the EPA. I'll let them discuss that. The  
11 scope of effects, there's a list of about 20 or 30  
12 parameters that are typically encouraged to be  
13 looked at for these field trials. We're  
14 interested in plant pest effects, so often disease  
15 susceptibility is an important characteristic for  
16 us but then there are other agronomic phenotypes  
17 that are looked at, as well as the vigor of the  
18 plant and its predilection to become weedier, that  
19 sort of thing. We do have a list of things.

20 So I'll pass the microphone over to Ritu.

21 DR. NALUBOLA: For FDA I was only going  
22 to say that we do have guidance on our website.

1 The 1992 policy document, as well as in 1996, we  
2 provided guidance on our voluntary consultation  
3 procedures.

4 I think some of these questions about  
5 the scope of effects and what results are  
6 measured, they're so dependent on the specific  
7 case, the plant, the food and really its intended  
8 use, that I think this is why the initial  
9 consultations are so helpful from our perspective  
10 because depending on the specific case, we can  
11 then look at the circumstances and the unique  
12 situation and then provide more information to the  
13 developer on the specific testing and safety  
14 assessment data that need to be collected.

15 MS. McGEARY: If I could, if you could  
16 maybe use the two case studies that you have put  
17 forward this morning as an example of what sort  
18 parameters and what you'd be expecting them to  
19 provide data on.

20 DR. BARBERO: So Ritu, there was a  
21 followup question on that. Let's have Mike do  
22 this, but I think it's worth thinking about for



1 either or both of those case studies, what some of  
2 those additional details would be.

3 MR. MENDELSON: From the EPA side, to  
4 answer Judith's question, we have a number of data  
5 requirements for microbial pesticides. Right now  
6 we do not have the data requirements in place for  
7 the plant-incorporated protectants, but much of  
8 the plant-incorporated protectants that have been  
9 developed, such as a BT protein, are microbially  
10 based. We utilize a number of pesticide  
11 assessment guidelines that are in place that  
12 address many of the points that you raise as far  
13 as statistical power, how the studies are to be  
14 run, et cetera.

15 Right now we've also had numerous what  
16 we call scientific advisory panels to get outside  
17 expertise providing input on how to run the  
18 studies. In 2001, EPA did a reassessment for the  
19 plant-incorporated protectants and looked at the  
20 types of data we were requiring. I think right  
21 now the best way to look at how we evaluate these  
22 are through our BRADs, or Biopesticide

1 Registration Action Documents. These are  
2 available on the same website which listed this  
3 meeting. There's a site for plant-incorporated  
4 protectants, it lists through there. For each of  
5 the registered plant-incorporated protectants it  
6 provides the details as far as how we assess all  
7 those data points. And essentially, just briefly,  
8 we look at human health, and then non-target  
9 effects and environmental fate.

10 DR. BARBERO: And Mike, while you're up  
11 there, there's another question specific to EPA  
12 for this.

13 MR. MENDELSON: Okay. The question  
14 here is: In addressing the herbicide impacts, do  
15 you consider the actual field formulations used or  
16 just a declared active ingredient?

17 So for the herbicide risk assessment,  
18 that's the chemical herbicide risk assessment, EPA  
19 considers the active ingredient portion for the  
20 tolerance and for the uses as far as the generic  
21 data, but there's also product-specific data  
22 that's required for the end use product as well.

1 So there's generic data on the active ingredient  
2 and there's a subset of product-specific data  
3 that's required on the actual formulation.

4 MS. McGEARY: And how is that data used?

5 DR. BARBERO: Can you repeat the  
6 question?

7 MR. MENDELSON: Yes. How is the data  
8 used for the formulation for the herbicide? It  
9 would basically be for the end use product  
10 primarily the acute toxicology and the precautionary  
11 labeling for that product.

12 DR. BARBERO: Thank you for those  
13 questions. We have another  
14 question here from someone else.

15 How might regulatory oversight differ if  
16 the herbicide tolerance in the canola resulted  
17 from targeted nucleotide changes in an endogenous  
18 canola gene without incorporation of exogenously  
19 provided DNA? And this is from John Salmeron --  
20 did I get that correct? -- from Precision  
21 Biosciences. Did I pronounce your name correctly?  
22 John Salmeron. Okay

1 Who would like to take this question?

2 MR. HOFFMAN: I'll go first. So our  
3 regulation is triggered based on these plant pest  
4 sequences, and so one way of doing what you're  
5 suggesting is to often use a plant pest sequence  
6 to add a type of endonuclease and then to make  
7 directed change, and then to remove the plant pest  
8 sequences in a subsequent generation. And so  
9 there have been cases where just a deletion has  
10 been made, and we have not regulated those. They  
11 have no plant pest sequences and it's just a  
12 simple deletion. Chances are you wouldn't make an  
13 herbicide tolerant phenotype that way. If you  
14 made modifications this way, we probably would  
15 regulate.

16 DR. BARBERO: I saw you nodding your  
17 head, so it seems like you got an answer to your  
18 question. Okay.

19 I have three questions here and we have  
20 just about five minutes left so we'll do these  
21 three questions and then move on to the next case  
22 study. These are from Mary Tedei Edens -- did I

1 say that right?

2 MS. TEDEI: Marie Tedei

3 DR. BARBERO: Marie Tedei. And the  
4 Eden's is?

5 MS. TEDEI: Eden's Garden CSA Farm.

6 DR. BARBERO: From Eden's Garden CSA  
7 Farm. Great.

8 So I will read all of your questions and  
9 then we'll see if we can field them appropriately  
10 for you. So the first question is: How are  
11 economic benefits weighed against risks to  
12 environment, health and the public?

13 MS. TEDEI: Those were the criteria that  
14 were up there, health risks to the environment and  
15 to the public health.

16 DR. BARBERO: Yes, that's right.  
17 Environment and public health.

18 MS. TEDEI: Versus the economic benefit.  
19 I'm curious as to how that's weighed.

20 DR. BARBERO: Okay. The second question  
21 is: What is considered an unreasonable or adverse  
22 risk of injury, for example, or unreasonable or

1 adverse effect?

2           And then the third one is: Under what  
3 circumstances would a petition be granted non-  
4 regulatory status or exemptions?

5           MS. TEDEI: During the R&D process.

6           DR. BARBERO: During the R&D process.

7           MS. TEDEI: So before we know that it's  
8 okay. While we're experimenting with it, under  
9 what circumstances do we just waive that.

10           DR. BARBERO: Under what circumstances  
11 would that be granted during the R&D process.

12           Okay. So it's probably best if  
13 everybody takes a turn at answering all three of  
14 these. Neil, do you want to go first? And I'll  
15 give you these three questions.

16           And thank you for your questions.

17           MR. HOFFMAN: I'm not sure I remembered  
18 everything, so work with me here. Okay. So how  
19 are economic benefits weighed against the risks?  
20 So one of the reasons we put the protection goals  
21 in the very first slide was that that is where our  
22 authority comes from, and we do not regulate based

1 on economic risks that are unrelated to plant pest  
2 and noxious weed risks. So our agency would  
3 consider whether or not there are risks that are  
4 to plant health, and if there weren't risks to  
5 plant health or animal health, then we would not  
6 even consider those risks. So that's the first  
7 one.

8 What is considered an unreasonable  
9 adverse risk? I've sort of alluded to that.  
10 We're looking for what is going to affect the herd  
11 of livestock, what is going to affect American  
12 agriculture. We're looking for weed risks and  
13 risks such as disease. We're looking at effects  
14 that might impact beneficials that impact  
15 agriculture, such as pollinators and that sort of  
16 thing.

17 And the third one was: Under what  
18 circumstances would a petition -- gee.

19 DR. BARBERO: During the R&D process  
20 would you grant exemption?

21 MS. TEDEI: I don't remember which of  
22 the three of you had the different -- because it

1 went kind of quickly.

2 MR. HOFFMAN: Now I understand the  
3 question. During the R&D process the strategy is  
4 to impose conditions that keep the GE organism  
5 confined so there is no exposure.

6 Risk is exposure times a harm, or if the  
7 exposure is zero, there is essentially zero risk.  
8 So that's the paradigm we're working under. If  
9 it's truly confined, there should be no risk, and  
10 so we don't grant any non-regulated status under  
11 R&D conditions, it's the permit or the  
12 authorization requires that conditions to keep that  
13 organism confined to a specific area.

14 MS. TEDEI: But then that's not clear in  
15 what we have. So to a lay person I'm going: Oh,  
16 my, we're just issuing waivers for this stuff that  
17 we don't know what it's going to do.

18 MR. HOFFMAN: There's no waiver in that  
19 case.

20 Who wants to go next?

21 MR. MENDELSON: I'll go.

22 I think, Marie, you first two questions



1 related to the EPA slide, so the first question  
2 had to do with how we use economic analysis with  
3 respect to the unreasonable adverse effects, and  
4 so that's a statutory issue with EPA under the  
5 Federal Insecticide, Fungicide and Rodenticide  
6 Act. So when we make a licensing decision for a  
7 registration, we take into consideration both  
8 risks and benefits and so the economic benefit is  
9 part of that, but in the cases we've seen thus  
10 far, where the economic benefit or the public  
11 interest has come in mostly is when we have a  
12 registration for a new plant- incorporated  
13 protectant where we have to ask for new data that  
14 we had not anticipated. So there's a provision in  
15 the law that when you conditionally register a new  
16 active ingredient, or in this case a new plant-  
17 incorporated protectant, and you're conditionally  
18 -- you're asking for data, so you register it and  
19 the applicant will be sending in the data after  
20 it's registered, that decision has to be in the  
21 public interest, and that's where we primarily  
22 look at the economic benefit. So that's the one

1 question.

2 SPEAKER FROM AUDIENCE: Hey, Mike. Do  
3 you want to clarify food different from FIFRA  
4 finding?

5 MR. MENDELSON: Yes. Excellent. Thank  
6 you. So that's for the licensing of the pesticide.  
7 For the setting the tolerance of the amount of  
8 residue of the pesticide in the food, or in this  
9 case for a plant- incorporated protectant in food,  
10 we do not -- it's based upon there's a reasonable  
11 certainty of no harm, so that the economic part  
12 doesn't play for the food aspect, but it's for the  
13 licensing of the pesticide, so that's where we  
14 look at the economics.

15 It says: What is considered an  
16 unreasonable adverse risk? And we would say  
17 unreasonable adverse effect. Again, that weighs  
18 both risk and benefit part of it. To date we  
19 haven't had to invoke the benefit part because all  
20 of the PIPs that we've registered have been  
21 determined to be safe.

