USDA-APHIS-BRS

Moderator: Richard George
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7:31 am CT

Man: Is the PA working in the room? It is. Good morning, and welcome to our public comment meeting on our proposed revisions to USDA biotechnology regulations regarding the importation, interstate movement and environmental release of certain genetically engineered organisms.

Today we're meeting at APHIS headquarters in Riverdale, Maryland.

Woman: Yeah, they're not working.

Dick George: The PA is not working? Test, test. Test. Is that working? No? We can switch mikes. How's that? Is that better? Sorry guys. (Gwen)'s shaking her head now. How's that? Better? I'm Dick George, I'm the communications branch chief for biotechnology regulatory services or BRS, which is a part of APHIS, the Animal and Plant Health Inspection Service, which in turn is part of the US Department of Agriculture.

Joining me today are BRS Associate Deputy Administrator Ibrahim Shaqir, on my far right, and our APHIS Deputy Administrator for BRS, Mike Firko.

Mike Firko: So on January 19 of this year, APHIS proposed the first comprehensive revision to USDA's regulations for certain genetically engineered organisms since 1987. So as we sit here the regulations are 30 years old. There is currently a public comment period that's open, it will remain open until this coming Monday at midnight, June 19, for a total of 150 days of comment period.

The goals of the proposed rules are first and foremost to protect plant health. That is the extent of our regulatory authority and our statutory authority, so that is always our focus, to protect plant health. But we are also making an effort to improve the regulatory processes to make them more transparent to the regulated community, to stakeholders, to the public, to everyone involved.

We also have as a primary goal to regulate at a level more commensurate with risk. This is continual improvement in terms of regulating commensurate mix. We also want to regulate, we want to eliminate unnecessary regulatory burdens. In the past 30 years, we've learned an awful lot about where risk comes from and where it doesn't come from, and we want to take advantage of 30 years of learning in that space.

We also see this proposed rule as a significant improvement in terms of enhancing development opportunities for small companies and opportunities. Our current regulations and our current petition process make it very difficult for anything other than large companies to receive a deregulated status. And we want to expand the availability of these innovations in modern technology.

So if finalized, the proposed rule would result in less regulation of genetically engineered organisms that pose little or no risk to plant heath. And they would involve more regulation of genetically engineered organisms that do represent a document, honest-to-goodness risk to plant health, plant pests or obnoxious weed.

But we have lots of information that's available out there, today the purpose of this meeting is to listen to your comments that you have for us about our proposed rule. Now I'd like to re-introduce our associate deputy administrator, Ibrahim Shaqir.

Ibrahim Shaqir: Thank you, Dr. Firko. So my job here is to convince you that, share with you, (unintelligible) by which you can share your comments with us. So there is a wealth of information on our website which you can see, and about our proposed rule. So the easiest way to reach, to find this website is to visit a search engine, such as Google, and search for Biotechnology Regulatory Services, click on the entry for us to get to our home page, shown here on the screen.

And then in the left navigation shown on the website, with an arrow you will see a link called Engagement on Biotechnology Regulation. Click on it, and you will get to a page explaining what we are doing with a list of documents including the Federal Register notice with the proposed rule itself, questions and answers, a regulatory impact statement, a draft environmental impact statement, and other helpful information.

So you can comment today on these documents or you can comment anytime through January 19, which I believe is this coming Monday.

Man: It's June.

Ibrahim Shaqir: June 19. Did I say January?

Man: You did.

Ibrahim Shaqir: Okay. June 19, okay? This coming Monday. At Regulations.gov, you can get there by clicking on the link, so at our website, or simply go to Regulations.gov and enter the docket ID number APHIS-2015-0057. You can comment in today's meeting, you will find fully captured that comment, we will fully capture the comment as part of the record. You don't also need to go to Regulations.gov to get your comments into the record, though of course you are free to do so if you choose to.

Mike Firko: So next steps, as we've said a couple of times, sometimes incorrectly, sometimes correctly, the comment period remains open until this coming Monday at midnight, June 19. After close of the comment period, we will review all public comments that have been received regardless of whether they were submitted through Regs.gov or made in one of the three public meetings. Either way, they all count as official public comments.

We expect the next few days between now and midnight at Monday to be eventful. When I checked last evening, we had 85 comments. I would not be surprised if that increased by three orders of magnitude. So most of the comments will be coming in over the next three days. That will have a lot to say about how long it takes us to address all the comments. We will be analyzing every single comment, analyzing every issue in every single comment, drafting responses to those comments, as we decide whether and how to revise our regulations. So with that.

Dick George: Thanks Mike. We are here today solely to listen and to receive your comments, not to answer questions or debate the merits or demerits of the proposed positions. If you have questions, make them part of your comment and we'll address them in our response to comments that will be published later in this process. As we've mentioned, this meeting is being recorded, and that recording along with a transcription of it will be posted to our website.

Today we will hear first from those that are in attendance in the room and have pre-registered to comment, then we will open the mike to others in the room who would like to speak but perhaps have not pre-registered. Then we'll open the phone lines to those of you who are attending via the web. We will initially limit you to five minutes each, but we are here for three hours. If we have time left over, we will invite those who have already spoken to elaborate on their comments if they like as time allows.

With that, we'll begin to take comments. We would ask that as you begin, please say your name and spell your name so our transcriber has a fair chance of spelling it. So having said that, our first commenter is (Roy Labanya). Is (Roy Labanya) here? (Roy Labanya). Guess not.

In that case, I know Richard Wilkins is here. Richard, you can come up to the podium to make your comment.

Richard Wilkins: Good morning. R-I-C-H-A-R-D W-I-L-K-I-N-S. So on behalf of the American Soybean Association, thank you for the opportunity to offer comments on the regulation of biotechnology. ASA represents all United States' soybean farmers on domestic and international policy issues important to the soybean industry, including biotechnology.

We have 26 affiliated state associations representing 30 soybean-producing states. My name is Richard Wilkins, I am chairman of the American Soybean Association. I previously served as ASA president, vice president, treasurer, and various other roles within the organization.

I farm about 400 acres of soybeans in Greenwood, Delaware, but my operation is diversified to include corn, wheat, barley, vegetables, hay and beef cattle. Managing a large variety of crops can be difficult, but keeping up with the rules and regulations can be even more challenging. I'm here today because of the importance of a science-based regulatory system and the impact that those regulations have on my operation and on soybean producers across the United States.

For soybean producers, biotechnology is an essential tool in our quest to produce enough food to meet the needs of 9.7 billion people by 2050. Not only does it allow farmers to grow more food but it also helps make it more sustainable. Right now over 90% of soybeans grown in the United States contain at least one trait derived from biotechnology, and that's great news for our planet. By using biotech to improve seed varieties, farmers can put less strain on the environment by using fewer inputs, like water, fertilizer, and pesticides.

That is why it is essential that this technology be regulated in a clear, science-based system that sets an example for regulatory systems internationally. First of all, I want to thank the US Department of Agriculture for their work on this proposal. USDA's stated goal to reduce the burden on regulated entities is something we agree with whole-heartedly. However, we do believe there are substantial changes needed in order to meet that goal.

USDA's recognition that new plant breeding innovations do not fall under their pre-market regulatory review is important. Certain applications of gene-editing technologies that are used to create plant varieties that could also be found in nature or created by older plant breeding methods. This sends a strong message to encourage innovation in agriculture. We believe USDA needs to build on this by making a policy statement outside of this rule-making and by leading efforts globally to encourage adoption of similar science-based standards.

Unfortunately other portions of the proposal would not encourage innovation. The proposal would shift how biotechnology is regulated to an up-front risk analysis. Essentially, any new variety, even in the research and development stage, would have to go through a complex risk assessment and public comment period even though only a handful of the thousands of varieties in the field trial will make it to market. This up-front risk analysis all but guarantees that only the largest companies would have the time and resources to undertake this process.

It would greatly hinder research and innovation, which could leave American businesses and farmers at a disadvantage globally. We believe that USDA should instead focus the regulatory burden on the varieties that are intended for market.

Another major concern is USDA's expansion of the rule to include noxious weed authority. Rather than reduce the regulatory burden as USDA wants to do, this would expand it while creating regulatory uncertainty and subjectivity. The re-evaluations as outlined in the proposal also create regulatory uncertainty by putting traits in permanent regulatory limbo. Not only this, but the regulatory status of GE plants are based on a risk manager's

evaluation and interpretation, which is subjective. USDA should instead focus on a clear science- and risk-based regulatory system for biotechnology.

In conclusion, ASA appreciates USDA's goals to update the regulations and reduce the regulatory burden on the agricultural community. But to do that, this proposal needs a lot of work. The rules should not be expanded to include noxious weed authority or include an up-front risk analysis that stifles research and innovation. Changes are also needed to reduce regulatory uncertainty. We look forward to working with you to create a risk- and science-based regulatory system for biotechnology on behalf of America's soybean farmers we appreciate the opportunity to comment.

Dick George: Thank you, Richard. Our next commenter is David Whalen.

David Whalen: Good morning, my name is David Whalen. D-A-V-I-D W-H-A-L-E-N. I'm a director of regulatory affairs for Forage Genetics International. Innovation agriculture allows producers to grow better crops using fewer resources, helping to confront both global food security and environmental challenges, while keeping United States' agriculture competitive. FGI strives to develop the highest-yielding and better quality forage varieties by combining classical plant breeding, applied genomics and the introduction of biotech traits.

FGI is a vertically integrated forage seed company involved in breeding and product development, seed production and sales of alfalfa and corn silage, all key forages for the United States' dairy and beef industries. As a trait developer, FGI has appreciated working with APHIS on science-based solutions in the past, and we commend the agency for revisiting its regulations now to ensure future technologies will be adequately regulated and that proven technologies that have been reviewed repeatedly over the course of many years will require less review resources from APHIS.

As noted above, FGI is supportive of the modernization of APHIS's rule-making process. However, with any changes to existing rules of this magnitude there will inevitably be practical challenges. Our comment focuses on these potential challenges as well as the proposed mitigations of these challenges.

So we'll look at four potential comments and the first one is on approval timelines. The current APHIS system is understandable and somewhat predictable, especially for technologies that are similar to other technologies previously regulated by APHIS.

Under the new proposed system APHIS would potentially deregulate based on particular characteristics of the proposed modification. While this approach has some very real benefits, including allowing APHIS to use existing resources to review novel approaches, the practical impacts of seed companies are difficult to predict.

For example, how long will it take for APHIS to determine whether something needs to be deregulated or APHIS to make a determination of nonregulated status under CFR 340? In order to mitigate this impact, APHIS should consider continuously expanding definition of safe harbors applicable to APHIS review. This would ensure APHIS resources are expended on those products that are truly, require export agency approval.

Second one is addressing traditional breeding methods. APHIS should clarify the role that traditional breeding methods have on the overall approval process. Will novel phenotypes created by methods that have traditionally been outside of APHIS regulation now be part of the review process? APHIS should ensure that any rule changes have the effect of increasing innovation in

agriculture, provided that any appropriate review and analysis has been undertaken.

Number three is the deregulated versus nonregulated products. The distinction between the product that has been deregulated and one that has been designated as nonregulated under CFR 340 leads to the same results in the United States. For example, a seed company is free to commercialize a product. However many foreign regulatory systems require an actual deregulation before they will begin their own deregulation process.

How will APHIS handle these situations? Under what circumstances would a product be deemed deregulated versus nonregulated? Would APHIS consider a family of nonregulated status to have the same legal impact as a deregulation decision? There's a strong potential to have the United States' regulatory system at odds with key foreign export markets, exposing seed companies to litigation risks and potentially stifling innovation.

The last one is the coordination with federal agencies. Any new rule-making should ensure that essential components of the current coordinated framework, such as the role that each expert agency plays in this process, is continued. APHIS as the expert agency regulating biotechnology should be given great deference when reviewing biotechnology matters. Lack of coordination between agencies including the point where each agency's review starts and stops could lead to uncertainty and bad results that could ultimately lead to reduction in innovation.

So in summary, APHIS is engaging in exciting and wide-ranging review of the current regulations governing biotechnology. FGI is supportive of this type of bold science-based action that will lead to increased innovation and

participation in agricultural technology, while also ensuring appropriate review of such actions.

Our comment is focused on practical, real-world impacts to APHIS' proposed changes while we have made suggestions to mitigate these potential effects. We realize that there are many different ways to accomplish the common goal of expanding technology in agriculture.

We appreciate the opportunity to comment and would welcome a chance to work with you in order to further science-based innovation as protective of plant health and the various agricultural stakeholders. Thank you for your consideration.

