UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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JOINT INDUSTRY/CONSUMER MEETING

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January 10, 2007
2:00 p.m.

Washington, D.C.

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Deputy Assistant Administrator,
Office of Policy, Program and
Employee Development, Food
Safety and Inspection Service
U.S. Department of Agriculture

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MS. CAROLINE SMITH DeWAAL
MR. STANLEY PAINTER
MR. SKIP SEWARD
MS. JENNY SCOTT
MR. KEN KELLY
MS. BARBARA KOWALCYK
MS. FELICIA NESTOR
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MS. ABBY DILLY
MS. KATHY GRANT

I-N-D-E-X

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(2:00 p.m.)

DR. RAYMOND: I'm not sure we're getting there, but we're sure, Dr. Masters did a wonderful job of going on despite the distractions, with the roadmap. That's probably the main theme of the whole RESOLVE Report is that you need a roadmap. We need to know where the stops are along the way. We need to know that people will be involved to continue the process of openness and transparency. We need to know what start up dates are. We need to know where, how many, and et cetera, et cetera, et cetera, and I couldn't agree more with the Report, and with all of you that said that many times in that report.

And I apologize if we've not gotten it to you yet. I thought we were close once and then we realized there were a few glitches and a few i's that weren't dotted and a few t's that weren't crossed, and we want to make sure we get those i's dotted and t's crossed, and I hope to have that roadmap by the end of this month. We'll get it to you though when it's ready to get you and when we've done all the things we

have to do to get it there.

I do realize it is the next big step, and when we do have a roadmap, I'm pretty sure I will have another meeting like this so we can discuss the roadmap. I promise you that.

One thing I'd like you to keep in mind as you continue to digest this lengthy report, it was a -- report. RESOLVE started the process of interviewing individuals and groups. That was long before we had our two-day meeting, and then part of the report reflects questions and answers from the two day meeting and the small workgroups and then more of the report reflects electronic contributions since the two day workgroups. So some comments were made in July. Perhaps the questions have all been answered.

So it's hard -- if you take the report at face value, it's pretty negative. But I think a lot of that was from concerns that were out there originally that perhaps have been resolved and to continue to resolve, I have asked -- to come up with a list of the questions that are in the report, the commonly referred to questions, put the answers next

to them, and we'll make that type of information available to you because some of you may know some of the answers and some of you may not know the answers. I want to make sure you all know what the answers are, whether we all agree with the answer or not.

One other question that came up several times is that the inference that this is about reducing the inspection workforce, this is about helping us with budget issues, this is about helping the Administration look good. None of the three.

Now if we can help the Administration look good, because we do a better job with food safety, that's a bonus. That's a bonus. No one is going to lose a job over this part of this process. The processing plants. It's not about job reduction. It's not about cost reduction. Remember the -- matrix that I used many times. There's three plants. One inspector covers three plants, still goes to all three plants every day, just spends a little bit more time at Plant A and a little bit less time at Plant C based on the data available to us. I can't say that enough times. We have to separate risk-based inspection

processing plants from what conversations we'll be having later about risk-based inspection slaughter plants. I won't be saying the same thing then Stanley. I will be saying that may have something to do with workforce and it may have something to do with budgeting. Processing does not, and I just ask you all to keep that in mind.

Another issue that comes up in the report that it does concern me is conversations about whether or not we're using an open and transparent process. I guess if I can be more open and transparent, I would ask someone to let me know how with the exception perhaps of the expert elicitation of the inherent risk of the product. Comments that we were just checking off the box to show we got stakeholder consultation, that does offend me somewhat.

Now we've done a lot more than check off the box, and I think RESOLVE is convinced of that, too, with their comments on page 49 where they say the changes between the Agency's description of PIR and ERC in the initial concept papers and later descriptions of the public workshop demonstrate

influence that stakeholder input can and has had on the evolution of FSIS' thinking about RBI. So that's our neutral third party that they got the feeling after talking to all of you and listening to all of you that we are trying.

I'm going to give you some examples that I hope will put that little issue to rest. A year and a half ago I heard that the hazard coefficient and hazard control and hazard control coefficient were bad things. You haven't heard us mention them since then. We recognize that NRs are not equal. You know, we've worked awfully, awfully hard to come up with a better way to measure the institution's ability to control risks, the establishment's ability to control risks. Big change. Took us a long time. It slowed us down but it was the right thing to do.

We will do a second expert elicitation on inherent risk of the product. I made that commitment to Caroline and others at the two-day meeting, and we will take many of the things that we heard at the two day meeting and incorporate them into this expert elicitation. There will probably be 24 members,

probably 8 from public health, problem 8 from -- scientists from universities, maybe not state universities, ones that's maybe not quite so closely related to industry, and there will be 8 scientists from industry. And we have -- well, we have solicited names and recommendations from our Advisory Committee on Meat and Poultry Inspection, and their subcommittee has provided us with candidates that we are contacting about that. We will use severity of illness. We've all had a peer review, and I promise you will have another meeting like this. Once that report is available, we'll get together and we'll hash it out again like we did the first expert elicitation. That's another commitment. That's something we heard, and we're definitely going to do that.

Food defense has been removed from the establishment's risk control. We heard that at the two day meeting emphatically. I'm not saying I agree with it but I'm not going to argue with 100 percent of you about whether it should be or not. It's gone. We'll do that in a different fashion.

Multiphased implementation that Barbara

referenced briefly. I'm not going to go into any detail for fear of going too far, but it will not be nationwide. It will be a very small roll out as we test the algorithms as we test the process. We heard that. We responded to that.

This meeting, the fact that the web is there, the fact that we continue to request and solicit electronic submissions of comments, our monthly meetings with consumers, our monthly meetings with industry, we will continue to have quarterly meetings as we go through this process with combined industry and consumers, our regular calls with Mr. Painter, our town hall meetings with our workforce, meeting with the Joint Council whenever Mr. Painter would request us to come and meet. And it's no longer the token 10 minutes, hi, how are you, out the door. It's two hours of questions and answers and give and take, trying to build some level of, of trust and confidence with our employees in that particular arena also, and then, of course, NACMPI will continue to be a sounding board.

I must say that one individual told me a

year ago that NACMPI was not the right venue for this to make it open and transparent because there aren't too many people really interested in serving on NACMPI because it had kind of gotten watered down and as we solicited names for the next round of members on NACMPI, I think it was 73 people submitted. So we have definitely raised the image of NACMPI and the desire for people to contribute to meat and poultry safety in this country. That was very rewarding for me. Whether it came about because of this or not, I don't know, but that's an aside.

Page 50 in this report also had a series, about seven or eight bullets of things that brought particular controversy and particular attention, and they felt -- RESOLVE felt that if we wanted to continue to have people come to the table and meet with us and visit with us and contribute to us, we would have to address those instances in some detail. And so Barbara and I and Bryce and others on the Management Committee have met. We will be having a series of very focused meetings. We definitely will have one fairly soon on NRs. What's our thinking on

NRs? Where are we today? It's certainly different than it was a year ago, and we shared that with you and we want to listen to you as we decide what the best route to go is. We changed it today. I mean the NRs continue to change. We want to share with you where we're at rather than not share.

We will probably have a meeting on how to use volume. That's another area that came up repeatedly in the two-day session, and we don't have a solid way yet. We're working on it, and once we have something that I can defend or be proud of, I would like to share it with you and have you pick it apart so we can change and alter it again, but it has to be ready before I want to share it.

Data, the information that industry has, there was controversy there. Do you use it or don't you use it. If you use it, how do you use it and, and have certain safeguards. We're still working on that, and we will have a meeting probably on that also.

And what we need most importantly, we heard repeatedly about attribution. We just participated along with the FDA and CDC at a conference in December

on risk analysis, and we presented some attribution data there. We are going to, with the FDA and CDC again, host another summit. It will be a different venue than the one we had in December or the one that Mike Taylor had. This will be down in the basement, across the building, in the room that we did the Avian Influenza Tabletop. It's a good room to have an interchange of ideas. People that were there at that meeting said that it was one of the best meetings they had. We're going to try to copy that venue for an attribution summit, FDA, CDC, us, scientists, industry, consumers, institutions of higher learning.

We've got an invitation list tentatively arranged. I'm asking for your feedback now on that particular summit. If you or someone in your organization or you've got an organization that you think we might forget, please e-mail us or something, let us know who might be attending. Most of the people around this table are represented one way or another on your tentative list, but help us out with that. We're not really sure yet, because we haven't send out the invitations. The date was set but the

date has been unset because I can't make it, the CDC can't make it and the FDA contract can't make it on that particular day. The three people that were going to lead this thing are all tied up in other venues. We're looking for another date. We're looking for the end of March. We're still looking around that timeframe so we can do it right. I just -- I want to let you know we have a list, and we certainly are trying to do the list and will continue to try to build this one up a little bit better.

To sum it up, I want to read from the RESOLVE Report, page 51, in their summary, I think it sets the tone for a good meeting today. "A foundation of common interests exist among stakeholder that would likely compel many to continue to provide input to FSIS if given the opportunity. These interests include, (1) mutual recognition and improvements to the meat and poultry inspection process, can and should be made; (2) risk should drive decisions about the best deployment of inspection resources to improve food safety and better protect the consuming public; and (3) FSIS is the Agency with authority over meat

and poultry inspection process should succeed in enhancing the meat and poultry inspection process."

