UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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LOW DOSE IRRADIATION IN BEEF

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September 18, 2008
9:00 a.m.

L'Enfant Plaza Hotel
480 L'Enfant Plaza, S.W.
Washington, D.C.

MODERATOR: MR. ROBERT TYNAN
Deputy Assistant Administrator
Office of Public Affairs and
Consumer Education
Food Safety and Inspection Service

FSIS:

MR. PHILIP DERFLER
DR. DANIEL ENGELJOHN
MR. PATRICK BURKE

USDA:

DR. RICHARD RAYMOND
DR. SCOTT HURD

Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

ALSO PARTICIPATING:

DR. TANYA ROBERTS
MR. GRAEME GOODSIR
MS. PATTY LOVERA
MR. JEFFREY BARACH
MS. NANCY DONLEY
DR. URVASHI RANGAN
MR. JOSEPH MENDELSON
MS. PATRICIA BUCK
DR. RANDY HUFFMAN
MR. DAVID PLUNKETT
MR. CHRISTOPHER WALDORP

I-N-D-E-X

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

(9:08 a.m.)

MR. TYNAN: Can everybody hear me okay?

UNIDENTIFIED SPEAKERS: Yes.

MR. TYNAN: Excellent. Welcome to all of you for our important public meeting. I'm Robert Tynan. I'm the Deputy Assistant Administrator in the Office of Public Affairs and Consumer Education.

We've come here today to discuss a petition requesting recognition of the use of low-penetration and low-dose irradiation on the surface of chilled beef carcasses as a processing aid. As you can see, most of the time we have on our agenda, and hopefully everyone picked up an agenda when they came in, as you can see on the agenda, we have most of the time devoted for public comment.

For purposes of this meeting, however, we're planning on limiting the comment period for any individual commentor to about five minutes. That's to ensure that everybody has an opportunity to comment, and if some of you folks have comments but didn't sign up, then we'll be able to

accommodate everybody's interest in getting their key points out this morning. Your input is important, and we do, in fact, value that input.

The meeting has surely generated some significant amount of interest for us, and if you do not have a chance to make your full comments this morning, I want to remind you that there will be an opportunity to do so in writing by submitting a written comment. We'll accept them until October 18th of this year, 2008, and they can be sent to our docket clerk or submitted through the federal e-rulemaking portal which is www.regulations.gov, and this is all spelled out in the Federal Register notice that announced the meeting, and we have that Federal Register notice on our website for those of you who want to refer to it in submitting your written comments.

On behalf of the Agency, I want to thank the folks who put this meeting together. I don't think they're in the room right now, but Keith Payne of our Congressional Public Affairs staff, Sheila Johnson and Faye Smith who you met at the

registration table, did an awful lot of work getting the meeting together. So I want to be sure to thank them for their efforts in getting us together today.

We all share the same objective here at the meeting. We certainly want to improve food safety and enhance public health. There's no, I don't think there's any disagreement about that interest on everyone's part.

The fact that we have such a well-attended meeting attests to the strong commitment of everybody here to make our food supply the safest it can possibly be.

As always, we're committed to having an open process, and we're looking forward to this morning's session to get your input, and we again thank you for your attendance at the meeting.

Let me begin the actual agenda by introducing Dr. Richard Raymond. He's our Under Secretary for Food Safety, and he'll be making some opening remarks. Dr. Raymond.

DR. RAYMOND: Thank you, Robert, and good morning, everybody, and I'll just echo Robert's

words in thanking you all for being here this morning on this important topic. It's your interest and your comments that help guide this Agency when it makes decisions.

As most of you in the room probably know, my time here is winding down. This is the last public meeting that I'll have the privilege of attending as a USDA official, I hope, because if I have to attend another one, that means something bad has happened in the next week and a half. So this is probably my last public appearance domestically.

Meetings like this, some of you have come to know, we do these a lot. It's always been my goal since I entered public service in 1999 to try to be as open and transparent as I could be. I learned that lesson from Secretary Johanns when he was Governor. He told me one time, he said, Doctor, when I look back at each stage of my career, when there was something I wanted to get done and I didn't get it done, it's probably because I forgot to talk to somebody and they blocked it. So he's always cautioned me to be sure you let everybody

have their say and be sure you listen to people and you communicate with them and you'll go further than if you just do things in a vacuum.