22 MS. McGEARY: But going to the case

1 studies, what would an unreasonable adverse effect  
2 be or what would an unreasonable risk potentially  
3 be?

4 MR. MENDELSON: Well, it depends, but  
5 certainly if it's something that caused grave harm  
6 to humans or to non-targets. That would then be  
7 balanced with the benefits.

8 MS. McGEARY: The economic benefits.

9 MR. MENDELSON: Correct.

10 MS. McGEARY: The economic benefits to  
11 the public you're saying.

12 MR. MENDELSON: Yes, to the public.

13 DR. BARBERO: So I think we may have  
14 covered those. We are running up against our time limit  
15 and we've got two questions  
16 that are relevant to this case study. I'm  
17 going to bring Mike back up because they're both  
18 about pesticides. But one of them is from Martin  
19 Levin: Who is responsible for monitoring  
20 compliance with the pesticide tolerance, how is it  
21 done, and how frequently is it done?

22 And then this one doesn't have a name.

1 What is your name, sir? Jeffery Campbell asked:  
2 Is there any testing or are the guidelines on tank  
3 mixes of pesticides used on crops?

4 So I'm going to just give you these  
5 pesticide questions and then we'll move on to the  
6 next case study after this.

7 MR. MENDELSON: Okay. As far as the  
8 pesticide tolerance, just generically for  
9 pesticide residues in food, we work together with  
10 our colleagues at the Food & Drug Administration,  
11 and largely they're involved with monitoring, also  
12 USDA has a program in place where they look at  
13 pesticide residues in food.

14 As far as is there any testing or  
15 guidelines on tank mixes of pesticides used on  
16 crops, there's guidelines on tank mixes used on  
17 crops, and this is not really a biotech question  
18 per se, but typically what's required is that the  
19 companies do a compatibility assessment and that  
20 is often put on the label, so whether that  
21 particular product is compatible for certain tank  
22 mixes. That data is often not submitted to the

1 agency but the companies are required to make sure  
2 that it's compatible with what's listed on the  
3 label for tank mixing.

4 DR. BARBERO: Okay. Are we ready for  
5 the next case study?

6 Thank you for your questions, really  
7 appreciate it. And for those of you who submitted  
8 online but we didn't get to those, we'll follow up  
9 with you and capture all those questions. So  
10 thank you very much.

11 So the next case study, if you are  
12 following along in the booklet that we have is  
13 actually case study #8, and this is a product for  
14 biomedical applications.

15 So this is a hypothetical genetically  
16 engineered rabbit. It's an animal that is  
17 genetically engineered to make a therapeutic  
18 protein insulin, recombinant insulin for treatment  
19 of humans that lack the ability to make this  
20 protein or have an inactive form of it. The  
21 rabbit genome is genetically engineered to express  
22 recombinant human insulin for use as a therapeutic

1 protein in the treatment of human patients that  
2 lack adequate functional insulin. The human  
3 insulin coding sequence is controlled by a 5'  
4 bovine alpha S(1) casein promoter sequence to  
5 allow expression of recombinant insulin protein  
6 in the rabbit's milk.

7           The genetic construct is micro injected  
8 into fertilized oocytes and the issuing embryos  
9 are transferred to the oviduct of a recipient  
10 animal. Also encoded in the vector and stably  
11 incorporated into the rabbit genome are upstream  
12 and downstream regulatory sequences that enable  
13 expression of the included codon- optimized human  
14 insulin coding sequence and insulator sequences to  
15 minimize the position effects at the locus of  
16 genome integration. Once a germ-line transgenic  
17 animal is identified (a potential founder animal).  
18 it is bred to establish a  
19 lineage of rabbits used in insulin expression in  
20 milk.

21           So which agencies have oversight and  
22 why? Well, the FDA will have oversight because the

1 recombinant DNA construct encoding the recombinant  
2 human insulin is integrated into  
3 the genome of the genetically engineered rabbit.  
4 Therefore, it is regulated as a new animal drug by  
5 the FDA Center for Veterinary Medicine. And also  
6 the recombinant insulin that is purified from the  
7 rabbit's milk is regulated as a human drug by the  
8 FDA Center for Drug Evaluation and Research.

9 MS. NALUBOLA: So this case study is  
10 really intended to illustrate the coordination  
11 that would occur within FDA between the two  
12 centers that Robbie just indicated. This would be  
13 between FDA Center for Veterinary Medicine and the  
14 Center for Drug Evaluation and Research, CDER.

15 So the developer's responsibilities  
16 during GE rabbit and insulin development, example,  
17 at the lab, the farm or the clinic,  
18 responsibilities of the developer really with  
19 respect to interactions with FDA would begin very  
20 early in the product development process. Under  
21 the Act -- here I'm referring to the Food, Drug  
22 and Cosmetic Act -- in general, a new animal drug

1 is deemed unsafe unless FDA has approved an  
2 application for that particular use or unless,  
3 among other things, it is for investigational use  
4 and is subject to an exemption.

5 So the developer must initiate  
6 discussions with FDA's CVM once the founder animal  
7 has been developed and the lineage is actively  
8 being characterized. The center would at this  
9 point open an investigation new animal drug file,  
10 INAD, into which the developer could submit data  
11 and information pertaining to this GE rabbit  
12 lineage. The developer also must obtain what is  
13 referred to as an INAD exemption, investigational  
14 new animal drug exemption. This would be from the  
15 FDA's CDER center, and that would need to be  
16 obtained prior to clinical trial activities  
17 associated with the recombinant insulin product  
18 derived from this line of GE rabbits.

19 The development of the GE animals  
20 constitutes clinical investigation because it  
21 involves studying the effectiveness of the drug in  
22 the target species and the effects of the rDNA



1 construct, including those of its expression  
2 products on the animal containing it. In general,  
3 the INAD regulations specify requirements related  
4 to shipping, labeling, recordkeeping, animal  
5 disposition and environmental considerations.

6 We also recommend that the developer  
7 schedule a meeting with us soon after the INAD  
8 file has been established. And then developers of  
9 human medical products involving GE animals should  
10 come in to discuss with FDA much earlier than for  
11 medical products not involving GE animals because  
12 the use of GE animals raises additional questions.

13 With respect to prior to  
14 commercialization, there are additional processes.  
15 The Act requires that a new animal drug be the  
16 subject of an approved new animal drug application  
17 based on a demonstration that it is safe and  
18 effective for its intended use. The developer  
19 must submit to FDA what is referred to as a new  
20 animal drug application for the rDNA construct in  
21 the rabbit, and the developer, among other things,  
22 must demonstrate containment measures to make sure

1 that the animal does not enter the food supply.  
2 This includes byproducts and derivatives,  
3 including appropriate disposal mechanisms. As is  
4 the case for all NADAs, after completion the  
5 agency will then post a summary of the information  
6 of the NADA file, including information used to  
7 assess the safety.

8 In addition, the developer must submit  
9 also a new drug application, and this would be for  
10 the insulin, for the recombinant insulin product.  
11 In order to receive FDA approval of the drug, the  
12 developer must demonstrate to FDA that the GE  
13 rabbit meets the FD&C Act's safety and effective  
14 standards pertaining to the animal and human  
15 drugs.

16 One other point, the developer must also  
17 submit to FDA under NEPA an EA, environmental  
18 assessment, or a claim of categorical exclusion as  
19 part of its NADA or NDA submission. For the GE  
20 animal, we would recommend that the EA focus on  
21 environmental issues, potential impacts related to  
22 the use and disposal of the GE animal and its

1 final product. The appropriate scope and content  
2 of the EA may vary widely depending on the GE  
3 animal product, the claim and conditions of these,  
4 and therefore, we recommend that the developer  
5 contact and work closely with us on all of these  
6 issues.

7 Another point to make is that in this  
8 case study, graphics as well as the narrative,  
9 while we don't cover the post-market monitoring  
10 and recordkeeping requirements, that may also come  
11 into play. And throughout the process, the  
12 developer should keep FDA's CVM and CDER apprised  
13 of activities related to their NADA and NDA  
14 applications, and adequate communication is  
15 important because we do have two different  
16 centers, one with the GE animal and the other the  
17 insulin.

18 We have, as I mentioned for the foods  
19 case, we do have several guidances that we have  
20 issued for industry. GFI-187 in particular is  
21 relevant for the GE animal piece of it, and then  
22 the new drug application requirements, we have

1 several guidances on our website for that as well.

2 So I will stop here.

3 DR. BARBERO: Thank you, Ritu.

4 Any questions from the audience on this  
5 one or from online?

6 SPEAKER: I was just going to ask one  
7 simple question. What is CDER that you mentioned  
8 in that last slide?

9 DR. BARBERO: So the question was about  
10 some of the acronyms that were used. The FDA has  
11 multiple centers that have responsibilities for  
12 different types of products, and there are two  
13 different components of FDA that would have  
14 oversight responsibilities for the genetically  
15 engineered animal that is used to produce a  
16 therapeutic drug for humans. One is the Center  
17 for Veterinary Medicine, CVM, and that is the  
18 center that would look at the animal itself. And  
19 the other one is the Center for Drug Evaluation  
20 and Research, and that is the center that would  
21 look at the actual human drug that was being  
22 produced by the animal. And they would work

1 together to make sure that both the animal and the  
2 drug have proper oversight.

3

4 SPEAKER: That would have been my  
5 question: Who oversees the safety and effect of  
6 the animals, the  
7 CVM?

8 DR. BARBERO: That's right. So the  
9 question was: Who oversees the safety of the  
10 animal? And that would be the Center for  
11 Veterinary Medicine which is a center in FDA. So  
12 FDA is wholly responsible, but there are two parts  
13 of FDA with oversight authority:  
14 one that is the Center for Veterinary  
15 Medicine, so they are the experts on the animal;  
16 and the other one is the Center for Drug  
17 Evaluation, and they would look at the drug that  
18 was being produced by the animal. And they would  
19 work together to make sure that all of the right  
20 information was there.

21 MS. NALUBOLA: Sorry if I went too  
22 quickly, but one of the things that we would look

1 at as part of this case study, what you mentioned  
2 about containment, and in containment measures  
3 multiple levels of containment would be part of  
4 the evaluation and to make sure and demonstrate  
5 that those containment measures are in place and  
6 are being implemented properly to ensure that to  
7 the extent these are animals are also food producing  
8 animals that they do not enter the food  
9 supply. We don't know about rabbits, but we have,  
10 like for example, chickens or goats that have been  
11 previously looked at.