Dick George: Thank you, thank you David. Our next commenter, Sapna Brown. Is she here? Sapna Brown. In that case we'll go to Alexis Baden-Mayer.

Alexis Baden-Mayer: Hi, I'm Alexis Baden-Mayer, I'm the political director of the Organic Consumers Association. And I want to begin by asking who in the room has read Stephen Druker's book Altered Genes, Twisted Truth. One person? Anyone on our panel? No?

Okay. This is a very important book for USDA APHIS regulators to read because the full history of how we got to this deregulatory stamp. We're now in the Trump Administration after many administrations further deregulating GMO's and the Trump Administration wants to take it to a new level.

Where we're not only going to further deregulate GMO's, we're going to hide information about GMOs are being tested, what's coming on to the market so that the public won't be aware at all about what's happening.

It's not just that we're going to have unlabeled, untested GMOs, we're going to have GMOs that are totally under the radar which is going to completely blur the lines between what is genetically engineered and what is not. Not in a scientific way, but in a way that resulting from this deregulation.

So I urge you to read Steven Druker's book, "Altered Genes, The Twisted Truth". Please read the book by Belinda Martineau, "First Fruit" about the Calgene Flavr Savr tomato and I think that's where we get to the root of where we are now.

Because when government regulators and government scientists first looked at the very first genetic modified organisms to potentially enter our food supply - they did want to do a very accurate and thorough risk assessment. They wanted to look at the science. They wanted to see experiments on what happens when animals ate these genetically modified - the tomato.

And what they found was very disturbing but it wasn't unexpected. We knew that it's dangerous to put novel proteins into the food supply and our bodies may react in bad ways to these new foods and that's what happened in the experiments in the Flavr Savr tomato.

The rash involved lesions on their stomach and at that point that's when the regulatory process changed from how do we actually discover the real science, the real risk related to GMOs to how do we avoid looking into the risks and the science around GMOs and that's when they came up the substantial equivalent review at the USDA.

And they started looking at an endpoint. You know masterly genetically modified things does it still kind of resemble normal foods and if so then can

we just treat it as normal food rather than actual doing real safety reviews to see what happens to animals or people who eat these foods.

So that's just as important. That's why I'm here to tell the real story, the truth about how we got to this point and of course the Organic Consumers Organization - the organization I represent with millions of members who are paying attention figuring out how to avoid genetically modified foods. Figuring out how to eat a clean diet. Discovering organic as as alternative. You know this is the story that they learned when they do their research and when they look at what books are available. And the industry thinks they're really getting away with something by creating new ways of genetic engineering like CRSPR and gene editing and getting these new techniques genetic engineering completely deregulated.

But there is a backfiring in the marketplace as well. People don't want to eat genetically modified foods once they learn that they haven't been safety tested. When they know they aren't labeled in the marketplace and so there's a backfiring.

Consumers end up wanting to reject this technology if they know and the government and the companies do as much as they can to prevent the public knowing about genetic engineering and that's certainly what's happening with this new gene editing. They're trying to sweep this out of the regulatory sphere so that people don't know about this way of genetically modifying our foods that is potentially dangerous.

The other problem here is what happens to the farmers? We currently have lawsuits on behalf of U.S. farmers who got their corn rejected from China and still haven't recaptured the Chinese market.

China is still buying corn outside of the United States because of a regulatory foul up on the part of the United States whereas the U.S. agencies said go ahead and grow this new Viptera of corn but China hasn't approved it yet, so the farmers weren't given good information. They grew only corn that China hadn't approved and then they were locked out of the Chinese market.

This a multiple billions of dollars at stake. Lost by U.S. farmers and we're seeing this we've lawsuits not only from farmers but we're seeing lawsuits the Archer Daniels Midland cargoes - the companies that buy the corn and have to market it globally-- so we're creating a huge failure in the marketplace for consumers, for farmers and you know we haven't even gotten to the environmental damage that is caused by unleashing into the environment.

Things like you know - growing a pharmaceutical in life. You know that's a great idea, and Bayer did that and that rice entered the environment and the USDA had to pull that variety of rice out of the market and tell famers we can't grow the rice anymore it got contaminated and it's not safe to grow it anymore.

There is just, you know the risks are nearly immeasurable and I think that going back to the original problems, that's where this went wrong. The genetic engineers realized that these products could not go through a regulatory process, could not go through a regulatory process for food safety or for the risk of contamination. Because if these products were adequately regulated it would take decades to get them on to the marketplace.

Because they're inherently unsafe. And it would almost impossible to control them once they got into the marketplace. Because if you are growing crops out in open fields, they are going to contaminate. And that's why we saw companies like Monsanto take an aggressive approach to actually find legal

ways to go after farmers and charge them with doing their intellectual property when the farmer was contaminated against their will.

And when the farmer was given the economic advantage in the marketplace. So I know it's an impossible ask at this moment with the Trump Administration. The Trump Administration gets tons of money from Dow Chemical. Dow Chemical is merging with DuPont. Bayer wants to take over Monsanto. We've got the Chinese who just bought Syngenta. We've got you know massive companies that control almost all of our food supply and so regulating at this point, you know it you paid their monsters. You all have created monsters and it's practically impossible to get these companies under control at this point.

But that's what I urge you to do because that is the right thing to do if you look at the science on this. If you go to "Altered Genes Twisted Truth", Steven Druker's book you look at the scientists in the regulator agencies originally said about these things and how they had to be regulated.

How they needed to be safety tested and go back to those original unbiased viewpoints. Four of these companies were able to take you know their lawyer, Michael Taylor, working at an independent law firm and put him into the FDA to go through the approval process of recombinant bovine growth hormone. Monsanto's first genetically modified products which was the first ever modified product to end up in the food system.

We still have cows being shot up with RBGH - the genetically modified bovine growth hormone - to make them overproduce milk and this product has been banned in most other countries, but we're still here as Americans seeing this great experiment. You know there are more countries that label GMOs than there are countries that grow them.

Because other countries didn't have their regulatory systems by corporations like Monsanto's. They maintained an independent scientific regulatory system that made it impossible for these corporations to convert democracies the way they did in the United States. And suppress science the way they did in the United States.

So we just need to go back to the beginning. We need to scrap these false assumptions that are not based on science. These false assumptions that these genetically modified foods are just the same as normal foods. I mean let's just see - they did this review under the - we had to use genetically modified animals they treat genetically modified animals as an animal drug.

And then they collected science from AquaBounty which produced these genetically produced modified salmon. And then they looked at the data on this salmon to see if the salmon was substantially similar to normal salmon.

I looked at the data and I'm seeing something that doesn't look like normal salmon because they're comparing we've got wild salmon, farm raised salmon, genetically modified salmon and looking at things like why do people eat salmon? Well we salmon for the Omega-3 for healthy fats.

You look at the amount of the Omega-3's that are in wild Alaskan salmon - off the charts. Great love of the Omega-3's. Then farm salmon - farm salmon gets really low when it comes to Omega-3's. Then the genetically modified salmon even lower than that, but the FDA ended up saying well it's you know kind of close to that amount of Omega-3s in farm salmons so we'll give a pound per less.

And they did the same thing when they looked at IGF-1 which is a growth factor levels of which correlate to certain cancers in human beings like breast cancer for instance. And they saw the genetically modified salmon when you compare wild, factory farmed, genetically modified salmon -genetically modified salmon has higher levels of IGF-1 than all the other types of salmon.

But they said but it's kind of close to factory farm salmon so we'll give it a pass. So this regulatory system --and that's not even getting into this idea like wait a second we're going to be eating a salmon that is mixed with an eelpout.

To take that gene from the eelpout that's never been in salmon before - that gene that allows the eelpout to grow when it's in cold conditions. Because the eelpout just keeps growing, the salmon naturally - the salmon has a very interesting life cycle and the salmon naturally goes through periods where the salmon doesn't grow so much.

And that's when the salmon in its life cycle and its environmental life cycle it's in places where the water is colder. So salmon naturally goes through a low growth cycle in its life.

The factory farms salmon people wanted to come up with a salmon that would keep growing and growing and growing and growing no matter what. And so they got this eelpout gene and they put it in the salmon and so now we would be eating or will be eating because this did get approved - as far as I know it's not in the marketplace but it wouldn't be labeled anyway so who knows.

So we would be eating an eelpout gene that we've never eaten before. But the regulatory system doesn't even review that. There will never --under this regulatory system-- there will never be an instance where we look at the science on what happens beings - human beings, we would have to do these as

animal experiments because it would be unethical. Like it would be unethical to feed human beings these genetically modified organisms in an experiment. Before they're approved.

Alexis Baden-Mayer: It would be unethical to do that. But the fact is we don't have these experiments and we are all part of the completely unethical human experiments going on now where there is no pre-market safety testing, nobody knows if it is safe to eat eelpout genes in a salmon or any other modification.

You know for the herbicide resistant crop, we thought we're eating genes and proteins that come from soil bacteria. And these proteins have never been in our diet before, but they're in all the herbicide resistant crops and we're eating, we're consuming these proteins. So it's really not surprising to see what medical professions - like the American Academy of Environment Medicine what they're seeing when they look at the very little safety data.

Because we do have some things like the Calgene experiment. You stated doing safety data, started looking into why there was a Flavr Savr tomato, was safe for consumption. And we have a little bit of data. And other countries went through similar things. And the UK it was potatoes. They started doing a safety study of potatoes.

It turned out that the animals weren't doing so well under those studies. The data was showing up to show up serious risks to human health and so they shut that down. You know that's how this works. The companies are willing to be regulated as long as it benefits them in the marketplace. And then the question is is our democracy strong enough to balance that?

Of course under Trump it is certainly is not, but it wasn't under Obama either. These are regulations that began with the Obama Administration - they go

back all the way to George H.W. Bush who took money from the industry and told the industry that they would be happy to move them through a process that didn't involve the regulation that the public demanded.

So we've never gotten pre-market safety testing. We've never gotten labels. We've never gotten close market monitoring and we've never gotten the protections that we need for farmers and that's why we had hugely costly contamination scandals.

We've had bent grass get out into the wilds and that was never approved. You know these supposedly we have a regulatory system that's monitoring plants, pests, risks and yet the genetic engineering experiment that we've allowed to enter the marketplace has completely created this huge problem with the weeds.

The weeds - because we know the herbicide resistant trait...

Richard George: Alexis, I'm going to ask you to finish your thought and we'll have some other people that have signed up. If we have time, we'll invite you to come back up to.

Alexis Baden-Mayer: Okay. Just for the record, I would like to state the Organic Consumer Association opposition to the new rule for 340. We don't appreciate the further deregulation of genetically modified organisms. We would like to see pre-market safety testing, labeling and we would like to see post market monitoring and protection for farmers for contamination. Thank you.

Richard George: Thank you Alexis. Is there anyone in the room that would choose to make a comment at this time?

Seeing none, we'll go to the phones. I'm going to ask (Gary Martin) has signed up to make a comment on the phone. (Gary) I would ask that you press one and then zero on your touch-tone phone. We'll see that and open your mike.

Operator: This conference is now in question and answer mode. To alert the speaker that you have a question, press one then zero.

Richard George: (Gary Martin) please press one and then zero on your telephone keypad. No. We'll get (Gary) in a minute. (Gary Martin) if you're there press one and then the zero on your telephone keypad and we'll open your mike. No? In that case we'll go to (Alexis Brubaker). If you're on the phone Alexis, would you please press one and then zero on your touch tone phone. Not there.

That's as many as we have signed up to comment. I would invite others in the room, if you're on the phone and you would like to comment and you haven't registered, I'd be happy to hear from you. You have only to press one and then zero on your telephone keypad. We will see that and we will open your mike and take your comment.

So if anyone on the phone would like to comment, please press one and then zero on your telephone keypad. While we're waiting, I'll remind people that you can also comment at regulations.gov through Monday midnight which is the close of the public comment period. Just go to regulations.gov and search APHS-2015-0057 will take you to our docket and you can leave a comment there or comment here.

If you are on the phone or in the room and would like to comment. If you're on the phone press one and then zero

No. Okay. In that case I would invite who has commented that would like to elaborate on that comments they're welcome to do so. Alexis.

Richard George: While she makes her way to the front of the room I will remind those on the phone if you press one and then zero on your keypad, we will see that and we will take your comment when we see it. So Alexis.

Alexis Baden-Mayer: So when…

Richard George: By the way will you please say your name and spell your name for our transcriber.

Alexis Baden-Mayer: Alexis A-L-E-X-I-S Baden B-A-D-E-N dash Mayer M-A-Y-E-R and the organization is Organic Consumers Association. So I wanted to emphasize this problem of Roundup resistant weeds. This is a problem is created through the genetic engineering process. It was quite predictable. The Roundup resistant trait came from soil bacteria and it can transfer quite easily from the plant through soil bacteria to weeds.