So thank you for attending this meeting so we can be open and transparent. I believe meetings like this help us with what some of you heard me say many times, the three Cs, communication, cooperation and at times collaboration. I think those are important. I don't think we can get from here to there and unless we remember to involve those three Cs and all of our various stakeholders.

Sometimes in public meetings like this, it can be tough getting criticized openly and publicly, and that does happen at times, and we need to get through that and understand that it does lead to a better product in the end to have these public discussions even if they sometimes involve some constructive criticism.

I think having these meetings does help build trust and respect amongst our diverse stakeholders, and through communication like this, I think we become educated. And I think by becoming

educated, it helps us to make decisions that will help us get through some complex issues at times to end up with a better product.

So I ask you all to keep an open mind as we go through this process, listen, become better educated and help us, guide us as we decide whether or not low-penetration, low-dose irradiation should be used on chilled carcasses as another step in trying to reduce pathogens in the products that we regulate.

One thing I do want to say right now is that there is no silver bullet at this time for improving the supply of the meat, particularly if you want to talk about *E. coli* O157:H7 in beef. There is no silver bullet.

We certainly don't view low-dose, low-penetration irradiation as a silver bullet. We view it as a possible intervention step along with the other intervention steps already in place in many slaughter processing facilities.

It would not be intended to replace what is currently going on. It would be intended to further

reduce the content of *E. coli* O157:H7 in beef period.

There will be other interventions that will come along also that will help further the safety of the beef supply, including vaccines, bacteriophages, food additives. None of those is going to be the silver bullet that will tell industry you don't need to worry anymore. They're just intervention steps that will help reduce the load, and that has to be our overall goal and we have to do it in a safe fashion.

Before I pass the mic back over to Robert, I just want to take a moment to thank you once again for coming out this morning, and I also want to express my sincere appreciation to you for working with me during my three years and two months as the Under Secretary for Food Safety at the USDA.

Forty years ago I walked through the doors of the University of Nebraska Medical Center as a freshman medical student, anxious to go out to rural Nebraska and practice medicine and save lives, and I went to a town of 425 people for my first clinic, my

first position. It was the smallest town in the United States of America that had a Joint Commission accredited hospital. And me and my partner and our staff were extremely proud of that. I like small towns. I like getting to know to people, you know, at a level you don't get to know people in a place like D.C.

And, when I was practicing medicine in that town of 400 people, I never thought, not in my wildest dreams, that I'd be sitting in D.C. someday as an Under Secretary for Food Safety, debating policies and communicating with all of you, trying to figure out how to make the food supply better and safer and how to have policy that would affect 300 million lives. That's a long step from a hospital in a town of 425 people or going to medical school in the State of Nebraska.

It has been a great three years and two months, and again I just want to thank you all publicly for helping making it a great three years. There's a lot of faces here I know now that three years and two months ago I wouldn't have had a clue

who you were or what you did, and we certainly got to know each other I think fairly well. And I'm going to miss some of you. Hopefully I'll see some of you in the future. I'm extremely happy that our paths have crossed. And I hope that the feeling is mutual.

For those of you who continually work with us, you are our external conscience. You make us better by putting our feet to the fire and insisting that we never get lax or lazy, and I do thank you for that, and I do thank you for the criticism of the Agency because it does make us look at ourselves inwardly and hopefully it does make us better.

And for some of you who I don't recognize your face, I have not met you, if this is your first time at one of these public meetings conducted by FSIS, please continue to be involved. It is you and it's groups like this and it's meetings like this that do help us understand industry. It helps us understand consumers' concerns, and it certainly helps us understand what our employees tell us, what's not working right out there in the plants.

We need you all to work with us. I encourage you to continue to follow this issue and other issues that are near and dear to your heart. And at this time, I just once more thank you for friendship.

And, Robert, for the last time, I look forward to hearing the comments from these individuals as the Under Secretary for Food Safety.

MR. TYNAN: It's been a pleasure, Dr. Raymond.

DR. RAYMOND: Thank you.

MR. TYNAN: Thank you, Dr. Raymond, very much.

I was remiss, I did not introduce two other folks that are at the head table with us earlier. To Dr. Raymond's left and to your right, I have Mr. Phil Derfler. He's the Assistant Administrator in the Office of Policy and Program Development, and to his left is Dr. Dan Engeljohn. He's Phil's Deputy in the Office of Policy and Program Development.