12 DR. BARBERO: Can you speak to FDA's  
13 ability to engage experts from other agencies?

14 MS. NALUBOLA: I mean, I don't know if  
15 in this particular case whether and how USDA would  
16 fit in, but as part of the evaluation, to the  
17 extent there is a role for other agencies or  
18 expertise that we could tap into from other  
19 agencies, we definitely do look at that,  
20 especially for environmental considerations.

21 DR. BARBERO: Right. Actually, I think  
22 that your point was that as a farmer you saw

1 rabbits as a farm animal, and so the question was  
2 why would USDA not be involved. But I think this  
3 is a lot of information that we're sharing with  
4 you all, but if you go back to one of those  
5 principles that guide the oversight of the  
6 products of biotechnology, it was that it's the  
7 characteristics of the product but also the  
8 intended application of the product that matters.  
9 Right? And not the way that it was made. And so  
10 in this case the FDA looks at it and says the  
11 application here is the production of a drug and  
12 we have a Center for Veterinary Medicine that  
13 knows how to assess the safety of changes made to  
14 animals and a Center for Drug Evaluation and they  
15 can do this.

16 This question is from Dan Nuckols:  
17 Please describe post-commercialization policing  
18 framework, i.e., longitudinal studies to identify  
19 intended and unintended consequences. So that's  
20 for this rabbit?

21 MR. NUCKOLS: It would be helpful if we  
22 had an actual case study, maybe, one that you had

1 some data on post-commercialization instead of  
2 emphasizing all these prior to commercialization.

3 MS. NALUBOLA: So I mentioned that there  
4 would be some post-market reporting and  
5 recordkeeping and several requirements that would  
6 apply here. I'm not quite sure about specific  
7 longitudinal studies but there would be as part of  
8 the NDA, the new drug application, as well as  
9 NADA, the new animal drug application, there would  
10 be certain post-approval records and surveillance  
11 that would have to met. I don't know if that  
12 gives you the description that you're looking for,  
13 but I'm not quite sure about your example about  
14 the longitudinal studies.

15 MR. NUCKOLS: Well, how do you ascertain  
16 that you've reached the goal that completes the  
17 mechanisms that you set out to do five years post?  
18 What's that framework that you can circle back and  
19 do an evaluative study?

20 DR. BARBERO: One way to break this question  
21 up is to consider the animal and the drug separately.  
22 You looked at the safety of the animal,



1 how would you ensure the conclusions were still  
2 valid? And for the drug as well. I think  
3 you could use this  
4 specific example to talk about that a little bit.

5 MS. NALUBOLA: I actually don't have  
6 more details to share. I mean, I can definitely  
7 get you in touch with people in the two centers  
8 who will be able to better answer that question.

9 MR. MENDELSON: I would be able to  
10 answer on EPA's side, not for this case study but  
11 he mentioned more broadly.

12 DR. BARBERO: Okay. So if you want to  
13 backtrack to one of the other ones.

14 MR. MENDELSON: Just to address your  
15 issue for post-commercialization, how do we look  
16 at the effects later on, and I think particularly  
17 EPA has a process of reassessing pesticide risk  
18 every 15 years. In the biotech area we've been  
19 more aggressive in that area. The first plant-  
20 incorporated protectants were registered in '95,  
21 in 2000 we did a complete reassessment, for BT  
22 corn we did a complete reassessment in 2010. And

1 often what we do at that point we look at the  
2 current science.

3 In the case of BT corn, what happened  
4 was there had been a number of meta studies that  
5 had been done and so it essentially pointed to the  
6 fact that it was -- at least for some of the non-  
7 target insect scenarios in that area,  
8 environmental fate, we kind of backed off from  
9 some of the requirements that had been more  
10 onerous based on the scientific advisory panel  
11 advice around the time of registration. So there  
12 had been a lot of work in the academic community,  
13 a lot of data had been generated, and we evaluated  
14 that and used that to kind of recalibrate for  
15 those particular products.

16 But we're continually reassessing  
17 pesticides at EPA and there's a 15-year cycle, but  
18 in the biotech area we've been a little bit more  
19 aggressive than that.

20 MR. HOFFMAN: So there was a question  
21 that pertained to the USDA involvement in some of  
22 this animal research. If the animal had been a

1 cow, would USDA APHIS or FSIS have had any  
2 responsibility for the animal entering the market  
3 supply?

4 APHIS Veterinary Services has relatively  
5 limited role in the regulating of GE animals, and  
6 to kind of give you an idea of what they would be  
7 involved in, sometimes animals are being made to  
8 be disease-resistant and there's the possibility  
9 of somehow those animals, particularly if they  
10 were imported into the United States, maybe now  
11 they're a carrier for a disease that's not in the  
12 United States. In that situation, APHIS VS would  
13 be very interested in regulating that. But let's  
14 suppose that animal was made resistant to a  
15 disease that's already very widespread in the  
16 U.S., they probably would just defer to the FDA.

17  
18 And as far as FSIS, FSIS is really blind  
19 to whether it's a GE organism or not. They have  
20 responsibility to inspect whatever they do, meat  
21 and eggs, I'm not even sure, but whatever it is  
22 they would do it independent of whether it was

1 genetically engineered.

2 I don't know if that answered the  
3 question.

4 DR. BARBERO: It was an online question.

5 So we are up against our time limit for  
6 a break. We will take a break now. We are only  
7 five minutes behind schedule, of which I am very  
8 proud because I like to stay on time. And we will  
9 reconvene in 20 minutes and go through the rest of  
10 the case studies. Thank you.

11 (Whereupon, at 11:21 a.m., a brief  
12 recess was taken.)

13 DR. BARBERO: Thank you, everybody. We  
14 will start now. Thank you so far for the great  
15 questions. For those of you who are online, I  
16 apologize that we're not able to ask and answer  
17 all of your questions. We are able to print those  
18 out and so we will be keeping a record of those  
19 questions and we'll try to find a way to consider  
20 those moving forward. I would like to request that if  
21 you are submitting questions online that you put your  
22 name and organization in there so that we know

1 who's asking those questions.

2           Now it's time to move on to the case  
3 studies around microbial products for pesticide or  
4 industrial applications. So the first case study  
5 will be, if you are following along in the book,  
6 case study #6. It's a hypothetical genetically  
7 engineered microbial pesticide. So this is a  
8 phytopathogenic bacterium that is genetically  
9 engineered to express a pesticidal substance that  
10 protects against insects. The genetically  
11 engineered living bacterium will be used to  
12 inoculate crops to increase their defense against  
13 insects.

14           The product is a bacterium *Clavibacter*  
15 *xyli*, that is genetically engineered to express a  
16 delta- endotoxin protein used for controlling a  
17 pest originally isolated from the bacterium  
18 *Bacillus thuringiensis*, so the protein was  
19 isolated from that other bacterium. The gene is  
20 controlled by a promoter that is derived from a  
21 bacterium. The gene, the promoter and the  
22 selection marker that is used to select

1 transformed bacteria during R&D are part of a  
2 vector that is transformed into the C.

3 xyli via electroporation. It is an  
4 endophytic bacterium and the genetically  
5 engineered bacterium will be used to inoculate  
6 corn to induce insect resistance in the plant.

7 Now, which agencies have oversight and  
8 why? The USDA because the C. xyli is a plant pest,  
9 and the EPA because the product is a genetically  
10 engineered microbial pesticide.

11 MR. HOFFMAN: So the USDA would regulate  
12 this organism similar to some of the cases that  
13 I've mentioned before, but there are some  
14 differences because this is a plant pest, we're  
15 not just talking about engineering a crop with a  
16 plant pest sequence, this is a plant pest. And so  
17 some of the differences are that it could not  
18 qualify for notification authorization, so it  
19 would only be done under permit. And in terms of  
20 commercialization, they could petition for non-  
21 regulated status but chances are because it's a  
22 plant pest, we may not grant it non-regulated

1 status, and this might be the sort of situation  
2 where we would only consider it under permit.  
3 This is a hypothetical, we haven't encountered  
4 this situation before, so it's not really clear  
5 what we would do.

6 MR. MENDELSON: So this is a microbial  
7 pesticide which is genetically engineered, and I  
8 want to point out little differences between this  
9 and the plant- incorporated protectants which, for  
10 instance, we mentioned a BT crop earlier. In the  
11 case of a plant- incorporated protectant, EPA  
12 regulates the genetic material and the pesticidal  
13 substance in the plant, in the case of a microbial  
14 pesticide, we're regulating the entire  
15 microorganism, so that's kind of a little nuance  
16 there.

17 So for small scale testing, also for a  
18 genetically engineered microbial pesticide there's  
19 a provision in our regulations that those that  
20 want to test these in the field have to notify EPA  
21 about the nature of the organism and what they've  
22 done, the field test, et cetera, to see whether an

1 EUP is necessary. So normally for most  
2 pesticides, an experimental use permit is not  
3 required under ten acres, but for a genetically  
4 engineered microbial pesticide, we require the  
5 developers to notify us and to essentially ask the  
6 question is an EUP necessary. So if we make that  
7 decision, then they have to come in for an  
8 experimental use permit; if they test over ten  
9 acres of land, they have to come in for an  
10 experimental use permit.

11 And at that stage also, of course, if  
12 any of this is going to get into the food supply,  
13 they have to get a temporary tolerance exemption.  
14 And the tolerance exemption essentially is a legal  
15 limit to allow for that residue in food or feed.  
16 Prior to commercialization, before they wanted to  
17 sell this, they would have to get a registration  
18 for the microbial pesticide and they would have to  
19 get a tolerance or tolerance exemption for  
20 residues of the pesticide in food or feed.

21 So again, one of the primary differences  
22 between the GE microbial pesticide and the PIPs is



1 they have to come in under ten acres and ask the  
2 question as to whether an EUP is necessary, and we  
3 regulate the entire microorganism as a pesticide  
4 product.

5 DR. BARBERO: We will do the next case  
6 study and then we can do Q&A on both of these case  
7 studies.

8 So the next case study is case study #7,  
9 if you're following along in the book. It's a  
10 hypothetical genetically engineered algae used for  
11 biofuel production. So this is a unicellular algae  
12 that is genetically engineered with a plant pest  
13 component to produce industrial oils for  
14 conversion into biofuels. The eukaryotic  
15 microalgae *Chlamydomonas reinhardtii* are  
16 genetically engineered to produce an enzyme that  
17 increases lipid biosynthesis. The extracted oils  
18 are later converted into biodiesel.