And so we have weeds now that have taken out the Roundup resistant, herbicide resistant trait and that has created a huge, huge problem for farmers. Any day of the week you can Google the Farm Trust, look what farmers are talking about. What's costing farmers' money and you will see that farmers are blighted by Roundup resistance weeds.

This is a hugely costly problem nationally, but it's just one of the things that genetic engineering has done to increase the cost of farmers through farmers. The other thing is that of course we have these huge monopolies that I mentioned. We have six big chemical companies and now that's merging into four because we have Dow Chemical and DuPont merging.

And I mentioned that Dow is a very large campaign contributor to the Trump Administration. Trump when he signs his executive order on deregulation, he handed the Dow CEO the pen. And that's what you do when you have an ally in your cause as President. And you and your ally have more cards to achieve an important piece of legislation you - as an honor you bestow your allies with the pen you used to sign that document.

So in this case when it came to deregulating pesticides like (Cholorpurochyl), or deregulating GMOs because Dow is one of the major users of the new CRISPR gene editing. So Dow and Trump are working very closely together and now they're merging with DuPont. Oh DuPont may be CRISPR --but anyway these companies are merging and becoming greater giants.

We have Syngenta becoming part of a Chinese government linked-company. So the story that I told you about current lawsuits on behalf of farmers because they were encouraged to grow Syngenta's Viptera corn and they were encouraged to do this by U.S. regulators who I guess just weren't paying attention because in China they had not yet approved this variety.

And it resulted in billions of dollars in losses for U.S. famers. So China - so now we have the larger ever chemical company in the world. A Chinese owned company and this company is now buying Syngenta's.

So Syngenta caused a problem for China so China stops that problem by just buying Syngenta's. So now they can control what Syngenta does and I guess they'll do a better job than U.S. regulators did of explaining to farmers, hopefully about what's the truth and what's not in China.

To me as the consumer that is incredibly frightening. So we have these largest agrochemical company in the world - a Chinese government company.

And it is buying one of the GMO companies knowing full well that U.S. regulator system over GMOs is flat out non-existent and the U.S. government will even encourage farmers to grow a crop that's genetically engineered but there's no export market for and let them suffer billions of dollars in damages.

So China knows that. Now they already own this huge agrochemical company and now they own Syngenta. So where is the great place to experiment with Syngenta's newest genetically modified organism? How's that the U.S. because they don't have a regulatory system to speak of especially now when we see what Trump is doing to it. Why not grow these novel GMOs here.

How about GMOs that produce pharmaceuticals or industrial chemicals because he's already seen U.S. regulators turn a blind eye to that and let farmers suffer the cost of having their pharmaceutical crop contaminate all of the rice crops in the United States and have a massive, massive economic lawsuits to farmers. Billions of dollars lost by U.S. farmers.

A variety of corn taken off the market eventually by the USDA but failed to regulate our pharmaceutical crop. So now we have these companies consolidating. We have Dow and DuPont merging. Bayer wants to buy Monsanto. China buys Syngenta and we've got BASF still standing.

Except for Dow and DuPont, all of these other companies are operating overseas. They look at their own public and have a responsibility to protect their own public. You know BASF, they sell stuff to the United States but they're not allowed to sell in Europe, a European company.

So that's what we're going to see overall with this regulatory breakdown in the United States. Not that it started at any particularly great level but we're

having - the Trump Administration you know pull it down to the lowest possible level, make sure gene edited crops like CRISPR totally fly under the radar. They're not regulated at all. Of course these public notice on the 340 rule points out oh yeah and this will also deregulate all those pharmaceutical and industrial chemical crops.

And we'll wonder where they're being grown. We'll have test spots and we won't know where they are. If you are a U.S. farmer, that should make you very, very frightened. But I guess the goal of this regulatory process is to get the point where nobody knows. There's no regulation and as you get contaminated well how would you know in the first place?

But we still have other countries with some scientific, some rigorous regulatory systems that have a public that are demanding cleaner food. The public in China is waking up to the problems in the food supply and just like Americans, increasingly demanding clean food and organic food.

And so the American people, especially farmers because this falls hardest on farmers and of course the public. We've got a U.S. public where more than half of all American adults are suffering from a diet related preventable chronic disease because of our food.

Now there is so little data on genetic engineering that it's virtually impossible to pin any of this on genetic engineering although there is a correlation between obesity rates by between weights of diet related disease and the introduction of the GMOs in the mid-1990s. But of course we shut down the science once we found out that the rats eating Calgene Flavr Savr tomatoes were doing stomach bleeds and you're like oh that is totally a mess.

Science on GMOs, we're not going to make the mistake of doing that again. Let's create a whole different regulatory system where we just look at is this tomatoes. It's genetically engineered pretty much like a tomato that's not genetically engineered. Does it have roughly the same nutritional profiles? It has roughly has the same carbohydrates and proteins and things. So we've created this completely unscientific totally deregulated system. So we have really very, very little data on the human health impact of consuming genetically modified organisms.

It's just not been listened to. And other countries saw the environmental dangers - the dangers to farmers and they shut down most GMOs without going through these rigorous food safety discussions either.

They're very, very few GMOs grown in Europe. I think it's down to one GMO that's grown in Europe. So most of the world doesn't eat the GMOs that we eat although Europe has a problem because they are importing brainless genetics engineered for their animals in factory farms.

So they've got that issue but we're the ones consuming the milk that comes from cow that overproduce milk because they've been given a genetically modified growth hormone. We're now the experiment grounds for all of the CRISPR. We're taking the new apples and potatoes and mushrooms and flax and corn and all of the new experimental vegetables that are entering the market.

We did the papayas in Hawaii. Most other countries aren't part of this experiment and so it's a little wonder that the U.S. has for developed nation we have the highest rates of obesity and diet related diseases. So of course the science hasn't been done.

So that's what needs to happen. We need to go back to the beginning, listen to what the first scientists of the U. S. regulatory agency said. Look at the few experiments that were done at that time, Flavr Savr tomato or the potato in the UK. We need to look at those experiments and then we need to assess from start fresh from the beginning. Because we just don't have a regulatory system that's worth preserving. We need to start fresh. It should come from the agencies - the agencies do have a responsibility. The FDA, the USDA, the EPA - they do have labor responsibilities under current law to regulate GMOs, to conduct pre-market safety testing and just one more thing.

Richard George: Alexis?

Alexis Baden-Mayer: American Medical Association which is not a radical institution when it comes to looking at hospice for the American public. The American Medical Association has said that we should shift from what the FDA currently does which is a voluntary assessment of GMO health risks and shift to a mandatory pre-market safety testing system for GMOs.

Richard George: Can I ask you to take a pause? I want to make sure that there's no one on the phone who's wanting to comment or in the room. So I'm going ask if you do want to make a comment and you're on the phone, please press one and then zero on the telephone keypad and let us know. We'll take a little pause here to see if anybody does.

We do have someone. I'm sorry. Let's pause for a second to see if we can get this worked out. Oh good. So if you're on the phone press one and then zero on your touch tone - your telephone keypad and we'll see that and open your mike.

Alexis Baden-Mayer: You know we had a huge GMO labeling to date last year in Congress.

Richard George: Just hold for a second.

Alexis Baden-Mayer: I just figured no one was speaking.

Richard George: There's someone apparently is trying to connect.

Alexis Baden-Mayer: Okay.

Richard George: Okay. So Sapna, Sapna Brown.

Sapna Brown: Yes. Good morning. How are you today?

Richard George: Very well thank you. Just hold one second. Alexis if you would just like to take a seat and you're welcome to come back up if we have more time. Sapna thanks so much and would you start please by just saying and spelling your name so that our transcriber might get it right and go ahead with your comment.

Sapna Brown: Certainly. My name is Sierra - Alpha -Patha - November - Alpha and last name Brown like the color. Thank you for the opportunity. I will be submitting comments electronically as well.

First and foremost with the recent update of the coordinated framework in early 2016 and we also seen the proposed deregulation of Canola. I don't where that is in the process, but there's three points that I want to make here today.

And first and foremost is that we cannot control GMO pollen. The initial coordinated framework draft that was authored by Dr. David Kinsbury, in the

80s was flawed. Dr. Kinsbury was also known to have ties to the biotech industry back then and to resign from his position with the White House Office of Finance and Technology policy.

So the initial framework was biased and it was flawed with an improper risk assessment - it never addressed the issue of GMO pollen and it still poses a threat to control GMO pollen.

And we don't understand the environmental impact of (unintelligible) and nor has it been tested on all the individual ecosystems within that GMO population and there's no way to control it. And that's a very big ripple in our ecosystem for which we do not understand the implications.

The other point I want to make is the conflict of interest. Right now biotech companies are able to manufacture GMO products and at the same time manufacture the pesticide that those GMO products must be resistant to. This is a conflict of interest. This is a bioethical issue that was never addressed when the initial GMO products were approved, when the initial policy was developed and now it's still poses an issue.

And because the biotech industry is a billion dollar industry no one is going to address this and I feel like just because this is a huge billion dollar industry that this issue should not be neglected.

The other problem that we have is a framework is supposed to help execute your policy. And here we're proposing an update to the policy and that's not the way it typically works. That is also a problem. We're not allowed to bring back plants from Hawaii yet we have GMO pollen that's able to comingle.

And this creates problems for the organic farmers as well. There is also no independent testing of the results that the bio companies claims against products. There is no third party or independent testing and this needs to be part of the approval process.

I will be submitting comments electronically that has more detail on the points that I have communicated here today. But in the meantime, we need to advance audits under the Lobbying Disclosure Act of 1995 for biotech companies, lobbying groups, companies with the GMA and individuals and federal agencies.

We also need to start reporting the conflict of interests and The Office of Government Ethics is the office that can address this for us. Christopher is the deputy director for compliance and you can call him at 202-482-9224 to communicate these conflicts of interests within the biotech companies.

This is the equivalent of a software company making an anti-virus program and at the same time making the virus. This makes no sense. Also we can demand an office of inspector general investigation for policy violations. Right now this is in violation of the federal acquisition regulation for contractor conflicts of interest.

This is applicable to the biotech industry and the relationship with producing the pesticides and the biotech products. So as long as the USDA inspector, you can reach her at 202-720-8001. This is also fraud. Because we have these huge conflicts of interest and we have behind the scenes lobbying going on, to protect these biotech companies, this is probable cause for fraud. And those can be reported at the GAO at 800-424-5454.

That concludes my comments for today.

Thank you.

Richard George: Thank you Sapna. So I would ask if there is anyone on the phone who would like to make a comment at this time. Please press one then zero on your telephone keypad. We'll open your mike and take your comments. We'll pause for a minute to see if we have any takers. One and then zero. No.

In that case if anyone would like to come forward or who's already spoken who would like to elaborate on their comments they're welcome to do so. Alexis.

Alexis Baden-Mayer: I'd like to comment on the lack of comments. We have a system that is so broken it has lost the trust of the American public. And I don't think there's anyone on my side of the issue in their right minds who believes that testifying today would make any difference to improve the situation for U.S. Consumers here at the USDA under Trump.

And so I think that's why we don't have a lot of people here. The system is broken. People know that it doesn't matter if they weigh in and also they know that the industry has so many back channels to the administration.

The close relationship between Trump and Dow Chemical is just one example. We have a revolving door that shuffles people between the Lawson's that represent the industry and the regulators. And we have many, many instances historically where we see justice of states probably the most famous incidents.

We have Michael Taylor, Monsanto lobbyist working for an independent law firm whose job is lobbying. He comes into the FDA after that and well first

he submits the action for RBGH - Monsanto's genetically modified bovine growth hormone and then as a regulator he gets to approve that same application.

That's insane and when as a consumer, as a voter, as a member of the American public when you learn these things, it makes you crazy and it makes you so hopeless. And then you start to think then how can I save my house - the house of my children and what can I do in my community with my neighbors.

What can I do to help get cleaner organic food into my neighborhood -- through the schools, through the grocery stores-- you start to think of really practical things and that makes so much sense? Growing your own food, learning about permaculture, learning how to grow organically, learning the environmental benefits of organic and looking at the positive things we can do with organic food.

I think that's where most of the members of the public have gone since the mid-1990s when we realized the U.S. government was totally controlled by companies like Monsanto. And there was zero hope that we would adequate safety tasting wavelength, etc.

There is a particular contact under what - for what is happening here today with the deregulatory rule and especially how it impacts the new GMOs that are created under gene editing techniques like CRISPR because in 2015 we had a massive fight over GMO labeling.