So they'll be with us listening to your

comments as well as perhaps responding to any questions that may arise during the session.

And last but not least, we have Dr. Scott Hurd, who is our Deputy Under Secretary for Food safety.

So let us then begin the substance of the agenda, and let me introduce Mr. Pat Burke.

Patrick is an industrial engineer and senior staff officer of the Food Safety and Inspection Service's Risk Management Division. He's been with the Agency since 1985 and has been with the Risk Management Division since its inception.

He is project manager on the evaluation of the AMI irradiation as a processing aid petition. And with no further adieu, I will turn it over to Mr. Burke to talk a little bit about the irradiation petition.

MR. BURKE: Hello. Let's go ahead and get into the meat of the project here. Okay. I'm Irish. That's okay. (Laughter.)

The Food Safety and Inspection Service is announcing that it has received a petition from the

American Meat Institute to recognize the use of low-penetration and low-dose electron beam irradiation on the surface of chilled beef carcasses as a processing aid.

One form of radiant energy used commercially is electron beam or e-beam. Energy from accelerated electrons is absorbed as they enter the surface of the product being irradiated. The electrons cause chemical bond breakage in the microorganisms, immediately, in addition to damaging the DNA.

In 1999, FSIS amended its regulations to permit the use of ionizing radiation for treating refrigerated or frozen, uncooked meat, meat byproducts, and certain other meat food products to reduce levels of foodborne pathogens and to extend shelf life. FSIS requires labeling of meat and meat food products that have been irradiated.

Under FDA's regulations, processing aids include substances that are added to a food for their technical or functional effect during processing but are present in the finished food at

insignificant levels and do not have any technical or functional effect in the food.

FDA's regulations provide that processing aids are not required to be included on product labels.

On July 8, 2005, AMI submitted a citizen's petition to FSIS requesting that the Agency officially recognize low-dose, low-penetration e-beam irradiation applied to the surface of chilled beef carcasses as a processing aid.

The petition requested that information concerning irradiation treatment not be required on the label of any products derived from the carcass.

The petition argues that low dose, and here we're talking less than or equal to 1.0 kGy surface dose, low penetration, 20 mm, e-beam irradiation is a processing aid because the electron beam has a functional effect of reducing pathogens on the carcass surfaces, but that once the energy from the electrons is absorbed, there's no further functional effect from that irradiation.

According to the petition, low-dose, low-

penetration e-beam application results in only a small portion of the carcass receiving the e-beam radiated exposure.

Now, the petition presents evidence that the use of e-beam irradiation is effective in reducing levels of *E. coli* O157:H7 on the carcass; second, has no effect on organoleptic properties or appearance of the carcass; third, has no lasting effect on the shelf life of the carcass or on product derived from the carcass; and, fourth, produces no significant loss of either macro- or micro-nutrients in the carcass or the product derived from the carcass.

In an Arthur, et al., 2004 study, *E. coli* O157:H7 was found on 76 percent of the beef cattle animal hides. In a McEvoy, et al., 2003 study, results showed that the *E. coli* O157:H7 can be transferred to beef carcasses during hide removal. There is a high probability that irradiation of beef carcasses could eliminate *E. coli* O157:H7 from the beef carcasses.

In support of their petition, the USDA

Agricultural Research Service's Meat Animal Research Center or MARC, conducted a study on the effectiveness of low-dose, low-penetration e-beam irradiation in reducing levels of *E. coli* O157:H7 on chilled beef carcass surface cuts.

Forty cutaneous trunci piece were inoculated with *E. coli* O157:H7, twenty with high concentrations of six logs and twenty with low concentrations of three logs.

One half of the high inoculated and low inoculated samples were treated with surface doses of 1 kGy with approximately 15 mm of penetration. The remaining samples were not treated.

Results for direct cell count plating show that the *E. coli* O157:H7 contamination of the untreated samples remain around the high inoculation levels. The *E. coli* O157:H7 was undetectable after 48 hours in irradiated samples that had been inoculated at the high level and were present at approximately 0.1 log after 120 hours.

Results for direct cell count plating show that while the *E. coli* O157:H7 contamination of the

untreated samples remained around the low inoculation level, for the low inoculation level, the irradiation treated samples were undetectable for *E. coli* O157:H7 after 48 and 120 hours.