19 The enzyme that increases lipid  
20 production was originally isolated from the  
21 soybean, *Glycine max*. The soybean gene is  
22 controlled by the cauliflower mosaic virus 35S

1 promoter that we've heard about before. The  
2 plasmid encoding the enzyme promoter and selection  
3 marker is introduced into the algae through  
4 electroporation. The algae will be cultivated in  
5 an open pond system and the remnants of the  
6 microalgae are intended for use as fish food.

7 Which agencies have oversight and why?  
8 USDA has oversight because the microalgae are  
9 engineered with a plant pest component which is  
10 the cauliflower mosaic virus 35S promoter. The  
11 EPA has oversight because the microalgae are  
12 engineered for industrial use with genes from  
13 outside the genus of Chlamydomonas, and as such,  
14 they fall under the rules implementing the Toxic  
15 Substances Control Act. And the FDA has oversight  
16 because the microalgae will be used for animal  
17 food.

18 MR. HOFFMAN: So again, just trying to  
19 focus on how this would be different than in the  
20 previous examples. The main difference here is  
21 this is something that is very new to our  
22 organization, and so they need authorization for

1 movements under R&D, when they go outside, they'll  
2 need authorization. Because we've never seen it,  
3 this would probably trigger our exception to the  
4 categorical exclusion under NEPA. This is a new  
5 species. There may also be a novel modification  
6 that raises new issues. So chances are we would  
7 do some sort of environmental assessment prior to  
8 field testing.

9           And I think the rest would be the same,  
10 it's possible that they could petition for non-  
11 regulated status. This is not a plant pest, it's  
12 just engineered with a plant pest sequence, so we  
13 may be in a position where we could grant it non-  
14 regulated status depending on the circumstances of  
15 this situation.

16           DR. SEGAL: Okay. So we have a new  
17 microorganism because it has genes from more than  
18 one genus. We call it intergeneric. It is being  
19 used for a purpose that's not excluded under TSCA.  
20 So in the first phase of the development of this  
21 microorganism if the initial development, the  
22 initial research and development occurs in a

1 contained system, there's no reporting requirement  
2 under TSCA, and contained can be anything from a  
3 lab, a contained greenhouse, or even something  
4 like a contained photobioreactor. In our  
5 regulations we have specified certain good  
6 laboratory practices that should be followed, but  
7 again, no reporting that's required at that stage.

8           The next stage or the next two stages,  
9 under TSCA, or under our regulations we don't  
10 differentiate in terms of scale of release. If  
11 something is released, if it occurs in an 800  
12 liter mini pond or if it occurs in a one-acre  
13 raceway pond, it's a release, and therefore, the  
14 vehicle that's used is the TSCA experimental  
15 release application.

16           Now, obviously, the review of these  
17 applications will vary based on the complexity and  
18 the scope of the intended release, but the actual  
19 manner of reporting to EPA will be the same. Not  
20 only do we have 60 days to review the case, if  
21 there are complications that occur, of course,  
22 during the course of our review, that timeframe may be

1 extended. There may be some needs to, for  
2 example, modify the intended research program.

3 So we're going to assume that all has  
4 gone well with the TERA, all the reviews have been  
5 helpful and data have been gathered during the  
6 course of the TERA that are useful, both for the  
7 developer in making their product and for us when  
8 we do our subsequent reviews for  
9 commercialization. When the time comes that the  
10 developer feels they're ready for  
11 commercialization, at least 90 days prior to the  
12 time they are ready to initiate production, they  
13 are required to report to us and provide us with  
14 microbial commercial activity notes

15 One thing I did not stress in the research and  
16 development phase is that in order to go to the  
17 field, EPA must issue an approval of the research  
18 program. However, when commercialization takes  
19 place, EPA is not a registration statute, so we're  
20 not going to be issuing approvals for  
21 commercialization.

22 We will review for risk for not only the

1 described preferred use that the manufacturer has  
2 intended but for all plausible uses of this  
3 particular microorganism that we have been able to  
4 ascertain whether here from the submittal or from  
5 whatever sources we have available. We have to do that  
6 because if we choose not to regulate at the end of  
7 our risk assessment and we say nothing, then those  
8 other plausible uses can be established either by  
9 this submitter or by somebody else.

10           So we will review in detail this case  
11 and there are several potential outcomes. One is  
12 the one I've just suggested: that we find that all  
13 the details provided shows there's no potential to make  
14 a finding that there may be an unreasonable risk  
15 to human health or the environment for any  
16 plausible use, in which case EPA remains silent.  
17 At the end of 90 calendar days, if the submitter  
18 has not heard from us, they can initiate  
19 production. If they do so, they will notify us  
20 with a notice of commencement, and this particular  
21 organism can be placed on the inventory of  
22 chemical substances.

1           If, on the other hand, we find that  
2           there are uses or there are production methods  
3           that may present an unreasonable risk, we can  
4           either unilaterally establish limitations, or  
5           preferably, we will go into negotiation with the  
6           submitter to mitigate risks, to find ways to  
7           mitigate risks, such that we don't have that  
8           finding. We will, at the end of the period, need  
9           to come up with a significant new use regulation,  
10          but at that point, again, the submitter will then  
11          be able to go into production under those  
12          conditions and the organism can be listed on the  
13          inventory of chemical substances.

14                 And I'll turn it over to Ritu.

15                 MS. NALUBOLA: So again, FDA would have  
16          oversight here because the micro algae will be  
17          used as animal food, as food for animals, and so  
18          FDA has oversight on that aspect. Prior to small  
19          scale trials or large scale trials, at this point,  
20          if not earlier during the product development  
21          process, we encourage the developer to come  
22          consult with us so that any food safety and

1 regulatory issues can be considered. And  
2 definitely prior to commercialization, we strongly  
3 encourage that the developer come and consult with  
4 us.

5 One of the questions that will need to  
6 be considered is whether the use of the micro  
7 algae for animals involves the presence of an  
8 unapproved food additive which would then, as I  
9 mentioned in the previous case too, trigger pre-  
10 market food additive approval process. And there  
11 are a couple of guidances that I think would be  
12 relevant that we have issued in the past that  
13 would be relevant here. One specifically is  
14 guidance to industry GFI-221 that talks about what  
15 different factors must be considered and the  
16 different pieces of information that would need to  
17 be provided as part of the food additive  
18 submission. And the guidance GFI-53 that specifically  
19 talks about products that are diverted for food  
20 for fish. So those are two different documents  
21 that would be relevant.

22 DR. BARBERO: Okay. Time for questions.



1 This question is from Allison Exall. Did I say it  
2 right? And help me to make sure that I'm getting  
3 this correct. Does the product have to be  
4 genetically engineered to be covered by this  
5 initiative? What about a product that is not  
6 genetically engineered, such as a seaweed extract?

7 So let me understand. You're asking  
8 about the product that might be used for food  
9 applications?

10 MS. EXALL: Or like sprayed on plants,  
11 crops. All these case studies are genetically  
12 engineered products. This whole conversation only  
13 addresses that?

14 DR. BARBERO: So you're asking a broader  
15 level question here, and we do have an answer.

16 MR. McNALLY: Yes. Thanks. Bob  
17 McNally, the director of the Biopesticide Program.

18 I think you're talking about a substance  
19 more like a biostimulant, and we're working on a  
20 policy on whether those are regulated or not.  
21 We're going to have a policy out later in the year  
22 because we know there are issues with those where

1 people are uncertain whether they're regulated or  
2 not. So it's not biotech but the same program at  
3 EPA is trying to come out with a policy to  
4 describe what you have to do with those or what  
5 you don't have to do. Does that answer the  
6 seaweed extract?

7 DR. BARBERO: I will answer  
8 your question about today. One thing that I think  
9 is really important to keep in mind here is that  
10 the agencies don't use the fact that something is  
11 genetically engineered as the primary criterion  
12 for whether it's safe or unsafe or there are risks  
13 associated with it. It's really about what are  
14 the features of that organism and what its  
15 intended application is.

16 In this case, because there are a lot of  
17 questions about genetically engineered organisms,  
18 we have focused this discussion on case studies  
19 that do have some sort of genetic engineering  
20 component to them. But the agencies that are at  
21 the table here today have a lot of expertise in  
22 regulating products that are not genetically

1 engineered and ensuring the safety of those as  
2 well, and many of these people and their  
3 colleagues can help you get answers to those  
4 questions as well.

5 MS. EXALL: I guess my question is does  
6 this biotechnology initiative, are there other  
7 kinds of biotechnology besides genetically  
8 engineered organisms?

9 DR. BARBERO: So the question is around  
10 the definition of biotechnology. I will refer  
11 back to the memorandum released in July of  
12 last year, which for the purposes of this specific  
13 effort provides a definition in there or a scope  
14 that we can put around this activity, and it is  
15 primarily focused on those sort of modifications  
16 that come from genetic engineering. Broadly,  
17 though, the agencies that are at the table here  
18 can help you think about how products across the  
19 spectrum of applications we've been discussing  
20 would have regulatory oversight. So I think the  
21 one real advantage to the way this  
22 system functions in this country is that these

1 people and the agencies that they work for think  
2 about the breadth of products and have experience  
3 with them, whether they are genetically engineered  
4 or not, and can assess them side by side.

5 Okay. I have a question here from  
6 Keerti

7 Rattore: If only algal genes or  
8 promoters were used to transform the algae, would  
9 USDA get involved?

10 MR. HOFFMAN: As far as I know, there  
11 are only three algae that are considered plant  
12 pests, and so under our current regulations, if it  
13 wasn't from any of those three algae that are  
14 parasitic, we would not be involved.

15 DR. BARBERO: Do you want to do that  
16 one?

17 MR. HOFFMAN: Sure. This is from Marie  
18 Tadei: During the R&D period when a study item is  
19 tested in an open field or an open pond, how are  
20 the tested items kept contained? That is, what  
21 parameters are used or measures taken to keep  
22 accidental release or contamination to the

1 environment or food supply at large?

2 Great question. What the USDA considers  
3 contained would not be in an open pond or an open  
4 field. That would be an environmental release for  
5 us. A contained facility we consider like a  
6 growth chamber or a greenhouse, there may be  
7 pressure on there to keep things inside, walls,  
8 more walls. For what we call a field trial, we use  
9 the word confined. That means that things can get  
10 out but the conditions are met to limit  
11 those GE organisms should persist in the  
12 environment.