We had the state rapidly moving toward the position where the states were going to label GMOs if the federal government would not. We had a series of valve initiatives and then our first win in Vermont. Vermont became the first

state to require labels on GMOs and Vermont would have decided what a GMO is. What needs to be labeled?

This fight was quickly rushed at that point to the U.S. Congress where Monsanto can easily influence the 435 members of Congress and the 100 Senators. That's a lot easier than going 50 states and having to deal with thousands of state legislators.

Although Monsanto does that pretty well too. They make campaign contributions at every level, but they quickly realized that this is a fight that they can more easily win than at the Federal level.

So they rush forward with legislation to label GMOs federally and that passed. Now of course there would be no real labeling that any consumer could recognize because the law you could put a QR code and if you've ever seen one, it looks like a language of an alien planet.

It's a square with blocks of black and white. And if you happen to be in know, you can hold your smart phone up to that black and white square to find whatever information you think might be behind that square.

So that was the labeling that the head of Congress came up with to obviously you know created by Monsanto and friends and the junk food industry. And the Grocery Manufacturers Association which represents the junk food industry and all of these process food products that are making Americans fat that contains genetically modified organisms. They're the ones who came up with this crazy scheme about how to so called label GMOs.

So this law in the regulatory process. It can't be implemented without regulation and one of the big issues in it because it's possible is that is a foot

in the door towards real labeling. Maybe if the American public is made aware oh yeah that QR code there that little black and white --you know box there that looks like nothing-- is supposed to inform you as to whether or not there are GMOs in this product.

It's possible that this could raise consumer awareness and create a demand for real labeling. But one of the things in this law that severely hinders those future positive impact of this law is that it has a very narrow definition of GMOs which would be further narrowed by this deregulation for 340 that would basically give a free pass and exempt almost all new genetically modified organisms created by these new gene editing technologies.

And so this is a very strategic moment for the GMO industry because as you know their first line of defense was make sure none of our GMOs ever enter any type of scientific (unintelligible) testing protocol. We do not want our GMOs fed to animals to find out what happens to those animals.

That is not the route that the companies wanted to go. And that's even like they were submitting their own data. We never even had a chance of the FDA, USDA, or EPA to demand independent science. That was never on the table.

But the companies would scout when their own data was examined. Same thing happened in Europe over Monsanto's corn when their own data that they submitted to regulators was reviewed by independent scientists and the independent scientists saw that there was a liver damage and kidney damage and there were signs of toxicity in the short-term non-governmental, non-independent short-term company data.

Like the company's own data hinted the House Standards related to GMOs. So that was the company's first line of defense. Like don't even ask us to

conduct our own animal experiments. We do not want to go through any type of safety testing protocol.

But then the second line of defense is we are not labeling even after the StarLink disaster when like all the corn had to be pulled off the grocery store shelves because we did not know where the unapproved StarLink corn was.

You know that's huge economic losses to the industry. Even after that, those are the last of two companies represented by the Grocery Manufacturers Association. You would think that even the processed food junk food companies would see the value of labeling so that they could prevent huge disasters where you have contamination from unapproved GMOs.

But I guess the companies, what they really want like just don't have approval processes you know. Don't even pretend. Don't even rubber stamp our own submissions? We don't even want the American public to know when a new genetically modified organism is in development.

And this deregulation proposal comes very, very close. In many instances actually will prevent the American public from knowing when there is a new genetically modified food entering our food supply. This is the moment in which there is no work that any member of civil society can do to balance the devastation left by this deregulation.

Because you know it's like a new genetically modified crop is going through the approval process. We mobilize comments to oppose that. We demand actual scientific data on its safety. We participate in the regulatory process. When that regulatory process is obliterated, as this rule will do for most new GMOs, there is nothing the American public can do. There is nothing as a

member of Congress or a governor. It doesn't matter if you have status within this democracy, there is nothing you can do.

You do not know if there is new genetically modified food at the grocery store that you may be picking up right now. You don't know. The regulatory system like I said earlier, the regulatory system is moving from unlabeled, untested to completely under the radar. Unknown. We are coming to a new era, brought on by the Trump Administration where you will not know. There is no way to know.

The government is not asking for any information. This rule takes us so very close to that and I believe the many GMOs this rule could be interpreted to allow that and of course…

Richard George: I'm just going to ask you to just take a pause. I just want to make sure there is no one who would like to comment who has indicated either in the room or on the phone. If you're on the phone you would press one and then zero on your telephone keypad to let us know you would like to make a comment. So we can pause it to see if there is anyone waiting.

One and then zero on your telephone keypad. Okay. No comments so if you would like to continue you can but for those that are here and not familiar with the building, the restrooms are right outside the door on either side of the elevators if you need to use the restroom.

Having said that Alexis.

Alexis Baden-Mayer: Thank you. So I mentioned earlier that there is practically no data on the actual human off impacts of consuming proteins from genetically modified

organisms. Proteins that have never ever been in our food supply that our bodies are not prepared to handle.

But there is a teeny bit of data and you know we've got the whole story of the Calgene Flavr Savr tomato, potatoes in the UK as I mentioned earlier. So there is a bit of data and when you look at that available data this is what the American Academy of Environmental Medicine says. There is more than a casual association between genetically modified foods and adverse health effects.

There is causation as designed by Hills Criteria in the areas of strength of association, consistency, specificity, biological gradients and biological possibilities. The strength of association and consistency between genetically modified foods and disease is confirmed in several animal studies.

Multiple animal studies show significant immune dysregulation including upregulation of cytochem, protein molecules involved in immune responses associated with asthma, allergies and inflammation.

So we don't know much about GMOs but we know enough for medical experts to give us that warning. Now in that instance why would anyone in their right mind further deregulate genetically modified organisms? Why would we do that?

We really have to move beyond this deregulatory era and finally institute the pre-market safety testing that is needed. And I'm open-minded. You know, what gives me the ammunition to oppose genetically modified organisms is that they haven't been safety tested. You know, that Calgene Flavr Savr tomato that did go through a semblance of scientific review with actual data although it was conducted by the company.

You know, that tomato didn't stay on the market very long. So, you know, it's like when we know something and we know that it's dangerous of course people are going to reject it. But I'm open-minded. If we do that type of (wordless) scientific investigation and we do find for real that genetically modified organisms are actually safe as opposed to they have a similar nutritional profile as normal food, which is our current regulatory practice, you know, I'm open-minded.

I think most consumers are. I think most consumers like the idea of new technologies that can improve our food. But they are not willing to be guinea pigs in an experiment where we're conducting a human experiment right now in the United States that would be unethical and illegal to perform if we actually did it under control.

You know, if we did it as a controlled experiment it wouldn't be allowed. I can't take a group of school children and say let's feed half of them organic and let's feed half of them GMOs. And then let's track their health over their lives. That would be, you know, if we were talking about a GMO that wasn't approved on the market yet, that wouldn't be allowed.

I couldn't do that. But that's actually what we've done. We've taken a whole generation and it's not my generation and I feel sorry to say but I, you know, I actually got to reproductive age before GMOs entered the marketplace. I graduated from high school in 1992. So it's not my problem. I've reproduced. My children are healthy.

It's a problem that rests on the younger generation, on my younger cousin who was born around the time that I was in college. So is - after I graduated from high school and this was when – she was born the same year that

Monsanto's genetically modified bovine growth hormone entered the market. And she probably drank rBGH milk, genetically modified milk for all her life.

And so far she seems healthy and smart and I am very proud of her. But, you know, it's like we're going to see this generation coming up, like my generation had problems with reproduction. And we're going to see the next generation coming up and we're going to see the health problems associated with our diet. And it's not all GMO and it's one of those things that makes it really challenging when you don't do experiments on these novel proteins that have never before been eaten by human beings.

And you don't actually test the GMO that you're putting into the food supply, you'll never really know. So, you know, is it high fructose corn syrup, the way that it's processed, the residues of Mercury or is it the fact that the genetically modified corn was modified with proteins that we never ate before.

So we don't – we just are left in the dark. And what we see right now, as I mentioned earlier is we do have a population that is growing increasingly unwell. More and more diet-related diseases, chronic preventable diseases, more and more cancers, more and more allergies, more and more issues with our kids coming up where we're having – we see a generation that is increasingly obese, allergic.

We have the whole autism problem, ADHD. We just see a population that's not well. We're, you know, maybe it's the junk food. Maybe it's that the junk food is genetically engineered. It's going to be really hard to tell. But there are medical professionals who as I mentioned what I read before is – that look at the data that we had when we considered having a real regulatory program for GMOs.

And they look at that data and they mention the things that have turned out to be chronic in our society. So they do talk about the autoimmune problems and the allergies. And they say that the little data that we were able to grab before the industry trounced on our regulatory system and our democracy, they say that that indicates the same problems that we're seeing show up in our population.

So I think it's just so important to safety test. That's all there is to it. And it's so important also for farmers to be protected. You know, I mentioned the contamination scandals that started in 2013 when Syngenta rushed the Viptera genetically engineered corn to the market and the USDA said grow it. And yet it wasn't approved in China and China rejected the corn from U.S. farmers.

And China is still not buying corn from U.S. farmers. The economic losses calculated by the farmer's lawyers and this is still in litigation - $13 billion in economic losses. Just the economic losses. And they're also asking for punitive damages. This is what happens when we don't have an adequate regulatory system.

We have poor human health and we don't know the cause. We have farmers who get contaminated and they lose their markets. Billions of dollars; $13 billion from one – one contamination event. It's just a disaster.

And this new rule is an invitation for more disasters. And it's an invitation for countries like China and a Chinese governmental connected, largest chemical – Agrichemical Company in the world now also owning Syngenta – it's an invitation for these companies to perform their experiments here in the U.S., under very, very little regulation.

And I'll just summarize. I haven't, you know, I've talked about what we should have and why we need it. But I haven't really mentioned…

((Crosstalk))

Alexis Baden-Mayer: …can I just – I have just a very brief thing. It's will take less than a minute.

Man 1: We have someone on the phone who's waiting for a lot of time. If you'd like to come back up and finish when there's time, that's fine.

Alexis Baden-Mayer: Thank you.

Man 1: Okay.

Alexis Baden-Mayer: Just one quick thing.

Man 1: We have someone on the phone. Can we open their mike please?

Clifford Laufer: Yes, my name is Clifford Laufer and what I see – on a very high level of this situation – is that GMO pollen is uncontrollable. It can go anywhere. And in fact in situations where GMO pollen has escaped and contaminated other crops it is the other crops who are penalized. The people who have those other crops who are penalized for this situation.

So you have this wild, uncontrolled propagation of GMO pollen. When you combine that with what these latest changes to whatever weak regulations already exist so that modifications to modifications – that is GMO modified GMO pollen is allowed to happen with no announcement, no determination, no way for anyone to know what's going on.

Then it seems to me you have an even more uncontrolled situation that is so dangerous that it's going to be impossible for anyone who wants to have a safe food source to have any confidence that their food source is safe. So these changes to the regulations are going so far in an unsafe direction that – please don't approve. Thank you.

Man 1: Clifford before you go…

Clifford Laufer: Yes?

Man 1: …would you still like – would you just please repeat your name and spell your name for us please so our transcriber can get it right. Thank you.

Clifford Laufer: Okay. Well Clifford, C – L – I – F – F – O – R – D, Laufer, L – A – U – F – E – R.

Man 1: Great. Thank you so much Clifford. Thanks for your comment.

Clifford Laufer: All right.

Man 1: Okay so I will ask if there's anyone else on the phone who would like to comment, please press "1" and then zero on your telephone keypad. We'll pause for a few seconds here.

Seeing none I would invite anyone who has commented who would like to comment more to feel free to do so at this time. (Alexis)?

Alexis Baden-Mayer: I don't think anyone has summarized for the record the impacts of this new rule for 340. So this is Alexis with Organic Consumers Association.

This proposed rule would exclude form the definition of genetically engineered organism vast categories of new GMOs produced through techniques like CRISPR which involves genetic modifications that can be obtained through mutagenesis, marker assisted breeding, tissue culture or protoplast, cell or embryo fusion or where the offspring of an engineered organism do not contain the genetic modification.

Now if you've ever looked at a patent for a novel food product you will see that the patent holder includes all of those techniques plus transgenesis. Because if you are a patent holder and you want to control your product you have to imagine every possible way your product could be created. And so my guess is that this is a very, very large loophole.

Because it's, you know, how are we going to prove that. I have a new GMO and I used transgenesis or gene-editing or whatever it was that I did but I'm going to claim – because of this new regulation – that it could have been done through these other techniques. Now how do you prove that I'm lying?