We intend to go forward. I don't think there's any secret there. We're probably not going forward as quickly as some of you thought we might try to go forward, and I think you'll like it when you get the map. We don't have all the data. That's one of the points of contention that has been raised many times. You need more data. You need more data. You need more data. And you've heard me talk about public health before, but I'm going to give you a couple of other opinions besides mine. You've heard mine.

This comes from the International Association of Consumer Food Organizations to Codex. The IACFO has ongoing concerns that risk management responsibilities are being delayed in order to complete lengthy and sometimes redundant risk assessments or to accommodate other regulatory procedures that postpone necessary risk management actions. This is clearly adverse to public protection.

World Health Organization, 2001 Strategic

Planning Report. Microbiological risk assessment is time and resource intensive and may not be necessary in all cases requiring risk mitigation.

And lastly, our own National Advisory Committee on Microbiological Criteria for Foods in the 2002 report, this consideration of risk may not necessitate in all situations an in depth risk assessment which requires extensive resources and time, particularly if it would unnecessarily delay timely protection of the public health.

Now those are three good quotes. There's also one in this book that Carol told me I had to read, and I found good quotes in there about don't wait until you get all the data, and then I went back to 1983. Risk Assessment in Poultry, and I've got two good quotes out of here, but I don't want to take anymore of the time of this meeting but if I get -- if I need them, I'll use them. They've been saying 1983, don't let perfect get in the way of good.

With that Bob, it's yours.

MR. TYNAN: Thank you, Dr. Raymond. Before we go any further, in responding to Mr. Waldrop's

(ph.) concern, I just want to check and see if we have some folks on the phone, in particular, Ms. Kowalcyk and Ms. Nestor.

MS. NESTOR: I'm on the phone.

MR. TYNAN: Barbara?

MS. KOWALCYK: Yes, I'm on the phone.

MR. TYNAN: Okay. Thank you. And two other individuals that I'd like to introduce would be Abby Dilly and Abby, I think you're on the phone also?

MS. DILLY: I am.

MR. TYNAN: And Kathy Grant. Abby and Kathy are two of the main people from RESOLVE and they're participating so that they can hear your comments and issues as well.

With that, I would like to begin the comment portion. I would remind you again that we have designated speakers for each portion from each group of individuals. You have five minutes for the presentation, a total of 15 minutes in each category, and I have a list here as things do happen, lists sometime change at the last minute. So if I call on someone and you are not to be the speaker or somebody

else has exchanged with you, that will be fine. Please let me know that when that happens.

The first discussion has to do with the RESOLVE Report's background and methodology, and beginning the discussion is the consumer groups of Ms. DeWaal. If you could introduce yourself and again your affiliation for the transcription, that would be great.

MS. DeWAAL: Thank you. It's Caroline Smith DeWaal. I'm Director of Food Safety for the Center for Science in the Public Interest.

Dr. Raymond, I want to thank you for inviting us to this meeting on the RESOLVE Report with industry, employee and consumer representatives. We appreciate the fact that consumer representatives will have six opportunities to comment this afternoon on the report. So I'm here to present the first of a number of consumer positions. My topic is Background and Methodology.

First, we think RESOLVE did an excellent job in the final report of capturing the many diverse comments of stakeholders on the concepts behind FSIS'

push to design a risk-based inspection system. This was clearly a challenging project. We were pleased to find many of our comments were reflected in the report, and its organization provided an opportunity to better understand concerns of other stakeholders.

We also appreciate the Agency's openness to stakeholder input, including the public meeting and ongoing monthly meetings with various stakeholder groups.

This level of discussion is essential if USDA is serious about redesigning its processed meat and poultry inspection programs to be more risk-based.

The RESOLVE Report really tells the story of risk-based inspection so far, and it provides a valuable jumping off point for the Agency's next steps. The Report has also led us to several important conclusions, which I will only introduce here and leave to my other colleagues to further elaborate on in their remarks.

First, USDA has not articulated a public health goal for the risk-based inspection program. Is the goal to reduce illnesses or inspectors? We

believe that this Under Secretary, you, Dr. Raymond, of all those with whom we have worked, is best positioned to clearly articulate the public health objectives of this project, and we urge you to do so.

Second, the report clearly describes concerns that many stakeholders share about the absence of legal authority to proceed with risk-based inspection. This Agency has a history of developing forward thinking programs, only to discover in Court that they fall outside the scope of the statute. Thus, we would ask that you fully articulate the legal authority for risk-based inspection as a critical next step.

Third, the report fully describes the calls from numerous stakeholders for a defined timeline for moving forward. Dr. Raymond, what FSIS is proposing to do is challenging and cannot happen overnight. If all the stakeholders could see a roadmap for the journey, which you've already promised, and sufficient timeframes, I believe that we could all participate fully and productively in the process. But when people are being rushed to reach judgments or

conclusions on unfinished products, it has been my experience that these programs often end up as the subject of Congressional oversight hearings or Court proceedings.

Finally, the report clearly supports the view that the foundation of risk-based inspection must be on sound data. We're concerned that FSIS may be trying to fit existing data into a project it wasn't designed for, much like using a screwdriver to the job of a hammer. It isn't that it can't be done, but the results are probably going to be less than fully satisfactory.

Thus, we would like to propose that the future of risk-based inspection, especially the parameters as they apply to establishment risk control, is built on data collected prospectively, once the framework is established. This would result in many of the issues raised by consumer organizations on data integrity as well as industry concerns and ultimately challenges based on due process. When it comes to data, let's build the car before we drive it. Then I believe we can all drive it together. Thank

you.

MR. TYNAN: Thank you, Ms. DeWaal. The next speaker we have to discuss Background and Methodology is Skip Seward from the American Meat Institute.

MR. SEWARD: Thank you very much. First, while I do represent and the other people who will be speaking on behalf of the industry today, we represent a coalition of industry people who have been addressing this. Certainly there are a lot of industry views that we may not represent. So I just want to make that clear up front. It's a vast area. So just to put that on the table up front.

First, RESOLVE -- by the way, I did give a handout of my comments. There may not be enough for everyone, but these are on the green page that I submitted for you, but first, RESOLVE conducted the task that they were asked to complete, and we agree with the conclusion that stakeholder input reflects the current state of stakeholder knowledge about risk-based inspection, and thus as stakeholders become more knowledgeable about risk-based inspection, their input will evolve as well.

One specific methodology issue that most stakeholders agreed that needed to be reexamined was the development of a risk ranking of meat and poultry products for use in describing PIR. We are encouraged that this important aspect of risk-based inspection will be reexamined at least one more time with clear directions for those asked to participate.

Now an industry risk-based inspection coalition has examined the idea of risk ranking and how the output from such a risk ranking could be used in the RBI algorithm. And the table that's provided in the handout illustrates an alternative condensed risk ranking for meat and poultry products developed by the industry coalition.

Now we believe that this risk ranking may assist in the development of the new expert elicitation and the examination of their output.

And for those of you who don't have the handout, this ranking goes from 1 to 6 1/2, and it just lists various product types from commercially sterile with the ranking of 1, to 6 1/2 for part cooked that appear to be fully cooked.

Now such a risk ranking would play a vital role we believe in simplifying the risk-based inspection process especially for establishments manufacturing numerous SKUs or products, each with their own PIR and ERC, and the SKUs could be grouped into these risk ranking categories without compromise.

The key element of the methodology used to obtain stakeholder input is transparency, as we've heard, and all stakeholders need to work together to optimize the development and subsequent implementation of the risk-based inspection, and to work on the continuous improvement process thereafter.

Industry encourages FSIS to open the development process parameter, to gain the value input from stakeholders before final algorithms, categorizations or other outputs are published or implemented in the field by FSIS as they have been doing. So thank you very much.

MR. TYNAN: Thank you, Mr. Seward. The third individual to speak on this particular component is Mr. Stanley Painter, and Mr. Painter, if you would identify yourself and your organization again for the

transcriber.

MR. PAINTER: Yes. My name is Stan Painter. I'm the Chairman for the National Joint Council of Food Inspection Locals, in layman's terms, the Union.

And, in looking over the report, maybe it was a little bit different than what I expected. It appears to be the gathering of comments and which, I don't know, maybe I expected a greater recommendation from RESOLVE versus the gathering of comments. And I'm still waiting for the other shoe to drop. The transparency and what have you that we've had thus far. The Union has enjoyed the participation and the ability to be a part where we've not been a part in the past, and we certainly appreciate the ability to do so. But, you know, maybe it will come with the slaughter portion of it, which I think is coming next.

And I don't know in my review of the report, it seems like we walked away with more questions than answers, and maybe I was expecting more answers to be given than questions outstanding. Maybe I'm wrong.

You know, we're developing a basis, and I realize you have to start somewhere, and we're

identifying problems. We're identifying issues, but I'm wondering, when are we going to identify solutions, and when are we have recommendations that will be given to stakeholders, that this is the problem.

I haven't yet had the Agency to identify a problem to the Union. I've asked a number of times, what is the problem? What is broken that we need fixed? And what part of the methodology do we need to change? And, you know, we just continue to get the same thing, you know, we're moving toward a more risk-based inspection. We have no vision, at least anything that's been shared, of where we're going and I haven't saw the background information that shows that we're not going in a positive direction. And if we're not, how are we going to get there?