They also did a second test. The results of the most probable number analysis were similar to that from direct plating. There was no low inoculation sample at 48 hours, and only 1 low inoculation sample at 120 hours that had a MPN value above the limit of detection. All the high inoculation levels were above the limit of detection.

The MARC study also addressed effects of low-dose, low-penetration e-beam process on organoleptic properties of treated product. In MARC's assessment of organoleptic impact, the flank steak was used as the model muscle. None of the flank steak sensory attributes were affected by any of the penetration treatments.

Three Hunter Color measurements were made in the MARC study and all showed some treatment effects. The effects of lightness and yellowness

were not linear with dose, and thus the investigators did not consider them to be meaningful treatment-related differences.

Now, the effects of treatment on redness value were linear. However, the researchers concluded that the magnitude of the effect was slight and would likely have no impact on consumer acceptance.

Now, in the second study they presented, a study of the effects of low-dose, low-penetration e-beam surface exposure on the shelf life of beef was performed by Sillikier, Incorporated.

Six beef plates were designated air exposed, and three of these were left untrimmed. Six beef plates were designated vac-pac and were all trimmed. Six of these twelve were treated with low dose, that was 1 kGy, low penetration, 15 mm, surface e-beam irradiation. The other six were left untreated as controls.

After the six beef plates were irradiated, the irradiated and control plates were randomly subdivided into four equal segments. Each segment

was allocated into time slots of 1, 3, 6, 9 days for air exposed, and 1, 10, 20 and 30 days for the vac-pac.

Microbiological tests were performed at each measurement time. The total aerobic plate count, hetero- and homo-lactic acid bacteria or LAB, total coliforms and Biotype I *E. coli* and to provide a measure of oxidative rancidity, thiobarbituric acid, or TBA, was analyzed throughout shelf life.

For the APC, LAB and total coliform counts of air exposed beef after 9 days, the irradiated sample were within 1.5 logs of the non-irradiated samples. For the APC and LAB counts for vacuum packed beef after 30 days, the irradiated samples were within 1 log of the non-irradiated samples while the total coliform counts were equivalent.

The vacuum packed beef TBA values ranged from limited, tolerably oxidized to somewhat oxidized over 30 days of shelf life. The air exposed beef TBA values ranged from limited, tolerably oxidized at two days of shelf life to oxidized at nine days of shelf life. All samples

were below the range of rancidity.

Based on the results of this study, the authors believe that the initial antimicrobial effects of the treatment appear to have been minimal, and over the course of the shelf life, the APC and LAB counts on the surface e-beam treated product increased to the point that quantitative levels nearly approximated that non-treated controls at the end of the storage period.

In addition, one of the principal measurements of shelf life and product spoilage, rancidity, as measured by the TBA, indicated that the treated samples would turn rancid slightly before the non-treated controls. These data appear to demonstrate that the e-beam surface treatment of beef plates does not have a lasting effect on the product shelf life.

A third study that was given was a literature review and analysis on the effects of low-dose, low-penetration e-beam irradiation on the levels of micro- and macro-nutrients that was conducted by Donald Thayer, a retired USDA ARS

researcher.

Concerning the macro-nutrients, Dr. Thayer found that there was no significant differences in the peroxide and iodine values of lipids following irradiation up to 10 kGy of the *m. Longissimus dorsi* of beef. Also, there was no significant changes following irradiation in the malonaldehyde concentration in beef *m. Longissimus dorsi*.

Now, concerning the micro-nutrients, Dr. Thayer found that water soluble vitamins in beef were unaltered. One water soluble and one fat soluble vitamin would likely be decreased, and that was thiamin and tocopherol.

For these two vitamins, Dr. Thayer estimated, worse case, that the maximum net decrease in the U.S. diet would only be 0.021 percent for thiamin and 0.014 percent for tocopherol. Dr. Thayer concluded that beef carcass surface low-dose, that's 1.0 kGy, electron beam irradiation would not produce a significant loss of either micro- or macro-nutrients from the U.S. diet.

FSIS has consulted with FDA about this

issue, and FDA has advised FSIS that, tentatively, it would not object to treating low-dose, low-penetration e-beam irradiation on the surface of chilled beef carcasses as a processing aid. FDA is still considering this issue and will likely consult further with FSIS.