It's officially if my patent says that it could have been done under any of these techniques because my patent was not written by scientists, it was written by a lawyer. And the lawyer's objective was to protect my intellectual property. So the lawyer made a laundry list of every single possible way this could be proved – or this could be produced.

How do you prove that my genetically engineered organism couldn't be made by one of these other unregulated techniques? It's pretty much impossible so this is a very, very large loophole. And it is definitely a (guest to dodge DuPont) and to all of the other companies that are using the new CRISPR and gene-editing technologies. And they're making this case like oh, yes, well I

mean we are genetically engineering this but we could have created it through different forms that you don't regulate.

And therefore you should not regulate us. That's a really crafty argument. You know, as a lawyer I applaud that crafty lawyer who came up with that. Probably a patent lawyer looking – hey look at this. What, you know, on our patents look at all these ways that we say we could create something and some of those are not regulated. And the way we create it right now is regulated, why don't we come up with a loophole that says it doesn't have to be regulated if it could be created through an unregulated process.

Genius. Absolutely genius. The Dow and DuPont lawyers and Monsanto – whoever was involved in that I applaud you now. It's evil genius.

And consumers watch out because here comes the train of new GMOs that are not regulated at all even though they actually are genetically engineered. But they created this loophole under the law to allow them not to be regulated if they could be produced through a technique that's not considered genetically engineered under the law.

It's so crafty it's, you know, it's - so it would be very hard for somebody to figure this out looking at the regulations if they hadn't looked at patents for GMOs. It's just beyond crafty. Evil, evil genius.

Here's another thing that the new regulations do. They relax permitting requirements that let us know when and where crazy new GMO experiments are happening. Let's go back to a scandal that the former Governor of Iowa and then former USDA Secretary Tom Vilsack weighed in on. The Protogene contamination scandal.

Protogene, company in Iowa, had this great idea. Let's make a pig vaccine and let's grow the pig vaccine in (corn). The same corn that we have in the human food supply. How about that?

And I guess the idea – yes it did kind of make sense because we see pigs corn so why not grow the pharmaceuticals that we give to pigs in corn? Great idea. Awesome. Let's – so we did. And then quickly because as we've mentioned and several of the commentators have mentioned, you can't control pollen. Pollen from corn can travel a very long distance.

And so these test plots, complete test plots, like government regulators had not said oh yes we think it's a great idea to grow for the market pig vaccines in corn – but they let them do it. And the thing was we knew that they let them do it because there was a regulatory system that required this process where you had to know when and where the crazy new GMO experiment was happening.

I think it was crazy that they let them do it. But at least we knew when and where it was happening. So that when somebody, thankfully, tested the corn – probably another government or maybe a USDA organic certifier like, you know, something – we're relying – we have such a broken regulatory system that we're relying on other people to catch our mistakes.

So anyway the mistake was caught. The pig vaccine – corn – ended up in normal corn and it created a huge problem. But of course the Governor of Iowa, Tom Vilsack at the time he said, you know, it would be – it would just be too horrible to put any restraint on this burgeoning new industry of pharmaceutical crops to institute regulations to protect farmers or consumers in this instance.

So the Governor of Iowa didn't step up and do anything. Later he was thanked by the biotechnology industry organization by getting the title of Biotech Governor of the Year. And we didn't get great regulations after that. Like the situation didn't change. And probably as we speak there are crazy experiments happening, pharmaceutical crops, crops producing industrial chemicals and they're growing right now, right next to the same fields that are growing our food.

It's happening. But we actually have a process right now in the law that allows us to know when and where. And this new rule obliterates that process.

And so like I said we're moving really, really, really close with this new rule to a point where we have no idea. The regulatory system has left the building. There's still new GMOs but we don't know when, we don't know where, we don't know what. And we're not regulating it anyway.

So that's a very scary place to be. All right. Here's another – so we're gutting this – this rule would gut the already weak approval process where the USDA rubber stamps Monsanto and Dow's own science so that for most GMOs the companies wouldn't have to submit any data at all.

And I mentioned that earlier because it's – we don't have a great system now. And we don't always require companies to submit data. We don't always require them to submit data with certain experiments that would actually tell us something about the human health impact of the new GMOs.

But we had a process where we could. And now we're about to head off a process where the regulator's hands are tied. The decision has been made. They cannot make a decision otherwise. We are not going to require data from the companies on health and safety, etc.

So we're just living dangerously close to zero regulations. And then as the rule mentioned or as the Federal Registry notice on the rule, the proposed rule mentioned, this rule proposes to end oversight of most bio factories. The GMOs that are engineered to produce pharmaceuticals and industrial chemicals despite their unique danger.

So they're – this rule is a deregulatory rule. And there is no safety – there's no way to catch it if a GMO has very dangerous, unique intent. So I mentioned earlier that this new rule seeks to exempt vast categories of new GMOs. Well what if one of those was designed to produce a pharmaceutical, an industrial chemical and it was put into the same food and grown right next to the same acres farmed growing the food.

And yet it's intended for industrial or pharmaceutical purposes. But it no longer meets the definition of GMO because that definition has been sapped of its power. It's been reduced to the point where most new GMOs are not going to be considered genetically engineered under the law.

Tough luck. There is no special requirement here that just because a GMO poses a particular danger that it should be regulated under the law. This is a huge loophole. This is a scary – I should say it's a scary, scary result of a huge loophole.

So probably when you're thinking oh yes the CRISPR stuff, all that gene-additive stuff and then anything that any company can claim what could possibly be produced through a form of modification that's not regulated as genetic engineering.

Man 1: Can I ask you to just pause, just for a second. We're going to invite those who are on the phone if they'd like to make a comment to please let us know by pressing "1" and then zero on your telephone keypad.

And now we'll pause just a second to give folks that opportunity. Or if anyone else in the room would like to make a comment just raise your hand. Be happy to take it. So we'll pause for just a second or two.

Seeing that there are none you're welcome to continue.

Alexis Baden-Meyer: Yes. So this rule is quite scary. Not only will – if this rule goes through and is finalized we won't know much about the genetically engineered food – or genetically modified foods that are entering the market after this. Because most of them won't be considered genetically engineered. And they won't be regulated any more.

This rule intends to create a very, very, very large loophole that many scary things could go through. And I think everybody, you know, it's like we get Washington Post articles that talk about how great CRISPR is. And there's so much, you know, like shiny, new, happy technologies propaganda out there because these companies are massive.

They spend a lot of money lobbying. They spend a lot of money on advertising. They spend a lot of money on influence peddling. They practically buy universities. They collude with scientists. They undermine our regulatory process.

I mean we just had information come out of the lawsuit on behalf of Roundup exposed cancer victims who are trying to get some justice for having been

victims of Monsanto's Roundup and having gotten Non-Hodgkin's Lymphoma from exposure.

We've got this lawsuit happening and then through that lawsuit we learned that Monsanto colluded with an EPA employee to shut down – basically shut down the regulatory process that was trying to determine whether or not Monsanto's Roundup is a probable human carcinogen as the World Health Organization has determined.

So we already have a situation where despite whatever regulations or laws are on the books, the companies get what they want. They do what they have to do to get what they want. And now we're just serving it up on a platter to them. The Trump administration is just saying here, why don't we rewrite the definition of genetically engineered so that most GMOs will never meet that definition.

We are ending the era where we learn more and more about genetic engineering. We are ending an era where we have the capacity to investigate what is in our food supply. It might not be safety tested, it might not be labeled but we at least had a regulatory system that allowed us to investigate as citizens and eaters to participate, to weigh in on the regulatory system.

Like how many more of these public hearings could possibly happen? I mean I'm not sure what more you could do to – legally. I mean probably a lot of this is not legal but I'm not sure what else any crafty Monsanto lawyer or USD regulator could think of to deregulate.

Like how many more opportunities will my organization have to come to a public forum and speak on the record about GMO regulation? I mean this might be it.

The way – the direction that this rule takes us – this might be it. After this if this rule functions the way that the companies intend it to and hopefully it won't. I mean I still have great faith that our court system can protect us from the worst possible outcomes of this rule.

You know, it's the last place we go to when the democratic process has failed us that the court system can require the government to follow NEPA etc., and follow certain rules to maintain an adequate regulatory system. But I fear that this is just getting so dangerously close to no regulation at all that this might be one of the last opportunities.

And so I'll be an old woman saying to people that are two generations from me do you know what happened to our food starting back in the 1990s. It will become like an old wives tale. People will wonder if it's an urban myth. Because there will no longer be a regulatory system that follows the progress of the industry.

And that is a very, very dangerous place for all of us to be. We need to have, you know, at minimum a regulatory process that keeps up with new technologies. Not keep up with them to exempt them; which is what this rule does. This rule's like hey gene-editing, cool. Exempt.

You know, this – we don't want to - it's not enough just to keep up with new technology so that you can deregulate it. That's not a good way to regulate. We need a regulatory system that can at minimum keep up with new technology to at least make the public aware of what's out there, so that we can choose organic.

Because if we can't tell, you know, this light might shift to the organic realm. Well it wasn't considered genetically engineered by the USDA, why can't they have it in organic. I think we're going to see those petitions coming before the National Organic Standard Board. And, in fact, we already have.

There is an Algae Oil, DHA which has been approved for use in organic even though my organization made the argument that it was genetically modified, that it was genetically engineered. Or under the organic definition we have – in organic we have excluded methods.

So now if – well as the USDA further narrows what can be considered genetically engineered then it's harder to keep these new technologies out of organics. Or should require that they be labeled because as I mentioned Congress passed a law to label GMOs, it's very weak. It doesn't require real labeling.

And now with this new deregulation they're going to interpret what should be labeled to be very, very narrow. So it's no place to start even to argue, you know, it's like you get to a point where as an advocate there – what am I asking for? I'm asking for things that the U.S. Government at the USDA has determined are genetically engineered to be labeled. Well that doesn't catch half of the real genetically modified organisms our there.

So this law doesn't just impact what happens at the USDA. It has ripple effects, ripple effects throughout our entire food supply. As a human being, as a citizen, as a voter, as a consumer it is going to be much, much harder to track the new GMOs that are entering our food supply.

They were never regulated. But now we won't even know that they're coming. And when we tried to develop a food system of clean food, of non-

GMO food, or organic food you have all these things in the environment that can potentially contaminate and yet they're not regulated. There will be companies that should – will even argue that they should be allowed in organics.

It's a very, very scary scenario to be in. And it's just time to take a step back. It's time to scrap this whole process and come up with the regulatory system that American consumers and American farmers have always deserved and always needed. We have to protect human health. We have to protect farmers and their export markets.

It's amazing what farmers have had to do under the – the process which we've had in the past which actually had a regulatory system as opposed to what this rule would propose. When new GMOs got rammed through the old regulatory system farmers had to make very hard decisions about how to protect the export market.

So for instance in California where the farmers are growing alfalfa for the export market and the Imperial Valley where they grow the most alfalfa for the export market in the United States, they had to just make an agreement. They had the Farm Bureau broker an agreement locally to not grow genetically modified alfalfa. And they just had to agree to it.

And there wasn't any – they couldn't look on anyone at the USDA to put in the restrictions on how these new GMOs should enter U.S. (fields). There is – the USDA has put so many things and these are regulated GMOs, far more regulated than the ones we will see in the future if this rule goes through.

But there was nothing to protect farmers once these new GMOs got into the marketplace. And so farmers just had to self-protect; conventional farmers as

well as organic farmers. It's extremely costly for organic farmers. They have to self-protect. It is a costly endeavor because every farmer is surrounded by all of the GMO crop. And all of the test crop as well.

All these pharmaceutical, industrial crops that have entered our fields. And now we're getting to a point where we won't even know when or where or how because often when you go to your regulatory agency as one of these biotech companies and you're making this argument that this rule invites you to make, this rule says we won't regulate you if your product could have been produced by these unregulated means.

It's really going to – we're going to get so little information about how these crops are actually produced. And not a regulation is slipping but that – as regulation slips our knowledge about our food supply goes down to virtually nothing. If the regulators can't require this information…

Man 1: What's this? Can I ask you to pause for just a minute? We'll go ahead and invite others to comment if they care to; whether you're in the room or on the phone.

If you're on the phone listening and would like to make a comment please press "1" and then zero on your telephone keypad. And we will take your comment at this time. Give folks a minute or two to do that if they choose to; "1" and then a zero on your telephone keypad.

Being there are no takers, you're welcome to continue.

Alexis Baden-Mayer: All right so I recommended especially to the APHIS regulators if you weren't around in the 1990s when these things first started to be investigated

and a regulatory scheme was being created for them, it's really important to read the history. And to know what happened.