So those are some of our concerns, you know, over the background and methodology. We just don't -- we still walk away with more questions than answers. Thank you.

MR. TYNAN: Thank you, Mr. Painter. The second topic that we're going to have today for

comments is Overarching Comments and Themes from Stakeholders. And what we're going to do in this section and other sections is we're going to start off with a different group and individual. So, Ms. Scott, if you could introduce yourself and your organization for discussion of the overarching comments and themes.

MS. SCOTT: I'm Jenny Scott. I'm Vice President of the Food Safety Programs for GMA/FPA, which is a merger of the Grocery Manufacturers Association and Food Products Association, for those of you who don't recognize that name.

The RESOLVE Report presents an excellent overview highlighting areas of agreement and disagreement with respect to the RBI initiative, and we appreciate having that overview.

Most importantly, the RESOLVE Report is clear that almost all stakeholders support in concept RBI, where it means properly allocating resources in a manner that enhances public health protection. And we also all agree that the Devil is in the details.

A number of valid concerns have been raised. How will this impact inspector jobs? What will be

required for establishments? And how will this have a positive impact on public health?

And FSIS is going to need to address these concerns as promptly and as fully as possible, but they can't be fully addressed without moving forward with the initiative and then making adjustments as needed. We have a rare opportunity here to target inspector activities to the areas in an establishment where operations are not consistent industry best practices and hazards are not well controlled. But this is going to take more education and workforce. Michael Rybolt will provide more thoughts about this when we get to implementation.

By reallocating resource, RBI should provide opportunities to enhance inspector knowledge about the best practices and provide them with the abilities to assist those plants who lack technical expertise and/or access to best practices that are available from trade associations and industry coalitions.

The RESOLVE Report indicates that some stakeholders believe that RBI fails to incorporate the essentials of a public health approach. We disagree.

If the product inherent risk and the establishment's control of the product's risk of causing illness are appropriately characterized, and inspection resources are appropriately allocated, to help the plant achieve better in-plant control of a hazard, then the risk to the public will be reduced.

You have to remember that RBI is layered over HACCP, which requires establishments to identify the hazards and implement appropriate controls for them.

According to the RESOLVE Report, many stakeholders appear to be in agreement that for optimized risk reduction and enhanced public health, we'll need to address the risk of a number of pathogens along the entire food chain. This is something to keep in mind for the future, assuming that RBI is successful achieving greater control over hazards with respect to the establishments and freeing inspector time for other activities but it shouldn't be a part of the initial implementation.

According to the RESOLVE Report, many stakeholders believe that FSIS lacks sufficient

evidence to justify major changes in the inspection program. Although all the data that could be used to support RBI are not currently available, this is not a reason to not move forward. The common thing -- theme among stakeholders was the lack of attribution data. Clearly this is important in allowing us to -- products that result in most illness. We do know the hazards of microbial pathogens and focusing on reducing microbial pathogens in any food product should be a positive step forward. As we get better attribution data, we will be able to make RBI work more effective, accurate and efficient as the report notes.

Also as noted in the RESOLVE Report, many stakeholders supported using industry data in calculating the plant's RBI score. RBI should reward those establishments that go above and beyond in obtaining data such as pathogen testing data and sharing those data with FSIS. The algorithm that FSIS develops should include a component to give credit to companies that conduct verification testing, share all the results with FSIS and then use the results to make

adjustments to their SSOPs and HACCP plans.

And finally, with respect to the stakeholder process, we really appreciate the Agency asking for input before the program is fully developed and carved in stone. We stress the importance of being transparent in this process, and we were really pleased to hear Dr. Raymond's remarks about transparency today. We think that if FSIS puts together the program with minimal input from industry, consumer groups and its employees, it's going to be reviewed with suspicion and criticism. However, if we have this open process where ideas are shared, and they're developed with everyone involved, we're going to have more constructive criticism in developing a better program.

So we are urging the Agency to go forward with their plans and have these additional meetings and sharing as much detail as possible as soon as they can, especially with respect to how the RBI score will be calculated and on the levels of inspection intensity that are envisioned for establishment of the various RBI scores.

We all have ideas about how a RBI system should look and probably all of us are going to have to compromise to a certain extent. The dialogues that we have had and the ones we will have in the future are the key in developing a better workable RBI system, a RBI system that should ultimately have a positive impact component though.

MR. TYNAN: Thank you, Ms. Scott. I notice nobody has made the timer go off. We're all staying within our five-minute timeframe. So that's very good. And thank goodness, Faye is here. She's helping me to remind me to turn the timer on. So very good. All right. In the same category, the next speaker will be again Mr. Painter.

MR. PAINTER: Regarding outreaching, the Agency has addressed an interest in getting comments from everyone involved, and getting the comments and compiling them and using them are two different issues. You know, we hope that this is not just a process of going through the motions of getting these comments and then not using them, or the comments from one group are taken more heavily than others.

The process of working in the environments that we have to work in to produce a wholesome product is certainly tasking on a daily basis, and the reward is putting out a safe and wholesome product, and the reaching out to the inspection staff regarding the phone calls that have been -- that are taking place now are certainly further encouraged and helpful, but we're asking that the comments in the RESOLVE Report and the comments that are gathered are used to the fullness of the ability and --

UNIDENTIFIED SPEAKER: What are you talking about?

MR. PAINTER: -- each, each group will have the ability to have some input and when the final phase comes out, each group will be able to see that their comments and their input in the process will be shown out in the field.

Now the process of establishments is still of a great concern to the inspectors in the field and we want you to continue to do as you're doing, and listen to the people as they continue to share their comments and their input. Thank you.

MR. TYNAN: Thank you, Mr. Painter. I want to remind the folks who are on the line that our format today, the only speakers are those that are here in the room and the two that are on the phone, Felicia Nestor and Barbara Kowalcyk. So if you have other comments, from other participants, we're not inviting you to do that at this time. So we'd ask that you not comment during the speakers as they go through.

The next speaker is Mr. Ken Kelly. Mr. Kelly, if you'd introduce yourself and your organization please.

MR. KELLY: Yes, I'm Ken Kelly, and I'm with the Center for Science in the Public Interest.

Good afternoon. Dr. Raymond, I want to thank you for bringing us all together here, consumer and industry to talk about the RBI process. I think we all really appreciate this opportunity.

And to echo some of the statements that have already been made, I think on behalf of the consumers, especially as relates to the overarching comments and themes, I think RESOLVE did a great job in bringing

together a lot of the concerns as best as they could, and I think that we all benefit from the report that they issued.

I'll be talking about, of course, overarching comments and themes on behalf of consumers. I think consumers and meeting with industry support the idea of a RBI system that would allow FSIS to allocate its resources to further improve public health or food safety rather, but a RBI system must be predicated on criteria that adequately reflects risks.

As the report states, industry and consumers have a number of concerns that have yet to be addressed. These include everything from the impact on the authority of FSIS personnel within establishments to how RBI will impact public health and the factors that will make up the algorithm for establishment risk control. I know that consumers have -- consumer groups have some particular concerns about the RBI system that I just want to mention fairly briefly.

Dr. Raymond, on more than one occasion, I

know that you've mentioned that FSIS, you see FSIS as the public health arm of USDA, and I know that we've appreciated those comments. However, I do want to make a point that consumer groups, that there's no clear measurable public health goal for the RBI process. If it is indeed to reduce food borne illness, then we feel the Agency needs to incorporate the essentials of a public health approach into the risk-based inspection process in order to meet that goal. The public health goals determine the data needs of the system and will allow optimized risk reduction.

We also feel that the Agency should go back and, as you've already indicated, that you've looked at some of the -- at the two reports that were put out, one by the Institute of Medicine and the National Research Council, and we're happy to hear that. Hopefully that will bring some additional thoughts to this process.

The RESOLVE Report also clearly states that there are concerns about the statutory authority of the Agency to implement the RBI system. And we feel

that the Agency, in order to address this concern, should articulate what law you believe gives it the authority to set and enforce regulatory and science based standards. And if FSIS finds that it doesn't have authority, is the Agency willing to go and ask for it?

Without addressing this underlying issue, we feel that FSIS may be putting the cart before the horse, and it has the potential to invite plants subject to an increased level of inspection to challenge the legal authority of the RBI system. And I have no doubt that there are many members of Congress that would like to know the authority as well.

From the consumer perspective, there's also concerns, as you well know about the use of data and the infrastructure in place to store the data. We believe that defining the criteria to be used to assess the measure risk is a significant hurdle to overcome in the RBI process. These criteria must be linked to the public health objectives of a RBI system through the use of scientific data. We feel that a

well defined public health goal, through it, the Agency can develop a data system to utilize the RBI.

FSIS should continue to work in a transparent and collaborative manner with all the stakeholders like you've done. We also feel; it's essential that FSIS take the time to evaluate the feedback that you receive from the stakeholders and clearly formulate the next steps in this process. And this should include a revised timeline, which I'm happy to hear you're in the process of developing, as well as addressing some of these concerns about the public health objective, the statutory authority and the use of data. Thank you.

MR. TYNAN: Thank you, Mr. Kelly. The next point in our discussion has to do with Product Inherent Risk, and the first speaker will be Mr. Painter.