13 What sort of measures are used?  
14 Isolation distances, scouting to make sure that  
15 there are no sexually compatible weeds or plants  
16 within a certain area. There are specific  
17 requirements for disposition of the materials,  
18 volunteer monitoring to make sure that the  
19 materials do not keep volunteering. Anyone grows  
20 corn, you know that it is very easy to get seeds  
21 germinating the following season, so there's  
22 restrictions on the use of that land until all of

1 the material that was grown has been used up. If  
2 you have a crop that you're testing that has some  
3 kind of dormancy, it could be several years of  
4 restrictions on the use of that land. So those  
5 are the sort of things.

6 There are also what we might call bio-  
7 containment or bio-confinement measures. You may  
8 have plants that are sterile, there's some cases  
9 where the trait cannot be transmitted through the  
10 pollen. So there are a number of both biological  
11 and physical measures that are used.

12 Mark, did you want to answer that for  
13 EPA?

14 DR. SEGAL: Yes. In large part, much of  
15 what was said also applies to us, but I want to  
16 focus on the cases where we're dealing with  
17 microorganisms. In an open pond we agree that  
18 these are releases but there can be limits. We  
19 actually have experience with algae and  
20 experimental releases. We have had one  
21 expressly with an open pond release and it was  
22 monitoring the site to determine just how much was

1 released, how far things released, what was the  
2 survival in terms of relationship to the  
3 production of the organism. So as these kinds of  
4 experimental releases take place, we will get more  
5 experience and understand what limits are.

6 But such things as isolation in terms of  
7 environment, if you're growing something in the  
8 desert and you have an organism that demands a lot  
9 of water to survive, that helps limit the release.  
10 It's still a release, we're not talking about  
11 containment. We don't use the term confinement  
12 but we understand it the same way.

13 DR. BARBERO: Okay. Let's move on to  
14 the final case study. So our final case study is  
15 a product with other applications. If you're  
16 following along in the booklet, it is case study  
17 #4.

18 This is a hypothetical genetically  
19 engineered rose, an ornamental plant  
20 genetically engineered with a plant pest component  
21 to increase the production of a pigment in its  
22 petals. The product is a rose, *Rosa x hybrida*,

1 that is genetically engineered to express a  
2 pigment from a black pansy, *Viola tricolor*. The  
3 trans gene is controlled by the cauliflower mosaic  
4 virus- derived 35S promoter and is introduced into  
5 the rose via *Agrobacterium*-mediated  
6 transformation. The purpose of the genetically  
7 engineered plant is to improve the quality of the  
8 product.

9           Which agencies have oversight and why?  
10 The USDA because the plant is engineered with  
11 plant pest components and is for ornamental use  
12 only.

13           MR. HOFFMAN: So there really isn't  
14 anything new on this one in terms of what the USDA  
15 would do. During R&D you would need a notification  
16 to move it, you'll need a notification to release  
17 it during field trials, and they could petition  
18 for non-regulated status.

19           The reason this one was interesting is  
20 the USDA would be the only regulatory agency  
21 involved in this one, and as Robbie said, the  
22 company intends to use it for ornamental purposes.



1 People want to grow this rose in their garden. I  
2 don't know how many of you are aware about the  
3 quest for blue roses, there have been contests for  
4 decades to get a blue rose. Well, they succeeded  
5 in doing it with genetic engineering.

6 The reason we wanted to mention this one  
7 is there could be some issues here if the company  
8 is thinking their market is people's gardens, rose  
9 petals, I suppose, can be consumed and I suppose  
10 they can be used for fragrance, and a lot of  
11 companies are interested in changing the fragrance  
12 of plants. So this is one where we would need to  
13 really coordinate very closely with FDA to make  
14 sure that there would not be food uses, or if  
15 there were potentially going to be food uses, we  
16 would really recommend the consultation with the  
17 FDA.

18 And I think in a case like this, this  
19 was a hypothetical, but as I think about it, it  
20 probably would be a good idea, if there's a  
21 possibility that this flower would be used for  
22 anything other than ornamental, to consult with

1 the FDA. The onus is on them to make sure that  
2 they meet all the regulatory requirements.

3 DR. BARBERO: By them you mean the  
4 developer?

5 MR. HOFFMAN: The developer.

6 DR. BARBERO: Any questions?

7 Well, if we don't have any questions, it  
8 looks like we have a little bit of time here until  
9 our next section. Why don't I do this? I will  
10 give you a little bit of an overview of what the  
11 next meeting will look like and provide some  
12 additional information.

13 And then we will take a short break and reconvene  
14 at about 12:40 to do the public comment. That will  
15 give us about 20 minutes and then we can do the  
16 public comment.

17 We do have one question. So the  
18 question is: What if the rose did not have a plant  
19 pest component, would it be regulated? And we  
20 don't have a name associated with it. I would ask  
21 that you please give us your name so that we can  
22 recognize you. Sorry, you did give us a name.

1 What's the name? Anna Muldoon.

2 MR. HOFFMAN: Yes, if the plant did not  
3 have a plant pest sequence, under the way we're  
4 regulating currently we would probably not  
5 regulate it. It's a hypothetical, there are other  
6 considerations we would need to look at, but if we  
7 talking about changing the flower color and they  
8 did that completely without using any plant pest  
9 sequences, our regulations would not be triggered.

10 DR. BARBERO: And just to further  
11 elaborate on that, I think it's important to go  
12 back to some of those principles as well as the  
13 protection standards that each agency operates  
14 under. Really, the system is intended to be a  
15 risk-based approach, so the agencies are on  
16 the look out for potential risks that are in their  
17 purview, and the process of making a product does  
18 not per se indicate that there is a risk  
19 associated with it. That's a very good question.

20 Let's go on. So our third public  
21 meeting is coming up three weeks from today. That  
22 meeting will be at the UC Davis campus in the

1 conference center there. We will have more  
2 information, including an agenda and how to  
3 register, available in the  
4 Federal Docket that is accompanying all of these  
5 activities, as well as on the USDA website. So we  
6 really look forward to having participation and  
7 engagement at that meeting, and please stay tuned  
8 as we will share more information about that  
9 meeting soon.

10 We'll come back to the public comment at  
11 12:40. Before that, though, I just want to make  
12 sure that you have an opportunity to see some of  
13 the other background materials that we have.  
14 Well, you know what I'll do? I'll leave these up  
15 on the screen while we take a break. So let's  
16 take a break now.

17 We'll reconvene at 12:40 for public  
18 comment. We have a list of people who have asked  
19 to give public comment. If you have asked, please  
20 come up to the front and Mike can work with you.  
21 We'll do three minutes per person and we ask that  
22 you stick to that so that we can accommodate

1 everybody and get out of here on time. Thank you.

2 (Whereupon, at 12:21, a brief recess  
3 was taken.)

4 DR. BARBERO: Okay. Thank you,  
5 everybody. So we will now be hearing some public  
6 comment from people who have asked to speak. Just  
7 to give a little bit of the logistics on it here,  
8 we have a list here with Mike. Hopefully you all  
9 have checked in with him to let him know that  
10 you're ready. He will call you out when it is your  
11 turn. When you come up, please come up to the  
12 podium here, and just in case it hasn't been  
13 obvious to you -- you know where I'm going with  
14 this -- there's a little piece of tape down here  
15 and you should stand on the tape, otherwise,  
16 people will be staring at your neck and not at  
17 your face.

18 (General laughter.)

19 DR. BARBERO: And we'd ask that you let  
20 us know who you are and keep it at three minutes.  
21 We have a little time here -- it's not little,  
22 actually, it's kind of large, but it will give you

1 an indication of when you're getting close to and  
2 then when you've reached the three-minute point,  
3 and then we'll ask you to wrap it up at that  
4 point.

5 And all of the comments that are given  
6 here are going to be transcribed and they'll be  
7 inserted into the docket as part of the full  
8 transcription of this meeting.

9 Mike, who do we have first?

10 MR. MENDELSON: Keerti Rattore will be  
11 our first commenter.

12 MR. RATTORE: I guess there are some  
13 advantages to being from Texas, I'm the first one.

14 Good afternoon, everyone. My name is  
15 Keerti Rattore, professor of soil and crop  
16 sciences, Texas A&M University, College Station.  
17 I want to thank you for the opportunity to share  
18 my experience with the Coordinated Framework and  
19 to offer my perspective on the effects that  
20 current regulations have on the development and  
21 deployment of genetically engineered plants and  
22 plant products.

1           My research interests are in genetic  
2   improvement of important crop plants. I work on  
3   the cotton, sorghum, rice, tomato and potato, and  
4   my research involves enhancement of disease-  
5   resistance in plants, conferring drought tolerance  
6   to crop plants, conferring insect tolerance and  
7   resistance, as well as improving the nutritional  
8   quality of the seeds.

9           For the last 18 years my primary focus  
10   has been on a project that involves elimination of  
11   Gossypol from cottonseed. My lab has successfully  
12   demonstrated in 2006 RNI-mediated reduction of  
13   Gossypol in the cottonseed to levels that are  
14   below what FDA and WHO consider safe for human  
15   consumption. If cotton growers around the world  
16   adopt this what we call ultra low Gossypol  
17   cottonseed, it can make enough available protein  
18   to meet the basic protein requirements of 500  
19   million people.

20           Additionally, elimination of Gossypol  
21   from cottonseed enables its use for non-ruminant  
22   farm animals, such as poultry or swine, at higher

1 feed ratios than is currently tolerated for  
2 significantly improved protein conversion and  
3 lower feed costs for the producers. Similarly,  
4 elimination of Gossypol enables the use of  
5 cottonseed in agriculture, thereby extending the  
6 protein in current agriculture feeds derived from  
7 marine fishes, a declining and increasingly costly  
8 resource.

9           Importantly, elimination of Gossypol  
10 from cottonseed enhances the value of cotton  
11 production to the U.S. growers which can help stem  
12 the historical decline in the U.S. cotton acreage  
13 and the loss of production to synthetic fiber and  
14 foreign producers.

15           Now, we're also committed to the  
16 humanitarian use of this cottonseed technology in  
17 places where food is less secure. I have seen  
18 firsthand how agriculture technology improved the  
19 health and well-being in my country of origin that  
20 is India, and I count the late Dr. Norman Borlaug  
21 among my mentors at Texas A&M, who instilled in me  
22 a passion to complete this work for the benefit of



1     humanity. His interest in my research has  
2     encouraged me to persevere for nearly 20 years in  
3     pursuit of this new cottonseed variety for  
4     humanitarian use.