So I recommended two books. One by Steven Druker, Altered Genes, Twisted Truth; one by Belinda Martineau who actually was the GMO spy interest. But this is a really great book that is really enlightening about the situation because Steven Druker, he was a public interest lawyer who through a lawsuit got a lot of documents from the USDA and the FDA to figure out what was going on behind the scenes.

So that's a great history. But Belinda Martineau, her book First Fruit she has the history from the company's perspective. Because she works for Calgene as a bioengineer on the Flavr Savr tomato. So these are our excellent histories. And like I said I'm going to be an old woman saying like did you all know what happened to food in the 1990s?

You know, it's going to be great because if we go this route as deregulation we just won't know what's happening – the new technologies that are entering the market. So this may be a very – I hope this is not the case but it may be that this is a very special, unique time in the history of the U.S. food supply when novel technologies were used to create new foods and we actually knew what was going on.

And so we have – we actually knew in the 1990s what products were entering the marketplace, how they were produced, what sort of scientific data there was to give us information about how they might impact human health. We actually knew. And we have these two books that are of great history of that time; very important for anyone who is, you know, most of us are too young to have lived through that and known what was going on at the regulatory agencies.

So even for people who worked at (basis) and USDA and FDA and EPA it may have – this is still an incredibly important history. So these – it produced a regulatory system that – what the scientists wanted – at the FDA what the scientists wanted was a sincere regulatory system that really would monitor these new GMOs for their potential human health impact.

And when that data was collected, data done by the company, when Calgene submitted its data for review the government regulators were very concerned because of the things that they were concerned might happen with genetic engineering were happening with the Calgene crust. The stomach legions with the rats was the one that, you know, that sticks in your mind.

But I want to read a little bit of what Steven Druker has written about this situation. Because he was the public interest lawyer who did a lawsuit challenging the government regulatory system for GMOs once it was finalized. So after considering doing real scientific regulations the government, influenced by Monsanto and other corporations decided to do this substantial equivalency system instead.

So instead of figuring out what happens when animals eat novel GMOs let's just see whether the GMO and the normal food is pretty must the same and then we'll decide if we ever have to regulate it. And so Steven Druker has written about this issue. And here's his summary of what happened.

And okay so he says, "Although it purports to be based on solid science and open flow of information on which science depends, the massive venture to reconfigure the genetic core of the world's food supply has substantially relied on the propagation of falsehoods. This advancement and very survival has been crucially and chronically dependent on the misrepresentation of reality to

the extent that more than 30 years after the creation of the first genetically engineered plant, the vast majority of people the world over including most government officials, journalists and even scientists continue to be misled about the important facts."

"Moreover contrary to what people would expect with biotechnology industry has not been the main source of the deception. Instead the chief misrepresentation has been issued by respected government agencies and eminent scientists and scientific institution."

"The following paragraphs describe several of the key deceptions and delinquencies that have been essential in enabling the genetically engineered food venture to advance. All of which are more thoroughly documented in my book," Steven Druker's book, "Altered Genes: Twisted Truth."

The disaster was caused by genetically engineered industries first edible product was obfuscated. Sorry I didn't read that right, let me repeat that. The disaster caused by GE's first edible product was obfuscated. The genetic engineering venture received an alarming jolt when its first ingestible product caused an epidemic that killed dozens of American's and seriously sickened thousands, permanently disabling many of them.

The product was a food supplement of the essential amino acid Tryptophan that had been derived by – derived from genetically altered bacteria. Although it met the standard for pharmacological purity like all other Tryptophan supplements it contained minute amounts of impurities. However unlike the conventionally produced supplements one or more of this accidental addition was highly toxic, even at extremely low levels.

Because none of the Tryptophan supplements produced via non-engineered bacteria had ever been linked to disease and because genetic engineering can create unintended disruptions within the altered organism there were legitimate reasons to suspect that the process had induced the formation of the extraordinarily toxic substance that caused the calamity.

Consequently the proponents of genetic engineering including the United States Food and Drug Administration, the FDA, which admits that it had the policy to foster biotechnology, strove to convince the public that the technology was blameless.

But to do so they had to issue a string of (respective) statements. Those deceptions have been highly successful. Consequently, despite the fact the evidence points to genetic engineering as the most likely cause of the toxic contamination.

Most people who know of this tragedy are under the illusion that the technology has been exonerated. Worse, because GE proponents routinely claim that none of its products has ever been linked to a health problem, most people aren't even aware that such a catastrophe happened.

The problems linked to the first GE whole food were also covered up. The first whole food produced via genetic engineering Calgene's Flavr Savr tomato was also problematic. Calgene voluntarily conducted feeding studies and the FDA scientists who reviewed them expressed concern about a pattern of stomach lesions that raised a safety issue.

The pathology branch concluded that safety had not been demonstrated. And other FDA experts concurred. They wrote that the data raise – quote – raise a

question of safety unquote and that they quote “fall short” end quote, of satisfactorily resolving it.

Another agreed that “unresolved questions still remain”. Nevertheless the FDA claimed that its scientists had determined that all safety questions had been resolved and that the tomato had been demonstrated to be just as safe as other tomatoes.

And because the FDA kept the lid on its own scientist’s memos no one outside the agency was aware of the fraud. The memos only came to light four years later in 1998 when my organization, Steven Druker’s organization, the Alliance for Bio Integrity led a lawsuit that compelled the FDA to hand over more than 44,000 pages of its internal files.

However, because the mainstream media has failed to adequately report what those documents revealed most people are still unaware of the FDA’s misbehavior. GE foods reached the market through governmental fraud. If the actual fact about the toxic Tryptophan and the troubling tomato have been disclosed the GE food venture might well have been brought to a halt.

And, at minimum, would have been slowed and subjected to more rigorous testing. A similar effect would have resulted if concerns that other FDA experts had expressed about GE (serves) in general had been publicized. Those concerns appeared in memos written a few years before the GE tomato entered the market.

And they revealed that the agency scientists didn’t agree with the biotech proponents claims that GE is substantially the same as conventional breeding. For example an FDA microbiologist stated, “There is a profound difference

between the types of unexpected effects from traditional breeding and genetic engineering." He added that GE "may be more hazardous."

A toxicologist warned that GE plants could contain unexpected new toxins. The director of FDA's Center for Veterinary Medicine stated CVM believes that animal feeds derived from genetically modified plants present unique animal and food safety concerns."

He explained that residues of unexpected substances could make meat and milk products harmful to humans. The pervasiveness of the concerns is attested by an FDA official who studied the expert input and declared the processes of genetic engineering and traditional breeding are different. And according to the technical expert in the agency they lead to different risks.

In light of the unique risks those experts called for GE foods to undergo careful testing capable of detecting unexpected side-effects.

Man 1: Man.

Alexis Baden-Mayer: Moreover the FDA biotechnology coordinator acknowledged there was not a consensus about safety in the scientific community at large. He also admitted that the allergenic potential of some GE foods is particularly difficult to predict.

Man 1: Alexis we're going to ask you to just pause for just a second. We're going to invite, once again, perhaps there might be some latecomers to the call if they'd be interested in commenting. And so we're – want to give them that opportunity every few minutes.

So is there anyone on the phone who would care to comment? We'd love to take your comment at this time. Press "1" and then zero on your telephone keypad. We will see that and we will be happy to take your comment. We'll pause for a second to see if anyone takes us up on that by pressing "1" and then zero in your telephone keypad.

I'll also mention if anyone else who has already commented would like to elaborate on their comments; they're welcome to do so. If you're on the phone you could press "1" and then zero. If you're in the room just raise your hand.

It seems that there are none at this time so you're welcome to continue.

Alexis Baden-Mayer: Thank you. I appreciate that. I just wanted, you know, looking through this again there's always been this issue of allergenic risks.

And so this last quote was from the FDA biotechnology coordinator who acknowledged – who admitted that the allergenic potential of some GE foods "is particularly difficult to predict." And that made me recall the review of the salmon, the genetically engineered salmon that the FDA approved under the Obama administration.

That – I mentioned already that the salmon had lower Omega 3s than any time of salmon including farmed salmon. And it had higher IGF-1 levels – a growth hormone that is – correlates – levels of which correlate with cancers in humans. So it had low Omega 3, high IGF-1and it actually was also, according to (Tufts) it was more likely to trigger an allergy than normal salmon, even the farmed salmon.

And then the FDA ultimately concluded that these differences while observable in the company's data – so (off a bounty) creates a genetically

modified salmon, they submit their data to the FDA regulator and then the FDA regulator review this data.

So even by the company's own data it was clear in this data that the FDA published and submitted for public comment that under all these things, good and bad, about salmon this genetically engineered salmon was an outlier. But ultimately the FDA chose to decide the differences were not large enough to make it necessary to regulate the salmon as I believe it should be regulated to conduct more pre-market safety testing, to label it, etc.

Or perhaps to keep it from the market considering these dangers like IGF-1 associated with cancer, high in the genetically modified salmon. That should be a reason but even the Omega 3 I mean we're chronically deficient in healthy fat in the American public. And salmon is one of the foods that we're encouraged to eat and the genetically modified salmon has very low levels of Omega 3.

So I just wanted to bring these comments on the history of GMO regulation up to date by showing how they play out, how the new GMOs go through the regulatory scheme.

So Steven Druker, author of Altered Genes, Twisted Truth continues; Nonetheless in May 1992 the FDA claimed that "the agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way." It also asserted that there is overwhelming consensus among scientists the GE foods are still safe, that they don't require any testing.

Accordingly the agency doesn't require a smidgeon of testing and allows GE foods to enter the market without any. If the FDA had told the truth and

disclosed the extent of concern of its own experts the subsequent history of the GE venture would have surely been very different and might well have been quite short.

At the least any GE foods that did not reach market would have been subjected to much more rigorous testing than regulators anywhere had required. The state of the research and the degree of expert consensus has been misrepresented. Like the FDA other GE proponents habitually claim there is an overwhelming expert consensus that GE foods are safe.

The American Association for the Advancement of Science has declared that "every respected organization" that examines the evidence has determined they are "no riskier" than conventional ones. But this is flat-out false.

For instance, in 2001 the (unintelligible) of Canada issued the report concluding that, A, it is "scientifically unjustifiable" to presume that GE foods are safe; and B, the "default prediction" for each should be that the genetic alteration has induced unintended and potentially harmful side-effects. Moreover the British Medical Association, the Public Health Association of Australia and the Editors of the Lancet, a premiere medical journal, have all expressed concerns about the risk.

And in 2015 a Peer Review Journal published a statement signed by more than 300 scientists asserting that there is not a consensus about the safety of GE foods and that their safety has not been adequately demonstrated. GE proponents also falsely profess that the safety of GE foods has been thoroughly demonstrated when in reality many well-conducted studies published in Peer Review Journals have detected harm to the animals that ate GE food.

In fact a systematic review of the toxicological studies in GE goods published in 2009 concluded that the results of “most of them” indicate that the products “may cause hepatic, pancreatic, renal and reproductive effects that may alter hematological, biochemical and immunological parameters the significance of which remain unknown.”

It also noted that further studies were clearly needed. Another review that encompassed the additional studies that had been published up until August 2010 also provided cause for caution. It concluded that there was an “equilibrium” between the research group “suggesting” that GE crops are as safe as their non-GE counterparts and “those raising still serious questions or concerns.”

Between 2008 and 2014 eight such research reviews were published and although some interpreted the data in favor of GE crop, as a whole they provided no grounds for unequivocally proclaiming safety.

As (Sheldon Krenski) a professor at Tufts University observed in a comprehensive examination that itself was published in a peer review journal “one cannot read the systematic reviews and conclude that the science on health effects of GMOs has been resolved within the scientific community.”

Yet GMO proponents routinely proclaim that it has been conclusively resolved and that safety is a certitude. Two compelling and disturbing conclusions, thus even from this brief summary it’s clear that the GE food venture has been chronically dependent on twisting the truth and this dependence can be readily detected in virtually every statement that’s been issued in support of its products.

A striking example is the guide to GE crops published by the U.K.'s Royal Society in May 2016. Although it professes to provide accurate science-based information, analysis reveals that its case for the safety of these crops is based on multiple misrepresentations.

So if the world oldest and most scientific institutions cannot argue for the safety of GE foods without systematically distorting the facts, it indicates that such distortion is essential to the argument.

Moreover when the multitude of distortions and deceptions that have been issued on behalf of these products over the last 35 years are compiled and irrefutably documented as in my book Steven Druker's book Altered Dreams, Twisted Truth the confusion that the GE food venture could not have survived without them becomes virtually inescapable.