MR. PAINTER: I worked for the poultry industry prior to coming into inspection. I worked for three years in a poultry processing plant, slaughtering and processing. I've been with the Agency for 21 years, and every day that you go to a

plant, just like every day you get out of bed, there's going to be risks. And in looking at what I see every day on a day-to-day basis, and what I see in plants, I ask myself why would we want to move into a system that is risky? Why would we want to put our consumers, our stakeholders, our people at risk?

And in looking at the RESOLVE Report, I found that it cited a number of risks that the stakeholders brought out, you know, we're seeing on a day-to-day basis. We're seeing the issues with, you know, with *Listeria*. We're seeing issues with *E. coli*, things of that nature, and our food supply apparently is not getting any safer.

And the concerns of the inspectors in the field is, how is risk going to be lowered? And I've saw the Agency in the past, if an issue happens, well, we had inspection there, regardless of how great or how minimal, we had inspection there, and then if we didn't have inspection there, you know, the plants would seem to blame it on the inspection. Well, you know, where was inspection? It went through because of inspection.

So, you know, there's got to be a point that we look at the process and say, are we moving in a direction that is worth the outcome? And I haven't saw that yet. And like I've reiterated over and over and over, I'm waiting for the plan. I'm waiting for the process, and I'm waiting for the Agency to share with the stakeholders as to how less is going to be best, and how less is going to be more. You know, without a plan, we can't move forward. Thank you.

MR. TYNAN: Thank you, Mr. Painter. The next speaker for Product Inherent Risk is Ms. Barbara Kowalcyk, who is on the phone. Ms. Kowalcyk, if you could state your name and identify your organization for us please.

MS. KOWALCYK: My name is Barbara Kowalcyk, and I am here as a consumer advocate.

First of all, thank you. I would like to thank the Agency for bringing everyone together, and as many speakers before me have said, I'd like to thank RESOLVE for doing an excellent job at facilitating stakeholder input in risk-based inspection in the RESOLVE report which I thought was

useful. I certainly hope that they will remain involved in the process as it goes further as it is evident from this one, that much more input is needed for stakeholders to reach consensus about RBI.

As alluded to in the RESOLVE Report, risk-based inspection is an idea that most stakeholders recognize the necessity of achieving -- food safety. For the past several years, USDA and FDA has been trying to support their public health function with fewer and fewer resources. It's becoming more and more apparent that we need a scientifically driven system that uses robust data to assess risk associated with food production distribution, and then weight those risks to determine whether their resources will provide the highest level of food safety to protect public health.

The development of such a system is an enormous task that needs to be undertaken seriously with due diligence. When confronted with such a monumental task, such as building an effective scientifically driven risk-based inspection system, one must come up with a process for attacking the

problem. For me, I tend to think in terms of the scientific method. The first step of this method is to identify the problem. Ultimately, the problem is that Americans are still being sickened by serious medical food borne illness. We must find a way to improve public health by preventing food borne illness.

Therefore, as was probably stated before me, FSIS must first establish concrete public health goals.

The second step in the scientific method is to develop a hypothesis, that is an idea about the solution for the problem. In this situation, the hypothesis is that risk-based inspection will make the best use of limited resources to improve public health. Of course, there's always a question about the appropriateness of any hypothesis and that remains an issue here.

Based on RESOLVE's Report, all stakeholders, including both industry and consumer groups, question whether or not FSIS even has the legal authority to implement a risk-based inspection program. It is

imperative that this issue be resolved before the Agency moves forward in the scientific process of developing the RBI.

The third step in the scientific method is to decide on a process for testing your hypothesis. Frequently when testing a hypothesis or theory, the scientist may have a preference for one outcome over another. It is important that preference does not bias the actual conclusion, otherwise, the validity and interpretability of the process will be called into question.

Therefore, it is the most crucial phase. FSIS must develop a detailed roadmap for developing a scientifically based risk-based inspection before a market or implementation of such a system. Otherwise, it would be like starting to build a house without first drawing out a set of blueprints. The roadmap must include not only the elements of risk-based inspection but also the methods for implementing and evaluating the program.

How will we know that we've actually succeeded in reaching our goals? Personally, I'm very

happy to hear Dr. Raymond talk about the need, that he recognizes the report establishes the need for this roadmap.

The fourth step in a scientific method is the actual data collection and analysis. Most stakeholders agree that the quality of RBI system is fully dependent upon the robustness of the data that supports it. Therefore, it is imperative that FSIS develops scientific data and a data infrastructure necessary to build an effective risk-based inspection that will achieve its public health goals.

Of course, the first step in the process would be to identify the needs and then determine what data is available and what must be opinion. Once FSIS collects the necessary advisory data and data infrastructure, then they can begin to implement on a small-scale risk-based inspections. Of course, this will not necessarily mean waiting for the perfect data which really only exists in textbooks anyway, but there are ways that we can make the best use of the data that we have and find things that will complement it as well.

The fifth and final step of the scientific method is to derive a conclusion, and that is evaluating the hypothesis. In this case, the risk-based inspection is to improve public health. As any scientist knows, the scientific method is a -- process. At the end of the process, these problems and hypotheses are identified and the process begins again. It should be recognized and -- that will improve public health.

FSIS should build a type of evaluation and reevaluation in any risk-based inspection program.

You might be wondering how this ties into product inherent risk, if the same process applies. According to RESOLVE's Report, stakeholders from diverse perspectives generally agree that the concept of considering the inherent risk -- produced by establishments and allocated inspection resources. However, it's clear from RESOLVE's Report, that FSIS' paper on product inherent risk raised many questions and -- raised many concerns but left many questions unanswered.

If we return again to the scientific

process, we must first identify the problem and then develop a hypothesis. Once that is done, we will develop a process for testing our hypothesis. This part of the process will be lacking in the development of measuring product inherent risk in risk-based inspections. According to RESOLVE's Report, stakeholders struggle to refer the questions about the paper and felt that they did not have sufficient information about FSIS' -- revisions of risk-based inspections against which to evaluate either the concept outlined in the paper or the potential effectiveness in helping achieve FSIS' vision.

This demonstrates the need for FSIS to develop public health bulletin that will provide a detailed roadmap for risk-based inspection as reported, before it begins the fourth step of data collection and analysis.

When no data is available, an expert elicitation can be used as a guide for further research and in some instances to develop the baseline, assuming that the elicitation has been properly designed and executed. In regards to FSIS'

expert elicitation, RESOLVE reports that almost every stakeholder group raised concerns about what they saw and continue to see, a lack of transparency about who was involved -- what information and functions they were given, what questions they raised, how and by whom the questions were addressed and whether the expert agreed with the process categories.

Furthermore, the report states that one of the biggest concerns raised by almost every stakeholder was the composition of the expert panel and stakeholders raised several concerns with the assumptions as first brought out in May, according to the products, according to the relevant risks of -- per serving, the product category of.

In that same vein, the report further states that many stakeholders including industry representatives expressed the view that severity of illness should be factored in when calculating inherent risk.

MR. TYNAN: Ms. Kowalcyk, you have just about 30 seconds.

MS. KOWALCYK: Okay. It is clear that there

are too many questions and concerns about the expert elicitation to use it as a foundation for assigning product inherent risk. The RESOLVE Report confirms it by stating that most stakeholders felt strongly that the expert elicitation should be redone with a broader group of experts, clearer -- and a different set of instructions. I -- thank you.

MR. TYNAN: Okay. Thank you, Ms. Kowalcyk. And I would remind everybody that you also have an opportunity to submit comments to our e-mail site that Dr. Masters mentioned earlier. So if comments run over and we cut you off, it's not because we don't think they're important, but we just have time constraints. So thank you, Ms. Kowalcyk.

I'm going to allow Mr. Seward again to finish up this point on product inherent risk.

MR. SEWARD: Thank you. Skip Seward, American Meat Institute, on behalf of the industry. For those of you who did get the handout, these comments are on the blue handout.

The RESOLVE Report did an admirable job of capturing many of the diverse opinions and questions

surrounding the concept of PIR or Product Inherent Risk. The industry RBI coalition has spent many hours examining this concept of PIR, its components and how such a measurement or assessment can factor into a useful variable in an RBI algorithm.

Industry recognizes that PIR is a key component of our RBI, yet believes that the establishment risk control associated with the product is the more important variable. Furthermore, if ERC or the establishment risk control is poorer for a product with a relatively high PIR, then volume becomes an important consideration, and we'll hear more about that from some of the other industry representatives.

For a given manufacturing establishment, especially those that produce a multitude of products with varying PIR rankings, RBI must take into account the frequency of manufacturing of the specific product and the fraction of the total production dedicated to each product, that is something along the lines of a production ratio. FSIS and all stakeholders need to establish and agree upon the frequency of calculation

of the RBI score associated with each product or PIR category, taking into account special non-compliance issues such as the issuance of a NOIE or recall, an establishment's request for recalculation and the production schedule that's occurring at the establishment. We suggest that a plan's rating generally be recalculated monthly.

However, we meet challenges associated with manufacturing sites that may modify production on a daily basis, based on customer orders. In these instances, a quarterly or semiannual recalculation may be needed and may need to be used rather than a more frequent calculation schedule that would be used on a more planned production schedule.

Maintaining the relevance and the accuracy of the RBI positioning of an establishment is critical to the successful implementation of RBI.