5             Today we are in the final stages of  
6     laboratory and field studies on this cottonseed  
7     for submission to the USDA and FDSA, but this  
8     regulating process has been arduous and costly,  
9     especially for people working in a university  
10    environment.

11            I just want to say that as a public  
12    sector researcher I understand the need to ensure  
13    the safety, both environmental and food safety, of  
14    any new plant variety introduced into the U.S.  
15    agriculture. I have no desire to see genetically  
16    engineered crops developed by public sector  
17    researchers held to any lesser standard of safety.  
18    At the same time, I submit that the current  
19    regulations impose significant opportunity costs  
20    on human and animal health, on global resources,  
21    and U.S.

22            agriculture production and trade. That

1 cost, while difficult for large private companies,  
2 severely limits public sector biotechnology from  
3 having an impact on producers and consumers.

4 So anyway, we face significant  
5 challenges to our global food supply and  
6 agriculture production systems. Genetic  
7 engineering and related technology for agriculture  
8 offer promising solutions that should be  
9 encouraged, not hindered by government policies  
10 and oversight. The U.S. federal agencies should  
11 seize this important opportunity to improve their  
12 long-term strategy for regulation of biotechnology  
13 products.

14 Thank you for the opportunity to share  
15 my perspectives.

16 MR. MENDELSON: Next we'll have Bob  
17 Hemesath, farmer, also with the National Corn  
18 Growers Association.

19 MR. HEMESATH: Good afternoon. Like  
20 Mike said, my name is Bob Hemesath. I am from  
21 Decorah, Iowa. I am a fourth generation farmer, I  
22 farm with my family. We raise corn and we have a

1 wean-to-finish hog operation. I traveled here  
2 today because the need for these products is very  
3 important to my farm and the livelihood of my  
4 family, as well as the sustainability of my farm.

5 The National Corn Growers Association  
6 appreciates the opportunity to provide comments to  
7 the OSTP and participating agencies. We have a  
8 longstanding position supporting science-based  
9 regulatory oversight of products eligible for  
10 review under the Coordinated Framework. From the  
11 grower's perspective, the Coordinated Framework  
12 allows the commercialization of important crop  
13 protection products in spite of increasingly non-  
14 risk based regulations that have impeded product  
15 development. Additionally, seed and technology  
16 companies have, for the most part, understood what  
17 regulatory obligations need to be met to bring  
18 value to the ag industry.

19 The value these products provide to  
20 growers is undeniable and maintaining access for  
21 growers is a priority for NCGA. These tools have  
22 revolutionized weed and insect management, opened

1 up new conservation practices, and increased the  
2 efficiency of farming operations. We use less  
3 pesticides, less fertilizer per bushel and are  
4 able to withstand the variability in weather to  
5 continually produce record crops year after year.

6 U.S. agriculture is the best in the  
7 world, due in large part to innovations regulated  
8 under this framework. This is what has been  
9 achieved to date, but we understand that demand  
10 for food will not be weakening any time soon and  
11 we have to be prepared to feed the growing world  
12 population in an ever-shifting climate. Adoption  
13 of biotech products is impressive. Herbicide-  
14 tolerant soybeans quickly exceeded 85 percent of  
15 the market within a few years of launching.  
16 Insect-protected corn is used by 90 percent of  
17 growers. These products are widely adopted  
18 because they add clear value to us and the rest of  
19 the food industry.

20 As with any crop-protected technology,  
21 making sure there is competition and options for  
22 growers makes each product more robust. For

1 example, when only one type of herbicide-tolerant  
2 was widely adopted without a robust alternative,  
3 that single mode of action was over- utilized.  
4 Growers want to implement a robust integrated  
5 management and can only do so with options to  
6 rotate into. The viability of current BT products  
7 depend on this continuous innovation and the  
8 framework needs to be continued to allow this  
9 development to occur.

10 U.S. growers also understand our place  
11 in the global market and how the world accepts  
12 biotechnology. Appropriate regulation has fostered  
13 trust and coordinated regulatory regimes for the  
14 most part. Moving forward, we want to remain  
15 resilient to global demand and avoid any changes  
16 that would create new trade barriers for our  
17 products. A predictable and science-based  
18 regulatory system allows it.

19 Finally, we want to look to the future.  
20 These are new and exciting methods for unlocking  
21 the genetic potential of our crops. These new  
22 techniques seek to more efficiently explore the

1 natural variability that is the foundation of  
2 breeding new and more robust crops. We don't wish  
3 to see these technologies hampered by onerous  
4 regulations.

5 NCGA recognizes that the Coordinated  
6 Framework works. The USDA, FDA and EPA have  
7 allowed safe products to become commercially  
8 available to support food security worldwide. We  
9 also recognize the recent efficiencies implemented  
10 by the USDA have gone a long way to clearing the  
11 queue and getting products to market. Let's keep  
12 this trend moving forward.

13 Thank you for allowing me to make  
14 comments today.

15 MR. MENDELSON: Next we'll hear from  
16 Jeffery Campbell.

17 MR. CAMPBELL: Hi. My name is Jeffery  
18 Campbell. I live in Fisher County. I'm here  
19 representing myself as a consumer and a producer.

20 My great-great grandparents moved to  
21 West Texas to the McKinney area in the 1890s and  
22 started growing cotton. My dad was about the

1 first generation that decided not to grow cotton  
2 and we're from cow country now. We keep a five-  
3 acre market where we raise Heritage Hogs, we raise  
4 Dwarf Nigerian Goats, mini donkeys, we try and  
5 keep about 500 pasture poultry a year, we keep  
6 chickens, turkeys, guineas, peafowl. We sell  
7 direct to customers and at a farmers market and  
8 farm stands which puts us in front of a lot of  
9 producers and a lot of consumers. I also work  
10 part-time for NASDA compiling surveys of things  
11 like that with farmers, so it puts me in front of  
12 a lot of producers also.

13 Cotton farmers in East Texas don't have  
14 much choice for seeds other than offerings from  
15 biotechnology companies. Roundup-ready products  
16 like Deltapine and FiberMax are basically the norm  
17 where we're at. Operators that use these products  
18 are stuck with very high seed prices and even  
19 larger chemical prices. The pests that chemicals  
20 are designed to destroy, we're seeing very bad  
21 problems everywhere with resistance to those  
22 chemicals, which we're having to use like a lot

1 more chemicals than we always have, more spraying  
2 than normal.

3 All of these aspects, they forced the  
4 closing of delinting plants because we can't  
5 delint the seeds anymore. They hurt American  
6 small farmers which are historically the backbone  
7 of America. The costs are really high and the  
8 returns are really low for us, especially with the  
9 weather conditions. We're not getting the  
10 results, we're not getting better numbers in the  
11 field.

12 Farmers around me are trying to grow  
13 organic and conventional cotton. Organic cotton  
14 only makes up a half a percent of the 5.2 million  
15 acres planted in Texas. We're forced to try and  
16 deal with the overspray of chemicals like Treflan,  
17 Roundup. These are all commonly sprayed on  
18 genetically engineered crop plants to prepare the  
19 seed beds and after the plants are already coming  
20 up. So we're having to stagger our plantings and  
21 work around them so that it doesn't destroy our  
22 crops. We're having to replant a lot of crops when



1 they are.

2 A lot of folks feel the small farmer  
3 shouldn't be the one that has to bear the burden  
4 of these. Vegetable farmers like myself, we face  
5 losing our whole crop because they're so sensitive  
6 to the drift of the chemicals. My neighbor, my  
7 buddy grows 150 acres of watermelons, and he  
8 plants every year with the intent that he'll lose  
9 a third of his crop to overspray. Acres of  
10 watermelons in Texas, you lose 50 acres, it's a  
11 lot of problem for a small farmer.

12 Time and again the biotechnology  
13 companies have made it very hard for farmers to  
14 find alternatives to their products. It's not  
15 very easy to find animal feed that doesn't have a  
16 genetically modified organism in it. It needs to  
17 be easier for us, the consumers. The farmers and  
18 consumers, we feel like there's no other option,  
19 what else we can get.

20 The extra production numbers are there,  
21 there aren't many alternatives. They not only  
22 hurt the people that don't choose to use the

1 products, but they're hurting the people that are  
2 using the products. It seems like an assault on  
3 small farmers these days because they don't meet  
4 the scale of economy for the large corporations.

5 Thank you for listening.

6 MR. MENDELSON: Next we'll have Jill  
7 Kauffman Johnson. Is she here?

8 (No response.)

9 MR. MENDELSON: Okay. Judith McGeary.

10 MS. McGEARY: Thank you. My name is  
11 Judith McGeary. I'm with the Farm and Ranch  
12 Freedom Alliance, which is a nonprofit that  
13 advocates for small farmers and independent  
14 farmers, many of whom are selling directly to  
15 consumers or into local markets.

16 Our farmers are deeply concerned about  
17 the current Coordinated Framework and believe  
18 there needs to be a fully revamped one that looks  
19 both at a comprehensive pre-release analysis and  
20 post-release monitoring and evaluation.

21 One of the key considerations that we  
22 think all the agencies should be taking into

1 consideration are human and animal health impacts.  
2 That needs to include the impacts not only for  
3 consumers who ultimately eat the food, but the  
4 health of the farmers, the farmworkers, and the  
5 rural residents, all of whom are impacted,  
6 particularly by genetically engineered crops that  
7 are herbicide-resistant and new waves of  
8 herbicide-resistant crops.

9           GMO foods should undergo long-term  
10 testing to ensure that they are safe for human and  
11 livestock use. The 90-day standard test is  
12 woefully inadequate when you're talking about  
13 foods that people will be consuming over their  
14 entire lifetime. And most particularly, we need  
15 this done by independent studies and data.

16           As I brought up during the question and  
17 answer session, one of our concerns is how the  
18 studies are designed. There seems to be a  
19 mismatch between the discussion that there is  
20 serious rigorous scientific study designed up  
21 front and what we are seeing.

22           And to use just two examples, in the

1 recent approval of AquaBounty salmon, it came out  
2 that there were several studies that had six or  
3 fewer salmon in them. This does not provide any  
4 statistical strength, and in essence, from a  
5 scientific perspective they're useless to address  
6 the concerns such as allergenicity that they were  
7 supposed to be addressing.