And another conclusion is equally obvious. The incontestable fact that the evidence has been methodically misrepresented is in itself compelling evidence of how strongly the aggregate evidence raises reasonable doubt about the safety of these foods.

Because it was as favorable as the proponents claimed, so if this was as favorable as the proponents claimed, there would have been no need to distort it so that's a common argument that is logically found.

If these genetically-modified organisms are so necessary and so safe, why won't the company submit to the premarket safety testing that institutions like the American Medical Association has demanded?

I want to go back to this issue, why are we standing in an empty room? Why has the public so lost faith in this process that it doesn't bother participating?

There's (truly) a problem of misrepresentation of the GMO issue. The most the click baits in the (least week) has been that Melania Trump has …

Man: I'm going to ask you to pause just for a second and I'm going to (unintelligible) that on the phone who may want to comment?

Woman: (Unintelligible) are you interested in this or are you just (illness) and food you don't care about? Just tell me where you are.

Man: I'm sorry, someone on the phone, please would you just to make a comment on our proposed revisions to biotechnology regulations? We're hearing some sound in the room, if you would just identify yourself and make your comment if you choose to. Hello?

((Crosstalk))

Man: I think someone on the phone is, are they not muted or …

((Crosstalk))

Man: Okay, I will invite anyone on the phone who would like to make a comment at this time to just press 1 and then 0 on your telephone keypad and we'll see that. You had a little strange audio there for a second or two. Also if you've already commented and would like to say more, please feel free to do so now by pressing 1 and then 0. Seeing none, Alexis, we invite you to continue.

Alexis Baden-Mayer: Thank you. Yes, I just wanted to mention that this publicly this debate is getting obscured by false news and as I began to say, the click bait in the last week or so stories claiming that Melania Trump has banned Monsanto from the White House and it turns out that this story was completely fabricated.

It was plagiarized from a story about an anti-GMO activist that used that woman's quote and claims that these are things that Melania Trump was telling a friend so it's you know, it's just amazing.

We're having to deal with this deregulatory pressure at a time truth is at a very high premium. It's very, very challenging to find-out you know, for your average voter, consumer, human being in the United States. It's really hard to know what's actually going on so if you, you know, Google Trump and GMO you would probably get that story about Melania Trump banning GMOs from the White House.

You probably wouldn't get the Federal Register notice that the USDA is considering changes to Rule 340 so it's a challenging time to be an activist organizing on this issue because it's very difficult to tell what's real and what's false in the news but that's why I'm here to correct the record and to help everyone learn and recall the history of how we got to this point.

Why are we in a continuing deregulation plan for GMOs rather than giving the public the safety testing, the labeling and the protection for farmers that we need so I want to I told you now two books that are essential reading on this topic, Steve Druker's book Altered Dreams, Twisted Truth and then Belinda Martineau's book First Fruit.

And I'd like to read you this article written by (Ken Rosenboro). It's called A Scientist's Journey from Developed GMO Believer to Skeptic and it briefly summarized Belinda Martineau's book. There are many imprecise aspects - this is a quote - "There are many imprecise aspects of genetic engineering, many related to our very incomplete knowledge about genetics and genomics.

That is why regulation of every product of this technology should be required and why they should be labeled" so that's a quote from GMOs tomato developer now skeptic and she's written a book about GMO foods.

So Belinda Martineau Ph.D. was the genetic engineer who helped develop the world's first commercially-available genetically-engineered whole food, the flavor-saver tomato but during the development of that tomato, she says, "She was transformed from a devout believer in the promise of agricultural biotechnology into a skeptic wary of its uncertainties."

Belinda now works in academic research. She wrote a book about the flavor saver and her personal transformation, First Fruit, the Creation of the Flavor Saver Tomato and the birth of biotech foods and occasionally gives talks to promote discussion of the technology "warts and all" as she puts it.

She also published a blog, biotech blog, biotech salon where she aims to clear "the entire situation" about the science supporting genetic engineering so this is an interview form and (Ken) says tell me about your involvement in developing the flavor saver genetically-modified tomato.

And Linda Martineau says, "I carried-out experiments and library research and coordinated outside researchers the company hired to carry-out additional studies and help write the documents Calgene, Inc. submitted to the U.S. Food and Drug Administration to demonstrate the safety of the flavor saver tomato."

Question, what led the flavor saver team to promote and label its tomato as genetically modified? That's something else you all might not remember if you weren't around at the time, this tomato came on the market labeled. It might be a big reason why it didn't stay on the market very long.

But I'll let Martineau speak to this. Martineau says, "I give credit for challenging transparency and the decision to label flavor saver tomatoes as grown from genetically-modified seeds specifically so the company's CEO at the time (Roger Salquist), we had nothing to hide and Roger thought consumers would be more accepting of the product if we were completely aboveboard about it."

Question, what caused the failure of the flavor saver tomato in the marketplace? Martineau, "The GM trait meant to keep tomatoes (firmer) while they ripen naturally on the vine didn't keep them sufficiently firm to allow trucking them to market on a large scale. Calgene spent more money getting the tomatoes to market in good shape than it charged for them in the grocery store."

Question, what led you to become skeptical about GM food? Martineau, "The major incident was when the FDA asked us whether we were sure that only the DNA we intended to insert into the tomato's DNA was actually inserted.

After we answered 'yes' they asked us to carry-out the experiment that would demonstrate that was indeed the case. In fact, the experiment showed what in 30% of the tomato plants, sometimes more, much more DNA, DNA that was not well-characterized and usually contains an additional antibiotic resistance gene, was inserted into our plants."

Question, the Calgene scientists weren't aware how this added DNA got into the tomatoes? Martineau, "We did not expect the additional DNA to be inserted and as far as I know, scientists still haven't figured-out how to avoid this from happening. There has been one case of a GM crop plant called BT 10 which contains such extra DNA, including a gene conferring resistance to

the antibiotic ampicillin. Fortunately the crop developer pulled the product from the market."

Question, what are other risks you see with genetically engineering of food? Martineau, "There can be risks associated with the genes being inserted. For example, the gene inserted into Star Link corn failed multiple tests designed to determine whether it could be a human allergen."

"The FDA and Center for Disease Control were worried enough about Star Link corn's possible allergenicity that the U.S. corn crop was monitored for the presence of that GM corn for several years after it was taken off the market. The gene in another GM corn crop BT 176 was found to present a much higher risk to monarch butterfly larvae than the other BT corn crop."

"There are also risks associated with the fact that genetic engineers have no control over where in a plant's DNA their gene will land and they often land in another gene, mutating that gene. Unexpected changes can occur in GM plants as a result of such unintended insertions and other possible mutations."

Question, John Vandermeer a professor of ecology and evolutionary biology at the University of Michigan has said that genetic engineering is based on "dramatically incomplete knowledge of the genome" which he compared to a complex ecosystem. Do you agree with that perspective?

Martineau, "I agree with Dr. Vandermeer. Genetic engineering is based on the reductionist belief that taking a gene out of its context in one organism and inserting it essentially randomly into another organism's genome comprises a 'precise' process that requires minimal regulatory oversight before being sold in grocery stores for human food.

I heard a plant scientist claim that "we know exactly what we're doing" with genetic engineering and then ask audience members to support grants for plants because "there's a lot we still don't know about plant genomes."

It might be laughable if this situation wasn't affecting the food system in the U.S. and worldwide. There are many imprecise aspects of genetic engineering, many related to our very incomplete knowledge about genetics and genomics. That is why regulation of every product of this technology should be required and why they should be labeled.

Question, what was your reaction to Professor (Seralini)'s study which found harm to rats fed GM corn being retracted by the Journal of Food and Chemical Toxicology?

Martineau, "I realize that there are issues with the number of strength of rats used and where (Seralini)'s results are test article related but I still think that the best way to resolve the controversy is to repeat the experiment using many more and perhaps a different strain of rats.

To retract the paper for being inconclusive is highly unusual and this entire incident "represents a dangerous erosion of the underpinnings of the peer review process" to quote an editorial in the current issue of Environmental Health Perspective.

And just to clarify this article, this interview is from March 2014 and the (Seralini) study was republished in another peer review journal.

Man: Alexis I'm going to ask you to just pause, I'm going to invite anyone on the phone who might want to make a comment to do so at this time by pressing 1 and then 0 on your touch-tone phone. If we have any takers.

There are none but before we continue, I'm going to suggest we just take a few minutes break. I could use a bathroom break myself and I'm sure others may as well so if we could take just five minutes and we'll come back and Alexis you're welcome to continue if you care to.

((Crosstalk))

Man: Five or six minutes, so we are back. I would invite those on the phone who might want to make a comment to let us know by pressing 1 and then 0 on your telephone keypad and (unintelligible) and seeing that there are none, we will invite Alexis to continue if she cares to. If you'd like to comment anytime during this meeting, just let us know and we will give your opportunity right away. Alexis?

Alexis Baden-Mayer: So I'd like to some of the specifics of this proposed rule and I'm going to use the resource Earth Open Source which you can find at earthopensource.org. All this information is compiled by scientists from the scientific literature and it speaks to this issue of how we're going to treat the new GMOs.

And the proposed rule attempts to open a very, very wide loophole for new GMO technologies and this information from Earth Open Source responds to that so I'd like to read this for you.

The question the answer is, is genetically modified or GM technology becoming more precise? Technologies have been developed that are intended to target GM, gene insertion to a predetermined site within the plant's DNA in an effort to obtain a more predictable outcome and avoid the complications that can arise from random insertional mutagenesis.

Some of these techniques use nucleases or genome scissors which allow the cutting of DNA and the insertion of new DNA in any position in the chromosome. The most popular of these new genome scissors are (TALENS), transcription activator like effective nucleases, ZFNs zinc finger nucleases, and most recently CRISPR (Cas9), clustered regularly interspaced short palindromic repeats.

These genome scissors are a combination of a unit to recognize specific regions of the DNA and enzymes to cut both strands of the DNA at a sequence determined by the genetic engineer. When the cell senses that this double-stranded DNA break has occurred, it stimulate the cells' machinery to repair it.

There are two possible outcomes, first simply allowing the repair to proceed where the cut end of the DNA are joined back together again, a process known as non-homologous (angus) and joining homologous, sorry, introduces a mutation at the mutation at the site of cutting by the genome scissors.

This is because non-homologous end joining repair is not perfect and the majority of cases base units of DNA are lost from the end of the DNA during the joining process.

Second, at the same time that the genome scissor gene is introduced into the plant stalk, the genetic engineer can also introduce a separate DNA molecule that has the same regions in it as the region that he is trying to modify in the host genome but which also contains a gene coating for the desired additional traits.

The artificial gene that has been introduced can align with the corresponding region of the host cells' DNA. In some instances the cell uses the second introduced DNA molecule as a guide to repair the double strand DNA break in a process known as homologous recombination.

The final result is the repair of the double strand DNA break but with the incorporation of the artificial gene at this predetermined site. By using these methods, genes can be knocked-out, silenced or mutated or new DNA including whole gene units can be inserted. Proponents' claim that these technologies offer "targeted genome editing."

However, these GM transformation methods are not failsafe. Two studies found that ZFN caused unintended genomic modifications in off-target sites in human cell lines. The simple word for modifications in off-target sites is mutation, that is, these techniques can cause unintended mutations in other locations in the genome, causing a range of potentially harmful side effects.

In another investigation using human cells, (CRISPR) from found to cause unintended mutations in many regions of the genome. (Why do) technologists still know only a fraction of what there is to be known about the genome of any species and about the genetic biochemical and cellular functioning of our crop species?

That means that even if they select an insertion site that they think will be safe, insertion of a gene at that site could cause a range of unintended effects such as disturbances in gene expression or in the function of the proteins encoded by that gene.

Even if there is no disturbance at the level of the gene, there may be disturbance at the level of the protein for which the gene encodes. For

example, a plant may have an enzyme that is normally inhibited by an herbicide meaning that the plant will die if that herbicide is applied.

If the plant is genetically modified to alter the enzyme so that it is not inhibited by the herbicide, genetic engineered for herbicide tolerance, there may be knock-on effects. Enzymes are not totally specific. If the activity of the enzyme is changed, the plant's biochemistry could be altered in the process, causing unknown chemical reactions with unknown consequences.

Moreover, because tissue culture must still be carried-out for these new targeted insertion methods, the muted genetic effects of the tissue culture process remain a major source of unintended damaging side effects and of course in the rule that is currently being considered, tissue culture is unregulated and supposedly doesn't need to be regulated whereas genetic engineering - this constricted definition of genetic engineering - is regulated.