As pointed out in the RESOLVE Report, there remains the significant question as to how volume or production contributes to the RBI analysis. Perhaps the high volume establishment that continuously delivers safe food should receive credit for their

high volume production as Jenny Scott mentioned earlier. If the high volume establishment is doing poorly in delivering safe food, the establishment risk control will pull in the necessary inspection staff based on the ERC criteria. Both -- as I mentioned, they'll elaborate on this point later.

It is also important that the food supply chain downstream from the processing established meat be considered to optimize the benefits of RBI. The product inherent risk can be established at the point of manufacture, but may be influenced dramatically by what occurs at retail and in food service.

Lastly, industry emphasizes the importance of education and training for inspection staff and processors on the concept of PIR and its contribution to those risk-based inspection analysis insuring that plant inspection staff and the process management staff equally understand the concept of PIRs as well as the other elements of RBI will improve the likelihood that risk-based inspection will achieve its objectives. Thank you.

MR. TYNAN: Thank you, Mr. Seward. We're

going to change topics and begin to discuss Establishment Risk Control, and the first presenter in this portion will be Ms. Nestor. Are you still on the phone?

MS. NESTOR: Yes, I am. Can you hear me?

MR. TYNAN: Yes, we sure can. Please go ahead. Introduce yourself and your organization.

MS. NESTOR: I'm Felicia Nestor and I'm with Food and Water Watch. Dr. Raymond, I'm not sure whether those of us on the phone were connected when you began your remarks. It seems that when I could hear what was going on, you must have been in the middle of your remarks. So what I'm going to say will reflect what I first missed, and if I missed anything, I'm sorry.

I want to say along with everybody else that the RESOLVE Report was really terrific in the sense that it captured the detail of everybody's feelings about RBI and the process -- perform. I've got one little caveat to that, which I'll get to later.

One of the things that you mentioned, Dr. Raymond, was that the -- meetings to discuss

further how NRs will be used and according to -- that will also include FSAs and I assume that all other measures of establishing -- You also mentioned if I'm correct, that you believe the Agency has already responded to the public feelings about NRs and I'm not really sure what that response is. I have been really interested in this -- since RBI -- and -- issue of connection between a particular type of NR and some public health goals -- issue and which NRs were going to be utilized and which were going to be ignored. For all of the years the discussions and for as many -- as we've brought up, I have not seen the Agency move at all towards any convincing connection between any particular type of NR and food safety or any particular type of NR and the fact that they don't reflect any food safety outcome.

So I'm hoping that, what I think I heard was that you're going to have a meeting on this where we will discuss this in depth because I think it really needs to be done.

I agree with Caroline that we just have to work -- have a NR system perhaps -- not sufficient

for a public health outcome, and you need to modify that but we really need to dig in look at the deficiencies of those records and get started in collecting some reliable data on what's happened in plants.

I'm not sure I --

MR. TYNAN: I'm sorry. It's a technical problem, and we're trying to take care of it. So press on, Ms. Nestor.

MS. NESTOR: Okay. --

MR. TYNAN: Okay. You'll have to speak up just a little bit. We're having trouble hearing you.

MS. NESTOR: Don Anderson I think gave a presentation at the last NACMPI meeting on trying to correlate particular types of NRs with adverse events like recalls or micro findings and, you know, I just reviewed that on the Internet. I'm not certain that there were any conclusive connections even, even solid tentative connection. So I mean again I just want to stress I really think we need to look over that.

The second issue is, Dr. Raymond, you again and you said this before, that the motivation for RBI

has nothing to do with getting rid of inspectors. And I guess, you know, I would -- I might agree with that if, you know, the literal meaning of what you're saying. It may not be put into place in order to get rid of inspectors, but it certainly seems to us that it is meant to try to deal with a dwindling number of inspectors you have working for the Agency.

And this was the one thing that I sort of was disappointed in, that RESOLVE mentions it in the report, but not in the section on measuring establishment risk and this has been my main point from the beginning. I think the Agency really needs to keep careful records of when inspectors are not in plants. Without those careful records, you cannot do any correlation between the absence of inspectors and any particular adverse outcome. You also can't make any estimation of how reliable the NR information you have is.

MR. TYNAN: Ms. Nestor?

MS. NESTOR: You don't know whether an abundance of NRs means that a plant is a bad plant or a plant is a plant that has more inspection than other

surrounding plants.

MR. TYNAN: Ms. Nestor, you have about 30 seconds.

MS. NESTOR: Okay. So OIG has recommended you do this. I think that if you don't start collecting detailed information of when inspectors are not in plants and not performing tasks because they don't have the time, you really don't have any convincing evidence that RBI is not driven by future cuts by this Administration for food safety inspection resources. Thank you.

MR. TYNAN: Thank you, Ms. Nestor. We're going to probably have a little technical thing on the phone in terms of shutting off the microphone so the phone callers will not be able to speak. According to my list here, Ms. Nestor, you were the last one. Was somebody else designated to speak that was on the phone besides Ms. Kowalcyk and Ms. Nestor?

MS. KOWALCYK: Not that I'm aware of.

MR. TYNAN: Okay. Fine. Then what we're going to do is we're going to cut off the sound from you. So when we get to the question and answer

period, you'll be able -- we'll turn it back on so that you can join us again. So you'll only be in a listening mode at this particular point.

The next speaker in this particular component, Establishment Risk Control, is Ms. Scott.

MS. SCOTT: Industry sees the establishment of risk control as being comprised of four key components, system design, system implementation, pathogen control and interventions. We've captured the in-commerce findings as part of implementation.

System design will focus on the food safety assessments, and the initial algorithm can be very simple with respect to FSAs. For example, if a FSA yields adverse findings that result in an NOIE or nothing, or it can be more complex with gradations based on the number and type of adverse findings. For example, you could have more points if the FSA results in more food safety related NRs or even more points if it results in a NOIE. This is making the assumption, of course, that more points are a bad thing to happen.

System implementation involves food safety related NRs, NOIEs and food safety related loopholes.

And system implementation can also capture the positive as well as the negative. We haven't dwelled much on this, but it was mentioned in the RESOLVE Report. This can be done in terms of credits for past completed without non-compliance.

The pathogen control component should vary by product type. Products that are tested by FSIS, different numbers of points should be given depending on the outcome of the testing. For example, for an RTE product, a ready-to-eat product, you might get no points if the tests are negative, two points if the product is positive, and four points if positive product has been shipped into commerce. And further, the company that has shipped that product to commerce would get points because of having a food safety related recall.

Industry verification testing for pathogens of concerned products, where all the data are shared with the Agency and results have been negative will result in a credit, negative points.

Industry can also be given credit for environmental monitoring programs that are consistent

with FSIS guidance with more credit being given for a more robust program that meets or exceeds the higher frequency of testing that is recommended by the Agency. For *Salmonella* testing in raw products, the points can be tied to the incident rates meeting performance standards or baseline guidance and for *E. coli* O157:H7 in raw ground beef or trim, this can be based on Agency testing results in products that have cleared the establishment's clear shipment review.

Again, industry testing results and how the establishment uses them could result in credits.

These are only suggestions for options since there are many permutations on how this component can be addressed. Interventions such as anti-microbial ingredients, processes or formulations should be a counted as part of the establishment risk control. These need to be validated interventions and the weight -- and the weighting given them, should be based on the results of validation studies demonstrating log production or log growth prevented. An example, you would give a negative one point for the intervention if it results in a one to two log

production, minus two points if there's two to four log production and minus three points if there's more than four log production or you have zero points if the intervention results in one to two logs growth over the shelf life of the product, minus one if there's less than one log growth, and minus two if there's no growth throughout the shelf life of the product.

Offering the incentive of negative points for voluntary industry adoption of pathogen testing programs and/or interventions is an excellent means for promoting public health enhancements within the industry.

We see volume as being the third component of the RBI score calculation along with PIR and ERC, but I'm going to mention it here because we don't have a separate component right now. We would encourage a variable weighting for establishment production volume such that volume has a maximum negative impact on the RBI score for establishments that demonstrate poor risk control as reflected in the ERC value and produce the riskiest products, the highest PIR values.

Conversely, product volume should have little or no negative impact on the RBI score in terms of having an excellent ERC value -- low risk products.

In the final analysis, it is a good performing plant that should be subject to less intensity of inspection where consideration is given to NRs or food safety related issues, the frequency of food safety related NRs in relation to the number of tasks completed, enforcement issues related to food safety, pathogen testing results where they're applicable, in-commerce findings such as recalls and the robustness of the system and its implementation based on food safety assessments. Any algorithm that is developed should reward good performing plants and result in increased regulatory focus on the ones that need more education, training, regulatory oversight can improve their food safety systems.

MR. TYNAN: Thank you, Ms. Scott. And having the final word on this segment, Mr. Painter.

MR. PAINTER: Mr. Tynan, what I'm going to do is reserve or yield my time regarding this subject and give written comment regarding this issue.

MR. TYNAN: Okay. That's fine. Since we have time for the employee organizations, I would offer an opportunity to Dr. Ragan or Ms. Morales, if you have any comments at this point that you want to share.

DR. RAGAN: I just have a few general comments, just in case we run out of time.

MR. TYNAN: For the transcript, would you identify yourself.

DR. RAGAN: Okay. I'm Valerie Ragan. I'm representing the National Association of Federal Veterinarians, and I appreciate the time, Mr. Tynan, to make a few general comments here.