8           Also, in looking at the effect, again  
9 focusing for a moment on herbicide-resistant  
10 crops, the field applications need to be addressed  
11 and not just the active ingredients. There's a  
12 study that was just published last month in the  
13 International Journal of Environmental Public  
14 Health showing that Roundup, the full product, is  
15 up to 100,000 times more toxic than glyphosate  
16 alone. We need to be addressing the real-world  
17 conditions when agencies are looking at whether or  
18 how to approve genetically engineered crops.

19           We also need to be in consideration of  
20 the social and economic factors. We're looking at  
21 things such as the emergence of more and more  
22 herbicide-resistant weeds. These are plant

1 pests. Whether the GMO crop itself is a plant  
2 pest or not, if it leads to the creation of  
3 superweeds, that is a threat to American  
4 agriculture as a whole. We also have to address  
5 the crop contamination and loss of crops to  
6 pesticide overdrift. It almost got buried in what  
7 you said, a third of a watermelon farmer's crop he  
8 expects to lose every year. That's unacceptable  
9 for agriculture to have to suffer through that.

10 I see the time and I'll wrap it up  
11 quickly. It's very important that the agencies  
12 don't say that it's done with initial approval.  
13 We have seen far too many times over our history  
14 that things that we thought were benign proved not  
15 to be so.

16 But there isn't a mechanism for tracking  
17 these things, both agriculturally and in our food  
18 supply, post-market, post-approval, in the  
19 market. We have no way of knowing if they  
20 actually do have adverse effects. That means we  
21 have no way of knowing if our regulatory system is  
22 working.

1           The last point I'd like to make is that  
2 all too often there's a discussion of needing to  
3 feed the world, and there's a rhetoric that  
4 involves either we have genetically engineered  
5 crops or we sit on our hands and do nothing and  
6 millions starve.

7           And this is reflected all too often in  
8 the regulatory analysis where the comparison is  
9 between the genetically engineered option and a  
10 do-nothing option or a chemically intensive  
11 option. There are other alternatives, and there  
12 are studies after studies that show, particularly  
13 at the international level, that sustainable  
14 farming not involving genetic engineering is one  
15 of the best ways to feed the world, not just our  
16 community.

17           So when the regulatory agencies are  
18 looking at whether to approve genetically  
19 engineered crops and you are weighing social and  
20 economic and humanitarian interests, it needs to  
21 look at all the alternatives, not set up the  
22 strawman of the genetically engineered crops are

1 having.

2 Thank you very much.

3 MR. MENDELSON: Next we'll have Marie  
4 Tedei.

5 MS. TEDEI: Hello. My name is Marie  
6 Tedei and I own and operate an organic farm just  
7 outside of Dallas in Balch Springs, Texas. I  
8 raise vegetables and Icelandic sheep and laying  
9 hens, all of which are raised using organic  
10 methods or fed using organic feeds. I am also the  
11 regional director of the Texas Organic Farmers and  
12 Gardeners Association here in North Texas.

13 Although mostly raised on native pasture  
14 in a sustainable way, it is important to me to  
15 have available organically raised, non-genetically  
16 modified supplemental feed grains for my hens, and  
17 when needed, for my yew. I'm concerned with the  
18 lack of independent long-term testing of  
19 genetically modified corn and soy commonly used in  
20 animal feeds of many kinds, including dog, cat and  
21 horse feeds, all of which I use. Unfortunately,  
22 most of the feeds on the market are not organic

1 and most contain genetically modified grains of  
2 corn and soy.

3           When these crops are genetically  
4 modified to accept multiple strains of glyphosate-  
5 based herbicides, the residue would then be fed to  
6 my animals, commercial and domestic, daily, and we  
7 know it is not safe to consume this herbicide. It  
8 is also not safe for those who work on the farms  
9 that raise these crops for the feed to so often be  
10 exposed to the herbicide, frequently without  
11 proper safety gear, or to then upon harvesting  
12 handle the grains that have previously been  
13 sprayed.

14           I also operate a farmer's market on my  
15 farm where consumers are regularly sharing with me  
16 their concerns over whether or not they and their  
17 families are buying non-GMO foods because there is  
18 not adequate labeling in the grocery store unless  
19 the product is certified organic or that they know  
20 if they are buying it from a farmer whom they know  
21 grows using non-genetically modified feed stock.  
22 Many were surprised last summer to learn that



1 their common summer squash are now in the  
2 genetically modified category, along with soy and  
3 corn. Our salmon supplier is up in arms over the  
4 potential for GMO salmon to be sold side by side  
5 with her wild caught Alaskan salmon without  
6 labeling.

7           As food producers and suppliers, we ask  
8 that oversight by the agencies be a formal  
9 assessment and regulatory process, not fast  
10 tracked, that is done prior to releasing crops to  
11 farmers growing where wind, honeybees and other  
12 pollinators carry pollen from genetically modified  
13 crops where they can harm the bees as well as  
14 contaminate other farmers' non-GMO crops and now  
15 genetically modified animals before they're  
16 released to the wild open seas where they can  
17 cross-breed with native non-genetically modified  
18 animals or other unintended consequences.

19           And we ask that as consumers a more in-  
20 depth and mandatory labeling process be put into  
21 effect, not blocked, before placed on the market  
22 for the general public to consume. Allergy

1 issues, as well as safety of consuming  
2 insufficiently tested by independent long-term  
3 studies concern us all and we respectfully ask  
4 that the process be more stringent and consumer-  
5 biased than it currently is.

6 Thank you.

7 MR. MENDELSON: Next we'll hear from  
8 Bill Peck. Okay, it doesn't matter. That's fine.  
9 John, go ahead. John Cumbers from SynBioBeta.

10 MR. CUMBERS: Good morning, everybody.  
11 My name is John Cumbers. In addition to working  
12 at NASA for the last seven years in synthetic  
13 biology, I'm the founder of SynBioBeta, a global  
14 activity hub for the synthetic biology industry.  
15 We bring together key members of industry,  
16 academia and regulatory agencies multiple times a  
17 year in various parts of the world to hold  
18 conferences, workshops and courses. This year  
19 we're running events in the United States, the  
20 United Kingdom and China, which all have a lot of  
21 support for this new fledgling industry. We  
22 maintain a company database of over 200 companies,

1 track investment in the field, and support  
2 entrepreneurs, investors, partners and  
3 policymakers in the field.

4 I'm uniquely qualified to serve as the  
5 voice of the synthetic biology industry. I wanted  
6 to speak to thank the OSTP and government for  
7 recognizing the need for the government to take an  
8 active role in the regulation of the products of  
9 biotechnology in the future. The rapidly growing  
10 industry in the last twelve months has raised over  
11 three-quarters of a billion dollars in venture  
12 financing. Venture capital has long been the  
13 mechanism by which many startups have been  
14 created, new industries born, and new economic  
15 growth and leadership in the United States has  
16 been made possible. Over the last 40 years of  
17 biotechnology, we've seen amazing new numbers of  
18 discoveries, including the structure of DNA, and  
19 also in our ability to read and now write DNA.

20 I represent over 10,000 people in our  
21 community and I'm excited that the government is  
22 looking forward to these new applications of

1 biotechnology because the community that I  
2 represent is passionate about seeing the products  
3 of their labor make it into the hands of the  
4 people that need it most, whether that's a new  
5 engineered cell line to defeat cancer, a new  
6 sustainable bio-based material, a fuel, chemical  
7 or food product. Biology is technology and has an  
8 immense amount of power to do good, and it's  
9 important that we support the community while  
10 building the future in a safe and responsible  
11 manner.

12 In particular, I represent a new startup  
13 community in the synthetic biology industry who  
14 are well educated, thoughtful and respectful  
15 citizens of this country and passionate about  
16 communicating the work that they do to a broader  
17 public. The current regulator system as it  
18 functions, however, is far from supportive of  
19 these passionate entrepreneurs, delaying them in  
20 decades of bureaucracy, paperwork and with  
21 sometimes irrational take on risk that does not  
22 represent the potential benefit of these

1 technologies and can be too one-sided towards the  
2 potential unintended consequences.

3 In addition, there's currently no  
4 regulation of biotechnology products and the  
5 regulation is siloed into different organizations.  
6 There needs to be more clarity and easier routes  
7 to market so that the entrepreneurs can more  
8 easily embark on a route to see their company and  
9 products succeed and investors have the confidence  
10 to back them based on known timelines.

11 There are a number of challenges in  
12 innovation posed by the regulatory system as it  
13 exists today. Given their experience in  
14 traversing the regulatory pathways to  
15 commercialization, small companies developing new  
16 products believe that the current regulatory  
17 framework imposes significant burdens on  
18 innovators and so reduces the economic potential  
19 of the industry. It's time to try a less  
20 burdensome regulatory approach aligned with the  
21 actual scientific consensus on the risks, and I  
22 want to applaud the government for taking on this

1 issue and thanking you all for being here.

2 Thank you.

3 MR. MENDELSON: Now we'll hear from  
4 Bill Peck, the CTO Twist Bioscience.

5 MR. PECK: Yes. I asked John to go  
6 first just to give some context for who we are.  
7 I'm Bill Peck. I'm the CTO of Twist Bioscience.

8 We're a small startup in San Francisco,  
9 California. We started three years ago and as of  
10 now we're just over a hundred people, we've raised  
11 about \$130 million of venture funding, and we've  
12 got a \$5 million government grant. And our  
13 mission is to provide synthetically manufactured  
14 genes to scale and accelerate the biotechnology  
15 field test design cycle. So it's very similar to  
16 the traditional engineering approach. I'm a  
17 mechanical engineer by trade, so I speak this  
18 language but with a strong accent. So typically,  
19 as in engineering, you go through a design-build-  
20 test cycle, and what the biotechnology community  
21 needs is access to genes to do that, and we're  
22 providing that.

1           An early and important customer is  
2 Ginkgo Bioworks from Boston, Massachusetts. They  
3 say their products are to engineer new organisms  
4 and self challenges across a range of industries  
5 from fuels to pharmaceuticals. In this capacity  
6 we are a tool provider, so we are not engineering  
7 the application so much as providing tools for the  
8 people engineering the application.

9           And there seems to be a natural  
10 hierarchy developing in this field: tool  
11 providers manufacturing genes and application  
12 engineers taking the genes and developing biology.  
13 So as a tool provider, we concentrate typically  
14 difficult technologies, so we bring the  
15 semiconductor world into biology, so we're using  
16 all the tools from semiconductor to scale and  
17 provide this product at unprecedented  
18 availability.