But I'll read for you also the part about tissue culture because that is a really risky and messy procedure as well so when we're talking about these so-called gene editing technologies, the effects could include unexpected toxins or allergens or an alteration in nutritional value, reduced ability of the GM crop to resist disease, pests, drought or other stresses, reduced productivity or vigor, unexpected environmental effects such as increased neediness.

According to a German newspaper, plants produced using these technologies are already being grown in greenhouses. The Independent Research Institute test biotech it is not known whether any of the plants have been released into the environment adding, okay, this is old news, obviously, okay.

I want to also all right, let's go on to rapid trait development systems - genetically modified or not - because that's also very relevant to this

discussion. The biotechnology companies BASF and Civus, C-I-V-U-S, I'm not sure how they pronounce that have developed oilseed rape and canola with a technique called rapid trait development system.

According to Civus, RTDS is a method of altering a targeted gene by utilizing a cell's own gene repair system to specifically modify the gene sequence in-situ and does not involve inserting foreign genes or gene expression control sequences.

The gene repair oligonucleotide, G-R-O-N that affects this change is chemically synthesized oligonucleotide short. A short, single-stranded DNA or RNA molecule. Civus marketed its RTDS crops as non-transgenic and as proposed without the insertion of foreign DNA into plants.

The company adds that crops developed using this method are quicker to market with less regulatory expense. Civus says that RTDS method is "all natural" and "none of the health and environmental risks associated with transgenic breeding" and "yields predictable outcomes in plants."

However, GM is a process and the definition of genetic modification does not depend on the origin of the inserted genetic material. Crops created with RTDS can and should be described as GMOs since RTDS alters the genome in a manner that would not occur naturally through breeding or genetic recombination.

The fact that no foreign DNA is inserted into the recipient plant's genome is immaterial. In addition RTDS still involves tissue culture which introduces genome-wide mutations. Some or all of these mutations, the latter in vegetatively-propagated plants, for example potatoes will present in the final marketed product.

Also there will inevitably be off-target effects from the RTDS process. The intent of the RTDS process is specific targeting but this technique is new and research has not been done to assess the frequency and extent of off-target effects. The old saying "absence of evidence of harm is not evidence of the absence of harm" is pertinent here.

And I just want to pause for a second, this is really important information that should be on the record so I will continue but I want to pause for a moment and say that it's really not what the U.S. should not be creating its own definition of genetic engineering because we have an international definition under (codec) and that we have that's the law.

That's the law that we have submitted to and it's not to U.S. regulators to decide what genetic engineering is as this rule attempts to do so the U.S. needs to follow (codec) and these are scientific reasons why and I'll continue with that because it's very pertinent to this discussion.

So to assess the fidelity and efficacy of the RTDS process and the extent to which unintended alterations take place at other locations in the genome during RTDS, many different studies will be needed.

For instance one important class of studies that must be carried-out is whole genome sequencing of RTDS GMOs, structural and functional analysis of the proteins present in RTDS GMOs, proteomics as well as an analysis of metabolites present would also be required.

In parallel the functional performance of these RTDS GMOs should be assessed. The agronomic performance, the impact on the environment and the

quality and safety of the foods derived from these RTDS-derived GMOs all need to be investigated including via long-term toxicological feeding studies.

Even changing a single gene whether it encodes an enzyme, a structural protein, a peptide hormone or a regulatory protein can cause unintended functional or structural disturbances at the level of the cell and the organization as a whole.

Man: Alexis, we're going to ask you to pause right there and we will invite anybody on the phone who may have come to our call a little bit late and who may choose to make a comment, please do so at this time.

You can do by pressing 1 and then 0 on your telephone keypad and we'll see that and we'll open your mike. We'll just pause for a second to give folks a chance to do that if they care to. While we're paused I'll take the opportunity to remind folks that the public comment period closes Monday at midnight.

You can make comments here in our meetings and also at regulations.gov and while you can simply search APHIS-2015-0057, it will take you to a docket where you can make your comment and see the comments of others. The comments today will be transcribed and posted to our Website. If you'd like to make a comment, 1 and then 0. Okay, seeing none, you're welcome to continue, thanks.

Alexis Baden-Mayer: Thank you so I will continue to read from earthopensource.org and specifically on the issue of whether the USDA should exempt vast new categories of genetic engineering and these scientists are making the point that no, they should not be exempted.

They have exactly the same risks and the point that they make and I'll quote, "Genetic engineering and the associated tissue culture processes are imprecise and highly mutagenic. They lead to unpredictable changes in the DNA, proteins and biochemical composition of the resulting GMOs which can result in unexpected toxic or allergenic effects and nutritional disturbances as well as unpredictable effects on the environment."

And to go back to the RTDS technology that I was reading about here, okay, so RTDS is a genetic modification process albeit more targeted than other recombinant DNA techniques add to crops for other organisms produced in this way must be treated in exactly the same way as crops altered using old-fashioned recombinant DNA techniques, namely through evaluation of functionality, utility and safety.

New does not necessarily mean better or safer. RTDS and other methods described above are new and they were designed to be more specific. This is a laudable intention but empirical evidence needs to be gathered on the safety and efficacy of these new techniques.

It is interesting to note that the biotech company Civus in its publicity materials for the RTDS method acknowledges the imprecision of standard genetic modification using recombinant DNA techniques so that's the industry's line.

They're like we've come-up with something that's totally different but in fact the scientists reviewing the data on that supposition are concluding that no, this is there's still the problem is always mutagenesis that cannot be tracked and that isn't tracked through the scientific process that creates the genetically-modified organism.

You're going to have mutations that you don't expect and that you don't know about and that's why we have a regulatory system which doesn't currently but should be there to do what the company scientists aren't going to do and look for those unexpected mutations and the impacts of those mutations.

So I do want to go through this point on the tissue culture because that's part of traditional genetic engineering but in this rule it's set aside and the companies are invited or would be invited to say that well I could have done this with tissue cultures so I don't have to be regulated.

And here's why tissue cultures should be regulated and how tissue culture is used in genetic engineering so this is about the GM process and I'll just go to the point on okay, mutations caused by tissue culture. Three steps of the genetic modification process take place while the host plant cells are being grown in a process called cell culture or tissue culture.

These steps include one, the initial insertion of the GM gene to set into the host plant cells, two, the selection of plant cells into which the GM gene has been successfully inserted and three, the development of GM plant cells into GM plant (slots) with roots and leaves with the help of plant hormones.

The process of tissue culture itself is highly mutagenic causing hundreds or even thousands of mutations throughout the host cells' DNA. Since tissue culture is obligatory to all three steps described above and these steps are central to the genetic engineering process, there is abundant opportunity for tissue culture to induce mutations in the plant cells.

In the case of plants that are vegetatively-propagated, that is not through seed but through tubers or cuttings such as potatoes, all the different type mutations

in a given GM plant resulting from the GM transformation process will be present in the final commercial crop.

In the case of soy, maize, cotton and oilseed rape canola, the initial GM plant can be back-crossed bred with the non-GM plant variety to achieve closer genetic similarity. This back-crossing enables many not all of the mutations incurred through the GM transformation process to be bred-out.

However, given the fact that hundreds of genes may initially be mutated during insertion of the GM gene cassette and during tissue culture, there is a significant risk that the gene or genes crucial to some important properties such as disease or pest resistance could be damaged.

In another example a gene that plays a role in controlling biochemical reactions in the plant could be damaged making the plant allergenic or toxic or altering its nutritional value. The genetic engineer will not be able to detect and eliminate many such harmful mutations because their effects would not be obvious under the conditions of the development process.

But these mutations would still be present in the commercialized crop and could cause problems. For instance, the non-GM parent crop may contain a gene that confers resistance to an insect pest. In the laboratory and greenhouse where the GM crop is developed, that insect will not be present and so the genetic engineers would have no way of knowing that the insect-resistant gene present in the GM plants had been damaged.

Only after the crop has been commercialized would it be discovered that the plants were no longer able to resist the insect pests so there's also a good section here on mutagenesis because again this rule suggests that mutagenesis is fine and so if you could create your GMO using mutagenesis, then we're

going to give you a path and we won't regulate you so okay so this is the fact is mutagenesis, where the problem, the reason why we have regulation of GMOs is because there are going to be mutations that the developer of the GMOs can't control, aren't aware of and don't intend.

That's why we have a regulatory system that's supposed to come-in after the developer has created a new GMO and checked for these things.

Man: Alexis, I was going to just pause because we're now about five or six minutes from the end of our meeting. I just would double-check to make sure that there's no one on the phone who may perhaps want to make a comment before the meeting ends at noon.

So if you would like to make a comment, please let us know by pressing 1 and then 0 on your telephone keypad and we'll be happy to take your comment at this time. Give it a minute or two, 1 and the 0 on your telephone keypad. Hello, you're on the phone.

Sapna Brown: Hello, good afternoon. This is Sapna Brown again. As we are concluding the comments for this hearing today, I just want to take a moment and call decision-makers regarding biotech products. There is a big elephant in the room that needs to be addressed and that is the conflicts of interest.

In addition, GMO pollen cannot be controlled. It's being comingled with other pollen. We do not understand the implications of this so please consider that as you move forward with the policymaking decisions. Thank you.

Man: Thank you. Anyone else on the phone would like to comment before we close here in a few minutes, please press 1 and then 0 on your telephone keypad. Okay. Pausing just a moment, no? Okay, 1 and the 0 if anyone would like to

comment before we end our meeting in about five minutes or so. Okay, seeing none, Alexis, would you like to continue? We will stop at noon.

Alexis Baden-Mayer: Okay, okay, thanks so my final thoughts on this regulatory process which aims to open-up a very large loophole for whole new categories of genetically-modified foods is that these disputes distinctions that the proposed rule make are really distinctions without a difference.

And this idea that you can invite the companies to say well, I didn't use trans-genes or I could have done it through a traditional or conventional breeding method like mutagenesis or tissue cell cultures, that doesn't make any sense scientifically.

And it's and as I mentioned it shouldn't be up to U.S. regulators to start assigning GMOs because there a (world) process at (codec) to do that and we should regulate GMOs as defined under (codec) but I'll read for final thoughts I'll read a little bit more of this Earth Open Source piece on the myth that genetic engineering is precise and the results are predictable.

And as I've mentioned this piece goes through all of the new technologies and the old technologies and shows how the common problem in all of them is unexpected and unknowable mutations that the companies that develop new GMOs will never find absent a regulatory process that checks their work so the truth is genetic engineering is crude and imprecise and the results are unpredictable.

GMO proponents claims that genetic modification is a precise technique that allows genes coding for the desired trait to be inserted into the host plant with no unexpected effects and of course it could be gene deletion as well. It's the myth applies in both instances but the genetic engineering and associated tissue culture processes are imprecise and highly mutagenic.

They lead to unpredictable changes in the DNA, proteins and biochemical composition of the resulting GM crop which can result in unexpected toxic or allergenic effects and nutritional disturbances as well as unpredictable effects on the environment.

GMO proponents claim that GM is a precise technology that allows genes coding for the desired traits to be inserted into the host plant with no unexpected effects. The first steps of making a GM plant, isolating the desired gene and cutting and splicing it to form the GM gene cassette in the laboratory is indeed precise.

But the subsequent steps are not in particular the process of inserting a GM gene cassette into the DNA of a plant cell is crude, uncontrolled and imprecise. It causes mutations, inheritable changes in the plant's DNA blueprint.

These mutations can alter the functioning of the natural genes of the plant in plant in unpredictable and potentially harmful ways. Other procedures associated with producing GM crops including tissue culture also cause mutations as does mutagenesis. That's why they call it mutagenesis.

In addition to the unintended effects of mutations, there is another way in which the GM process generates unintended effects. Proponents of GM crops paint a simplistic picture of GM technology that is safe on a naive and outdated understanding of how genes are organized within DNA and how they work. Same applies …

Ibrahim Shaqir: I'm going to stop you right there. We've reached the end of our meeting, okay, thank you very much. Thank you for your comments, so we want to

thank Alexis and all the others who commented today. Today's our last public comment meeting, public comment period closes on June 19th at midnight.

Ibrahim Shaqir: So with that, that we can continue to comment online anytime through the 19th of June and regulation.gov and by typing APHIS-2015-0057 in the search box. You can also find us on the Web by searching biotechnology regulatory services or also by visiting our Website that we are providing on the slide and you will find tremendous information about our proposed rule.

We will consider all comments received and we will before we decide, before deciding how or whether to finalize the proposed revisions on biotechnology regulations. Dr. Firko will close this meeting.

Mike Firko: Thank you to everyone who participated in this public comment meeting. The public meeting is now closed. Thank you.

Richard George: Thank you.

((Crosstalk))

Operator: Your conference is ending now. As requested by the host, please hang up.

END