First of all, we will be providing some written comments for you, but before I make a few general comments, I also would like to thank Dr. Raymond and FSIS for the invitation for our organization to be a part of this discussion. And I'd also like to thank Dr. Masters for the excellent work that she's done in working with us in resolving issues and trying to move forward in some of the things that we've been trying to do.

Our organization is one of federal veterinarians. We represent not only FSIS veterinarians but others as well, but our interest is in improving the operations of the agencies they work for as well as the work that the veterinarians do. And along those lines, I'd like to say our organization supports scientifically based risk-based inspection. I would underscore scientifically based. We recognize that this RESOLVE effort which we appreciate the opportunity to have been part of the initial discussions is a starting point, not an ending point. And we would like to continue our participation. We've had our President of the organization, now past President, involved in the earlier discussions and he felt it was extremely valuable not only to have the opportunity to have employee input but to be able to bring back to us some of the discussions that were ongoing so that we could then formulate our own thoughts and next steps as well.

Along those lines, I would like to say that I think it's important to include all the different

organizations, employee organizations. They have some really different viewpoints and perspectives, and I think that has value in moving forward.

The intent I think of moving forward in a step-wise implementation process with trying it out on a small scale is an appropriate way to do that. This is a new, very complex way of doing things, and I would like to say our organization would like to continue to be involved in those discussions as the plans are being made for that. The important thing I think for us is that the process works as it is envisioned and that is in the process -- rolling, that it does succeed in what it's attempting to do, and I think in order to do that, our vendors in the field have a good hands on experience and would be willing to put together a task force or workgroup to look at those procedures, protocols, et cetera, before they're tried to make to help you make sure that they will work as they're envisioned, and I think that we are more than willing to provide you that input early in the process because our interest is in making sure that it does function as it is so envisioned.

I would also like to say that some of our veterinarians have expressed an interest in working with the plants or consumer groups in developing the best practices. So I would offer that, too, as well, if you want some veterinary help from experienced veterinarians in developing your best practices. We're willing to put together a group to do that as well.

So those are just some general comments. We will provide you some written ones but our interest is in doing what we can to help this process to make sure it functions as it should. Thank you very much, Mr. Tynan.

MR. TYNAN: Dr. Ragan, thank you. Ms. Morales, did you have any comments you wanted to make at this point?

MS. MORALES: Well, actually I want to thank Dr. Raymond and Dr. Masters for the invitation to our organization. I represent the Association of Technical and Professional --

MR. TYNAN: ATSP is very good with their professional work with microphones. They're not quite

so -- (laughter).

MS. MORALES: I appreciate the opportunity for us being here and similar meetings that you have been having recently.

We're going to be submitting our comments. So besides that, Dr. Masters -- previously.

MR. TYNAN: Okay. Thank you, Ms. Morales. That closes out the Establishment Risk Control.

I'm sorry. Dr. Patel, did you have any comments you wanted to make from your organization? I apologize.

DR. PATEL: No, I don't have any.

MR. TYNAN: Okay. Thank you. That closes out the Establishment Risk Control portion, and the next topic for discussion is Implementation. And the first speaker in this is Michael Rybolt. Mr. Rybolt, if you could introduce yourself and your organization.

MR. RYBOLT: Thank you, Mr. Tynan.

My name is Michael Rybolt. I'm the Director of Scientific and Regulatory Affairs for the National Turkey Federation.

Dr. Raymond, I want to thank you on behalf

of the coalitions, the RBI coalition for bringing everybody together today.

I have been asked to talk only on the implementation portion of this section. Rather than going into the ins and outs of hows and whens and wheres, I'd rather focus on something that we think is the more important part or a key part to the implementation, and if it's overlooked, the risk-based initiative in advancing food safety may not happen, and that is training for the inspectors. Implementation is a key part as is the development of the risk-based process, but training the inspectors is important as well for risk-based inspections to be successful.

This theme had been captured by the RESOLVE Report on page 44. Rather than reading that whole thing, just some captions from that. Stakeholders recommended that FSIS assist plants by guidance related to approved or accepted controls. This is very key. The inspectors are in the plants and can -- that information. There have been experiences in the past where plants for some reason have not had access

to such information and as a result, a contaminated product had been produced. One instance that comes to mind, there was an establishment that had a *Listeria* problem and it was traced back to hollow rollers on a conveyor belt and everybody knows that hollow rollers -- replacing hollow rollers has been an industry's best practice for sometime now. That's because hollow rollers can serve as harbors for pathogens such as *Listeria*. For some reason, this plant did not have this information. They're not a small plant, but they did not have that information. Like them, many other plants are members of associations and do not have access to that information but one key component that they do have is the inspector in the plant can provide information to them, wherever that information may come from, directly from FSIS or through other educational venues. If we want to advance food safety, we need to use dedication and expertise of the inspectors. And as Dr. Ragan just mentioned, they are experts. They do have best practices. They can disseminate that, but we should do this not in a command and control style, not in a regulator's style,

but as a facilitator of best practices and current science. The Inspection Act statute authorities FSIS not only to take regulatory action but to also insure that the meat and poultry product produced in the U.S. are wholesome and safe, and to meet this need, training and regulatory requirements is not the only component. It is essential to provide training in real worlds, on the ground level, real world food safety.

Therefore, we request and recommend that as part of the implementation program for risk-based inspection, that the Agency incorporate training for the inspectors. Thank you.

MR. TYNAN: Thank you, Mr. Rybolt. Mr. Painter, you're up again.

MR. PAINTER: Yes, I certainly would welcome more training for the inspection staff as that has just been mentioned and, you know, we, we have to put it forward in a way that everyone is informed, everybody has all the same information, in order to implement a new process. And thus far, I'm waiting to just see that as far as the, you know, as far as that

information for implementation.

Dr. Masters mentioned the statutory requirements for the labor organization and certainly I can say with implementing this process, sharing all information that is known at the time will certainly expedite the process and certainly not give rise to things that may impede the process if the Agency wants to move forward, with the sharing of full and complete information, you know, to accomplish that goal.

I feel as though the implementation of risk-based is questionable as has been mentioned a number of times earlier in order to meet the law, and certainly as the Agency moves forward with the implementation of risk-based in slaughter, I certainly have even more questions with the legality. And, you know, it's got so that the Union is, is certainly looking into those areas to see the legality. You know, with the implementation of this process, I would certainly be interested in the Agency's General Counsel and their views as far as the implementation as to say, you know, what are your views and, if so, how did you arrive at those views. How are you going

to implement this process in order to accomplish the mission of the Agency to meet the needs of the consumer, to meet the needs of the industry and abide by the law. And what provision of the law? Be specific, other than to say that we are meet the guidelines of the law. Thank you.

MR. TYNAN: Thank you, Mr. Painter. The next presenter we have is Mr. Corbo. Mr. Corbo, would you introduce yourself and your organization please?

MR. CORBO: Tony Corbo, Food and Water Watch. And, first of all, I want to thank RESOLVE for doing an excellent job in terms of summarizing the comments. They were voluminous. You had to wade through the public meeting transcripts and incorporate the written comments that were submitted in addition to the interviews, and I think you did an excellent job.

As the report reflected, I think the implementation portion of the public meeting was the most confusing, and I really felt sorry for Mr. Palesano who essentially got thrown up there naked essentially (laughter) and, and who was essentially

asking us for direction and we were looking for direction from the Agency and it was like two ships passing in the night. And I thought it was a disaster I frankly though, but, but I think, you know, from the consumer perspective, in terms of the implementation, and I think we have some serious concerns over the, the legal authority of the Agency, to proceed with this program. And I am heartened to hear that there is going to be some sort of roadmap and timeline that's going to be presented, but I think, I think, you know, we have some serious concerns about whether you have the legal authority to, to do this, and you're probably going to hear this, you know, from folks up on the Hill, you know, very shortly and, you know, the fact that the approach that has been articulated so far, that this was going to be implemented through, through notice and directives, I think you may be getting yourselves into some trouble.

And so I'm glad that you're going to, you know, finally have some details in terms on how you plan on implementing this, but again, to reiterate the points that my colleagues, my consumer groups have

indicated that, you know, before we even get to implementation, you have to clearly articulate the public health goals. You have to have the data to do this, and you have to an -- plan. Thank you very much.

MR. TYNAN: Thank you, Mr. Corbo. I have to comment though, I've known Mr. Palesano for a lot of years and the thought of him in front of a public meeting naked (laughter) truly is a frightening thought.

Our next topic is Opportunities and Next Steps. And we're going to start off with Mr. Painter.

MR. PAINTER: I would like to say, I do appreciate the opportunity in being here, the invitation from Dr. Masters and I guess you'd say her prior -- tour here, and Dr. Raymond as well. And I've already approached by RESOLVE in order to participate in the process of the moving forward in the next steps of the process and share the Union's willingness to do so and to be a part and to share our comments. Thank you.

MR. TYNAN: Thank you, Mr. Painter.

Mr. Lange, who is sitting to my left, said it would be even more frightening to see him naked in front of a group. (Laughter.) I'm sorry. That's not fair to Ms. Donley who has to make the next comments.

MS. DONLEY: I want it on the record that I'm fully clothed. (Laughter.)