19           So as this becomes, as John talked  
20 about, the ability to write DNA -- so I've been  
21 involved in reading DNA for the past 15 years and  
22 now we're into a world where we're writing DNA --

1 so as we enter this world, it's a whole new form  
2 of engineering. And it's not limited to just  
3 biology, actually it's just information in  
4 general. So if you look to the New York Times, I  
5 think in December, there's an article where we had  
6 a collaboration with Microsoft. And I believe one  
7 of the engineers from Microsoft will be coming to  
8 UC Davis to speak to us, and they're using DNA as  
9 a data storage media. So biology can be used to  
10 store the information on this computer, the DNA  
11 can be used to store that information for long-  
12 term data storage. So it's a marvelous thing as  
13 we know as it exists today to store information.

14 So does the orange mean I'm out of time?  
15 Very good. Right to the end.

16 MR. MENDELSON: You have another  
17 minute.

18 MR. PIKE: So at Twist we especially the  
19 support the construction of a really open and  
20 frank conversation with everyone, all the  
21 stakeholders, everyone from -- I'm a farmer too, I  
22 have a small farm that raises canola -- and so all



1 the farmers, the people that use the products, the  
2 application engineers, the EPA, the USDA, all of  
3 them, we'd like that open conversation to really  
4 make sure that we're doing the right thing.

5           So I'll just read now: While policies  
6 and procedures require both time and monitoring  
7 from small companies like Twist, our company is  
8 committed to accelerating scientific research to  
9 improve lives worldwide. Synthetic biology holds  
10 great promise for improving human health and the  
11 global environment. Twist Bioscience is proud to  
12 be a part of this promise and also support the  
13 principled. use of the technology.

14           Finally, we also applaud the efforts of  
15 the agencies represented here today and support  
16 the efforts to refresh the Coordinated Framework  
17 to reflect the current biotechnology companies.

18           Thank you.

19           MR. MENDELSON: All right. Is Jeffrey  
20 Farrell here? Great.

21           MR. FARRELL: My name is Jeffrey  
22 Farrell, and I am a former university lecturer,

1 public school teacher, a teacher of literature and  
2 drama, something that is not typically heard from  
3 in these settings.

4           And I'm here today because I have  
5 children, I know many people who are well  
6 educated, and myself too, I have post-graduate  
7 degrees including work here at UT Dallas,  
8 Washington University at St. Louis where I studied  
9 biology and left that behind me, and pursued work  
10 in the world of literature and drama, including  
11 work at Yale University, and I've received grants  
12 from the National Endowment for the Humanities,  
13 from the French Ministry of Culture.

14           And these issues that we're talking  
15 about today are significant. It is not merely  
16 about marketable technology. Marketable  
17 technology is not the same thing as science, and  
18 many times we who oppose this biotech onslaught  
19 are labeled as Luddites and anti-science fear  
20 mongers. Well, that's simply not true.

21           What I would suggest is that the entire  
22 process so far, as I've studied -- Washington

1 University is in St Louis, home of Monsanto, our  
2 friends. Right? What I have observed in the 30  
3 years of this process is that the oversight of it  
4 has not been sufficiently guided, that there are  
5 some serious problems right in the heart of the  
6 system.

7 Now, I'm not going to get into further  
8 details and I'm not going to change your minds,  
9 most likely, if you have your minds set, and  
10 you've said before how important with the  
11 economics and all like this, and our president has  
12 offered this biotech blueprint, of course.

13 Can I help you?

14 SPEAKER: No, I'm just making sure  
15 that's okay.

16 MR. FARRELL: That's okay. Thank you  
17 for interrupting me.

18 SPEAKER: Sorry.

19 MR. FARRELL: That was like 30 seconds  
20 of my time.

21 If we have this kind of interference  
22 this way, if we have a problem at the very heart

1 of the oversight process, which in many cases it  
2 can be demonstrated, there needs to be something  
3 else done.

4           And I'll leave you with just one thing,  
5 and I'd like for you to consider how tobacco, the  
6 process of tobacco over a hundred years, and I'll  
7 be very brief. In 1900 there were no manufactured  
8 tobacco packages or anything like that, but the  
9 technology allowed tobacco to be placed into  
10 actual cigarettes, mass produced, put into  
11 packages and then shipped off, sold. They were  
12 then approved through our federal agencies. At  
13 the time EPA didn't exist, all these agencies  
14 didn't exist, but our military did and they were  
15 provided in rations to our soldiers.

16           Well, if you look at the consumption of  
17 cigarettes from 1900 when the technology first  
18 arrived until 1965, the growth in consumption of  
19 tobacco spiked. In 1965 you know what happened.  
20 Right? Our surgeon general said, Cigarettes are  
21 dangerous. Consumption began to drop  
22 significantly.

1           We do not have 65 years to prepare  
2 observations and studies to demonstrate the  
3 hazards of the biotechnology. Mr. Peck observed  
4 earlier just a moment ago how the DNA receives  
5 information and it can be encoded with vast  
6 information.

7           This is true and all the more reason  
8 that we need to be particularly sensitive to these  
9 issues of development and to avoid the hubris --  
10 and it is hubris -- that is potentially far  
11 greater damage than what we're looking at here in  
12 some of the smaller issues.

13           I want to thank you very much for taking  
14 the time to listen and I appreciate being here.

15           MR. MENDELSON: Next we'll hear from  
16 John Salmeron, director of plant science,  
17 Precision Biosciences. Is John Salmeron here?

18           (No response.)

19           MR. MENDELSON: Okay. Next is Suzie  
20 Marshall with the Texas Organic Farmers and  
21 Gardeners Association. She wasn't able to make it.  
22 Okay.

1 All right. Was Lisa Griffith here with  
2 the National Family Farm Coalition?

3 MS. McGEARY: So I'm presenting these on  
4 behalf of Lisa Griffith with the National Family  
5 Farm Coalition.

6 The National Family Farm Coalition,  
7 representing thousands of independent family  
8 farmers, ranchers and fishermen throughout the  
9 United States, wishes to state our support for a  
10 fully revamped Coordinated Framework to regulate  
11 biotechnology products in the U.S.

12 The current Coordinated Framework seems  
13 designed to advance the release of GMOs, not to  
14 ensure their safety. We hope that the FDA, EPA,  
15 USDA and other agencies take the opportunity to  
16 change the course of the regulatory review by  
17 adopting an approach that seeks to ensure, first  
18 and foremost, that GMOs and their accompanying  
19 pesticides are safe.

20 This new framework must be based on a  
21 comprehensive pre-release analysis of any new GMOs  
22 that addresses the concerns of and the

1 socioeconomic, environmental and health impacts on  
2 the farmers or fishermen, their families and the  
3 rural communities neighboring GM crops. We also  
4 believe that GM foods, including seafood, should  
5 undergo long-term testing to ensure that they are  
6 safe for livestock and human consumption.

7           The U.S. Government agencies responsible  
8 for testing, approving and monitoring GMOs should  
9 not rely on information provided by those who  
10 manufacture GMOs or who profit from their  
11 production to determine how to test them. Each  
12 agency has the means, authority and public  
13 responsibility to regulate GMO crops and the  
14 pesticides used with them to ensure safe planting  
15 and harvesting that does not harm farmers, their  
16 livelihoods or regional biodiversity.

17           For the past 20 years we have watched  
18 government agencies approve dozens of GM crops,  
19 despite concerns raised by farmers, fishermen and  
20 other members of the public. These concerns  
21 include, but are not limited to: reduced farmer  
22 choice in non-GMO crops due to the consolidated

1 seed industry; the loss of independent seed  
2 dealers and other rural businesses, leading to the  
3 overall demise of rural communities throughout the  
4 U.S.; crop contamination from seeds and  
5 pesticides; fence row to fence row planting of  
6 GMOs resulting in habitat loss for birds, bees,  
7 butterflies and other wildlife, along with  
8 increasing numbers of concentrated animal feeding  
9 operations where independent diverse family farms  
10 once stood; the reduced use of crop rotations and  
11 cover crops; the emergence of scores of herbicide-  
12 resistant weeds; the loss of organic and non- GMO  
13 certification for farmers, followed by lower  
14 prices and market share; diminished research and  
15 development of non-GM seeds at public  
16 universities, including land grant colleges; and  
17 the unproven but noted correlation between cancers  
18 and other diseases in rural areas where herbicide-  
19 resistant GMs are widely planted.

20 We reiterate our stance that in a nation  
21 built on opportunity, U.S. Government agencies  
22 should ensure that our farmers and ranchers have



1 the opportunity to raise non-GMO crops without  
2 worry of contamination from one element or another,  
3 and that genetically modified crops approved by  
4 these agencies are safe for consumption. The  
5 ongoing deregulation of new herbicide-resistant  
6 GMOs based on the current uncoordinated framework  
7 is completely at odds with USDA's efforts to  
8 promote local foods, rebuild rural economies and  
9 provide healthier foods to school children.

10 Thank you for the opportunity to present  
11 these comments.

12 DR. BARBERO: All right. Is that it  
13 from everybody?

14 Okay. We had one question from online  
15 which was when and where will a recording of this  
16 meeting be posted. So this will be transcribed  
17 and placed into the docket, and there will also be  
18 a recording of this posted on EPA's website, the  
19 same website that you used to register for the  
20 meeting.

21 So with that, I thank you all for coming  
22 and thank you to everyone online for listening and

1 spending the morning with us, and look forward to  
2 further discussions on this. Thank you very much.

3 (Whereupon, at 1:25 p.m., the public  
4 meeting was concluded.)

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## 1 REPORTER'S CERTIFICATE

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4 DOCKET NUMBER: FDA-2015-N-3403

5 IN RE: PROGRESS ON MODERNIZING THE  
6 REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS

7 DATE: MARCH 9, 2016

8 LOCATION: DALLAS, TEXAS

9

10

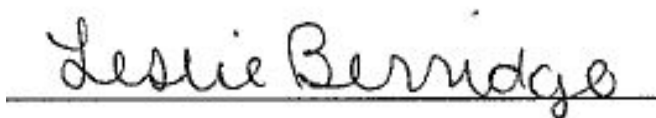
11 I hereby certify that the proceedings and evidence  
12 are contained fully and accurately on the tapes  
13 and notes reported by me at the hearing in the  
14 above case before the U.S. Environmental  
15 Protection Agency.

16 Date: 3/17/2016

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19

A handwritten signature in cursive script that reads "Leslie Berridge". The signature is written in black ink and is positioned above a solid horizontal line.

20 Official Reporter

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