MR. TYNAN: The next speaker is Ms. Donley. Would you introduce yourself and your organization?

MS. DONLEY: I'm Nancy Donley and I'm with STOP, Safe Tables Our Priority. First of all, if I can make it through these scribbled notes that I've been jotting down here because, Dr. Raymond, you took a lot of stuff off, the quotations off of this that I was going to be using. I want to thank you, Dr. Raymond, and FSIS and staff for recognizing the importance of opening up this process and providing an opportunity for all interested stakeholders to exchange ideas, information and concerns.

I guess my question though with how you opened up the meeting today as you said that, you know, we're doing this process for processing facilities but not for slaughter. I guess it's why

aren't we treating that with just the same amount of attention to detail as we are the processing.

That said, I'd just like to say that I'm very happy to hear you say that you are putting this a couple of phases in place and that you articulated a number of meetings that are going to be open in the future for all of us to participate in. I think that will be very helpful, and we will wind up with a better product in the end. I just hope please provide adequate notice for those of us who are on really tight budgets and if you could make materials available, that we could all arrive prepared and utilize the meeting time in the most effective way, that would be very helpful as well.

Risk-based inspection is a good concept. The HACCP PR rule is risk-based in nature. But I want to say that if it is not done correctly, risk-based inspection could have an unintentional negative effect on the safety of meat and poultry and again unintentionally put the public at higher risk of food borne illness.

So before proceeding with implementing a

risk-based inspection program, the first steps should be to -- should be as follows, and you've heard this from my colleagues and the consumer community, we need to know -- there needs to be a clearly articulated set of public health roles. You stated that this process is not being driven by budget issues and job issues or cost reduction. So I'm assuming that it's for public health reasons and there should be something that is measurable and, and that we can assess how good this process really is.

The second thing is again, the legal authority. You're going to face authority. You heard it from Mr. Painter here. You see it on page 9 in the RESOLVE article that you're going to receive a challenge from industry on it as well.

Without having performance standards that you are -- that you have the authority to set and enforce performance standards, this will not have any teeth. A risk-based inspection system doesn't have teeth, and you need those teeth. And I really urge you, we all urge you, please, there are a couple of bills in Congress that will give you those teeth.

Senate Bill 1357, this is in the 109th Congress and HR3160 called the Meat and Poultry Pathogen Reduction Enforcement Act, and I'm sure there's others as well.

There also -- you must -- the importance of good data and a good data infrastructure is key to a good risk-based inspection system, and then again the detailed roadmap and timeline that you talked about.

That said, I look forward to racking up my frequent flyer miles (laughter) and coming to Washington, D.C. I spent a lot of time in the basement of the USDA during the HACCP PR meeting and I look forward to it.

MR. TYNAN: Thank you, Ms. Donley. The last presenter is Mr. Johnson. Mr. Johnson, would you introduce yourself and your organization please.

MR. JOHNSON: Yes, Dennis Johnson, Olsson, Frank and Weeda. I guess as the final speaker, I'm going to have the last word (laughter). I appreciate all that FSIS has done on RBI and more still needs to be done. Although I don't want to get into a legal debate here, the Agency does have the authority. We can talk about it later.

As one of my professors in college always said when working on a solution, it helps to know the answer. With RBI, we've been focusing too much on the solution and not enough on the answer. RESOLVE recognized this in its report and noticed there was a lack of a clearly or lack of an easily accessible, clear and detailed description of FSIS' total overall vision.

I'm not here to give you FSIS' vision, but I would like to provide our view on RBI. Currently all plants are assigned equal inspection coverage, the exceptional, the average and the regulatorily challenged.

RBI does not allow us -- without RBI, we cannot vary the coverage within these plants. But what RBI allows us to do is if there is a problem with the chronic or the challenged plant, we can move inspectors. Now you're going to notice I'm never going to remove the Hershey Kisses from the cups, and it's not my intent to do so now or in the future.

But what I'm afraid of is I think the system has gone about as far as it can go. Using *E. coli*

O157:H7 as my example, in 2004, 2005 and 2006, the Agency's ground beef averages of testing was 0.17. In 2005, 2006, there were 38 positive at inspected establishments. Based on information my clients have been able to derive, we estimate that approximately 40 to 50 percent of these positives came from establishments that ground less than 1,000 pounds of ground beef on the date of the sample. And we estimate that approximately one-third came from establishments that ground less than 50,000. So therefore we have about 75 to 80 percent of all the ground beef positive for the Agency in the last two years came from establishments that do low volume of grinding.

Looking at the FSIS trim baseline, excluding the results of one large plant, I don't want to go that way, not my client by the way, all the other positives were plants that were other than top 50 trim producers. Looking at FSIS recalls for 2006, they were up to 6 to 8 from 2005. Looking at the amount recalled, total amount from the 6 to 8 was a total of 12,600 pounds, about 2,000 pounds of recall.

Questions, do you have a resolution or what's going on or what can be done? Now I can't answer why this is occurring, but I do have an opinion based on conversations with new clients over the last two years.

In May of 2005, I had a new client who had recalled product because he did not hold all the implicated product. Why did he not hold all the implicated product? He was using it to clean up the clean up roll even though in a 2004 FSIS corrective, the common source rule was used which basically means if you have a lot of product that was used in a positive sample, you're supposed to hold the remainder of that lot. He didn't know that. He ended up with a recall.

In March 2006, I had a client, a new client, with exactly the same problem. He did not know the common source rule.

In 2006, I had a client tell me I can get a certificate of analysis for all my raw ground beef components, not just the trim. Yeah. That was covered in an October 2002 Federal Register Notice.

There's not an unwillingness to comply. With all the rules, policies, scientific development, we need expertise. As Dr. Rybolt indicated, the inspectors are important and essential for us to advance public health by assisting plants in improving their operations, not commanding control, not regulatory enforcement, but in the sharing of public health expertise.

FSIS' vision may not be ready for prime time. Innovation never is. But we need to act now. We are no longer making progress. We are stagnating and in the area of public health, stagnation can figuratively and literally result in illness and death.

For the next steps, RESOLVE has called upon the Agency to do what it has already done as a springboard. To us what needs to be done is clear. You have our comments. We want to see your draft. We want to see your draft and then we want to get everybody, the consumers, the Union representatives, Agency officials and industry, get back together, go into a room, lock the door and not come out until we

do it. Just tell us when and where, and we'll be there.

We hope the others here are dedicated to food safety will come. No posturing. No given agenda. With the expertise, the dedication and the commitment of those gathered here today, we can develop a program which will serve today's needs and which will grow as our experience under the program grows. We need to move. We need to move now. We've run out of time. Thank you.

MR. TYNAN: Thank you, Mr. Johnson. The next segment of our meeting today is answering questions. And rather than take questions immediately from the table, what I'd like to do is invite some of the other visitors from industry, from the consumer group, from the employees organizations although I don't see any others, to get the first shot at asking any questions or those folks on the phone that have not had an opportunity to speak. So I'll invite anyone in the room that has a question or wants to make a comment at this point.

MS. BUCK: Yes, this is Pat Buck, and I'm

interested in food safety, and I have a comment to make about what I've been listening to everybody. Like our last speaker, I do tend to agree that we're running out of time and we need to move forward. However, moving forward should not be done at the risk of ending up 10 years from where we are right now, and that is that we don't have the infrastructure in place to -- the food borne illness that we see with specific food products. And that's -- to say about all of this. But what is FSIS doing with reporting a food borne illness and that the meat sources for -- their data and their attribution attempt back to the, you know, product --

MR. TYNAN: Thank you, Ms. Buck. You were breaking up a little bit on your cell phone but I'll ask Dr. Raymond or Dr. Masters if they want to --

DR. MASTERS: I think I got the gist of what Pat's question was and, Pat, we had a little trouble getting everybody on the phone. I know early on in the opening comments, I did announce that CDC, FDA and FSIS collectively are going to host an attribution summit. We set a date for March 27th, but we had to

take that off after checking calendars. It will be sometime in that timeframe. We'll include the scientists, consumers, industry and other governmental agencies, to get together to listen to what each agency is doing for attribution, how we can work together better. CDC is actually coming in. They're here today and tomorrow to talk to us about Food Net/Pulse Net, how we can continue to improve those tools that we use for attribution data. So we definitely heard about attribution. We take it serious. We will ramp it up a little bit more.

MS. BUCK: Thank you. The other thing that I noticed and I know it's an extension of the first thing, the other thing that I'm very concerned about is that throughout this whole process, we've talked about, you know, risk assessment, risk analysis. We have to do better at the risk communication. I think that's what the last speaker was also talking to, was that we need to do a lot more information sharing. These meetings will help but we also have to have a plan for getting the information out into the hands of the farmers, the processors, the science community,

the medical providers, of course all the regulators and, you know, all the different consumers, whether they are consumer groups or just people that are eating food on a daily basis. So I would like to see as we put RBI together that the risk communications are very well thought out.

MR. TYNAN: Thank you, Ms. Buck. Anyone else on the phone that has a question?

MR. FOUCHE: Yes, if you don't mind.

MR. TYNAN: Please.

MR. FOUCHE: I, too, did not pick up the first part of it. We did not hear Dr. Masters and Dr. Raymond came in at the very end. You don't have to talk it all over again what was said but just give the essence of what Dr. Masters and Dr. Raymond said so that those of us who could not be in Washington today could maybe know where you were at.

MR. TYNAN: Yes. Can I ask you to identify yourself and your organization please?

MR. FOUCHE: I'm Ron Fouche (ph.). I'm with the Eastern Meat Packers Association.

MR. TYNAN: Thank you.

DR. RAYMOND: I'll try to condense this real quick, Ron, for Pat and others. Barbara, Dr. Masters started out by explaining some issues that we have with the bargaining unit. We cannot move forward with this project until we discuss it with the bargaining unit and they have had a chance to evaluate all the legal things. And there's going to be two phases. We'll be rolling phase one which will be very small projects to test out algorithms, to test the science, you know, to -- we'll educate first a limited part of our workforce and then we'll see how that education worked in their working in the plants, how to better educate, and then I talked basically some of the points that were made more than once in the RESOLVE Report are going to be addressed with individual summits, instead of having broad, general meetings as we have for the last year and our monthly meetings which we will continue to have. We'll also have very focused meetings. One would be on NRs and, Felicia, I'm not sure if you heard it, I want to make sure, because you raised NR issue. I'm very proud of where we've gone with the NRs, and I think it's about ready

now to share with industry and consumers and our employee workforce and see if they're equally proud or if they've got new ideas that we haven't thought of which I'm sure we'll have some more, but we've come a long way with how we envision using the NRs, but we continue to change it. We changed it even this morning. So it's not that we've got anything in granite.

We'll also have single topic meetings on the attribution, but we're also strongly consider having them on volume, considering having them on industry data, a couple of areas that we will decide upon, but those are the ones that Dr. Masters and I have discussed that are big enough issues, that we really want to share what we've got, when we've got it in a sharable form so we can get the input as we go forward with them.

So some of this will be strictly phase one issues like, for instance, NRs, there may be a different NR issue for phase two as we see our roadmap and learn more about that. I think that was the highlight of what we talked about that, and we did

promise the roadmap which resonates throughout this report. We thought we had one ready a few weeks ago, and we found a couple if i's that weren't dotted and t's that weren't crossed, details that needed to be worked out before we could share it for discussion, but we had also promised, made a commitment today, that we will -- we are working diligently on that. We're getting very close to having the discussion with the bargaining unit. We can move forward past that, and then we'll have a time frame, a map, that we will discuss with you all and hear your thoughts on.

MR. FOUCHE: Thank you, Dr. Raymond, and again I think speaking to the entire general industry, I'm very sorry that you're going to lose one of those strong arms, Dr. Masters. We were very happy to finally have somebody who understood the meat inspection business at the helm, and I hope that you will be able to find somebody else who has a strong arm to figure out how the industry and how the inspectors and so forth work together.

DR. RAYMOND: The only way we'll ever be able to match Dr. Masters if FDA approves cloning for

humans also. (Laughter.) But we can't do that. We are obviously doing due diligence in our search for our new administrator but, believe me, there will be another Dr. Barbara Masters. I was just extremely fortunate to come in at the time that she was the Acting Administrator and had been for quite sometime but she became my mentor and taught me and said you need to get here and you need to go there, and you need to read this and you need to say this. There's some pretty long days for the first few months, but if I would have come in with someone who didn't know the business like Barbara, I wouldn't be sitting here today talking to you all. So I will say that publicly, Barbara, thank you.

DR. MASTERS: Thank you both. And the only thing I would add to what Dr. Raymond said is I added that you can continue sending your written comments on the RESOLVE Report to our risk-based inspection website where all of our materials are housed, and that's the risk-based inspection at fsis.usda.gov. And so you should feel free to send your information to that website.

MR. TYNAN: Do we have any other comments or questions from the folks on the phone?

(No response.)

MR. TYNAN: Okay. If not, I'm going to open it up to the group as a whole.

DR. RAYMOND: I just want to go over a couple of other issues besides -- I thought Felicia hadn't heard about the NRs. We certainly hear about the training and when you see our roadmap, you'll see that training is right out there big time and it's been -- trainers or people responsible for it are here at the meeting today. I mean it's no small happenstance that the folks are here listening to these comments also. The legal opinions, we got them verbally. We'll get something in writing, if I'm allowed to share that, I'm not, I can't make a commitment there until I talk to General Counsel, we'll find out. Because if that helps bring some anxiety down, I'll certainly make that effort.

The public health objective, we will delineate an outline and have them very clearly -- along with the roadmap.

And then lastly, Nancy, I think you're the one who raised processing versus slaughter. Those are really separate issues. They're separate issues regarding legality. They're separate issues regarding rulemaking. They're separate issues regarding possible employment numbers, possible budget numbers, and so we have truly tried to differentiate the two. The reason we're talking about processing is we're ready to talk processing. The slaughter risk-based inspection, slaughter we just brought to the last NACMPI meeting for them to start considering. It's in its very infantile stages. That's why we're not -- we have nothing to discuss really on that, that's why.

And RESOLVE also is going to begin a process to kind of replicate what they've done with processing but I just urge people to keep these as two separate projects.

MR. TYNAN: Other questions from the group? Yes. Ms. Donley.

MS. DONLEY: I just have one question and it's regarding phase one. Do you have any sort of idea as far as the timeframe of phase one? Are we

talking year, years, any sort of idea here? And the second part of the question is, I also jotted down here, data gathering during. Is that just data from these small meetings that we're talking about, the taco meetings that we're talking or is there also, you know, attribution data gathering and other type of data?

DR. RAYMOND: We're always gathering attribution data. CDC is always gathering attribution data. I mean that's ongoing and will continue to be ongoing. We're gathering volume data now. Our inspectors are gathering volume data, and that will be a project that will be ongoing as volume does change. I'm going to ask you for advice about what I can say about timelines. Probably not anything now?

UNIDENTIFIED SPEAKER: Within a couple of weeks we expect to have a --

DR. RAYMOND: I think Nancy's question was are we talking about rolling this out over six months, a year or two years. I think it's best we not discuss that. When we get the roadmap out, Nancy, in three weeks or so, you'll have it. I just don't want to do

anything to interfere with the process that we have to follow up and need to follow up.

MS. BUCK: Dr. Raymond, this is Pat Buck again. I have one last thing to throw out to you. Is there going to be some kind of board of appeal that's built into the RBI system so that consumer groups or, you know, industry groups or whoever can somehow come, you know, keep this process going, openness and transparency?

DR. RAYMOND: I don't know if I can call it a board of appeal, Pat, but as long as I'm here, at least, we'll continue to have monthly meetings with the consumers. I can't speak for the next Administrator, but --

MS. BUCK: Well, yeah, we know. We'd like to have it in place that it would happen even if you aren't the Administrator.

DR. RAYMOND: There's always other methods, of course, through the Administration, through Congress to have, you know, voices heard. Again, I guess you might call that a board of appeals. Industry certainly has the channels to appeal any

actions taken against them, be they NRs or anything else, and -- but as far as, I guess you're saying where do we go if we want to drop this thing? I don't know. I guess you go to your Congress person to begin a conversation.

MS. BUCK: That's an awful lot of hard work which you well know I'm not against. It's just that it would that now would be a time to put something in place so that all of us could more easily come to the table with our concerns. Just a suggestion.

DR. RAYMOND: I understand. I think, you know, there's so many things that the Federal Government and the state governments do and the local governments do that make us have regress and there are ways challenged to go that -- not just risk-based inspection but anything we do or anything else the USDA does or the whole Federal Government does.

MS. BUCK: Okay. Thank you.

MR. TYNAN: We just have a couple of minutes left. Are there other questions from the group?

MS. NESTOR: I have one question. This is Felicia Nestor.

MR. TYNAN: Yes, Ms. Nestor. Go ahead.

MS. NESTOR: Is FSIS contemplating a separate meeting on the type of credits. I think it was Jenny Scott that was talking about the industry should get credits for this or that type of food safety practice? Are you going to be collecting comments from consumers on that?

DR. RAYMOND: We don't have anything scheduled or contemplated at this time, Felicia, on that particular subject. It's certainly one that we would entertain if we got enough input that we should do one.

MS. NESTOR: Okay. I think that's important because I was just citing the ConAgra recall as an example of the assumption that interventions were very effective.

DR. RAYMOND: We're certainly trying to pin down those that may be a bigger stumbling block, that we'd like to get, you know, by in and continued improvements of those areas, and that's one that kind of seems to filter to the top after I get past NRs, volume and data, we'll throw that in the mix. We're

probably a ways from using that stuff right now in our formula. At least the stuff that I've seen so far from the Agency does not take that into account yet, but before we would, we would definitely have that type of meeting. It's 4:00, and before I turn it back to Robert to close up, I want to thank everybody again for coming and participating by phone. Thank you all for your brevity. The comments were right on. It's just want we needed to hear. We got a little bit more focus on what we need to do for our next steps, and look forward to the next meeting. We don't know when it will be yet. It will depend on the roadmap.

DR. MASTERS: Send your comments.

DR. RAYMOND: And send your comments. Thank you very much.

MS. NESTOR: Thank you, Doctor.

MR. TYNAN: With that, I move we adjourn, and have some Kisses.

(Whereupon, at 4:00 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

JOINT INDUSTRY/CONSUMER MEETING

January 10, 2007

Washington, D.C.

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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Nicholas Guarino, Reporter

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