FSIS has tentatively concluded that there is merit to consider low-dose, and that is less than or equal to 1.0 kGy, and low-penetration, 20 mm, e-beam irradiation on the surface of chilled beef carcasses as a processing aid.

Data submitted showed that the low-dose, low penetration surface e-beam irradiation will produce a significant surface reduction of *E. coli* O157:H7 on chilled beef carcasses. The e-beam treatment does not appear to have a lasting antimicrobial effect that would extend the shelf life of the products, and it appears that there is no significant difference in color, odor, or taste between treated and untreated products.

Relevant studies appear to support the assertion that the low-dose, low-penetration e-beam

irradiation treatment would not produce any significant changes in the macro- and micro-nutrient content of the treated products. Further, the entire beef carcass is not irradiated, only the surface of the carcass.

Now, the issues to be discussed. Is there any additional evidence to support or contradict the evidence presented in the AMI petition on the specific application of low penetration of 20 mm and low surface dose of less than or equal to 1.0 kGy electron beam irradiation on the surfaces of chilled beef carcasses as a processing aid?

Second issue, is there any evidence indicating that FSIS should consider the cumulative effects of the absorbed dose delivered in accordance with the AMI petition and any subsequent absorbed dose such as a result of further irradiation of ground beef?

Third, should FSIS consider requiring irradiation process controls if irradiation is considered a processing aid? If so, what would they be and what impact would they have on the low-dose

irradiation of chilled carcasses?

And fourth, are there factors that FSIS has not considered? And, if so, what are they and what impact would they have?

And that concludes the presentation.

MR. TYNAN: Thank you, Patrick. What I thought we might do before we begin the formal comments regarding the presentation that Patrick made, we'd like to entertain maybe some questions from the audience, if there's some clarification on any of the issues that Mr. Burke brought up.

We'll see if we can't get the microphone to you. This gentleman is going to take care of that for us. Thank you.

Rather than come to the mic for this purpose, why don't we just -- we'll get the mic passed around. Can you do that for us or, Roger, can I impose on you. Would you consider that?

DR. ROBERTS: Tanya Roberts, retired from the ERS. I had a question about the *E. coli* Biotype 1 you said that was used in the test. Does that include O157:O11 or other STECs?

MR. BURKE: For the one that Dr. Thayer was looking at or --

DR. ROBERTS: Well, you mentioned it earlier in your slides. Let me see which page it was, that that was what you were looking -- the process does not have an effect on shelf life, and it included the reduction. You were looking at Biotype 1 *E. coli*. Yeah, I guess that was Dr. Thayer.

MR. BURKE: Dr. Thayer.

DR. ROBERTS: Slide number 26.

MR. BURKE: Slide 26. Oh, okay. Is that the one that mentions the Biotype 1 *E. coli*?

DR. ROBERTS: Yeah.

MR. BURKE: That's all he tested, the Biotype 1.

DR. ROBERTS: What kind of *E. coli* is it?

MR. BURKE: Well, actually in the study, as you see the study, he didn't go into detail on that exactly what he was talking about.

DR. ROBERTS: Does it include STECs?

MR. BURKE: Generic.

DR. ROBERTS: Generic?

MR. BURKE: Yeah.

DR. ROBERTS: So it would include them.

MR. TYNAN: Okay. Just as a reminder and sort of the process we'll use, if you could please identify yourself and your affiliation for purposes of the record. Yes, sir.

MR. GOODSIR: Graeme Goodsir is my name from Harrisburg area, Pennsylvania. I'm a meat industry consultant, and also in part of my work, I represent the British meat industry here in North America. I've had a full career in the industry.

Just a because question. Why did it take three years for the petition to come up? Did it take that long for research, or were there other reasons?

MR. BURKE: We received the petition in 2005. Yeah, we were basically making sure we understood what was being asked, make sure we went back and looked at the studies and, you know, in the sense that we were making sure we did a thorough job on this thing before we brought it up, the petition,

for a public meeting.

MR. TYNAN: Do we have other questions, clarifying questions before we get into the actual comments?

(No response.)

MR. TYNAN: Okay. There being none, I guess we'll invite the commentors, and I have a list here. So I'll go through those in the order of the way people signed up, and then if there are still some comments remaining, we'll, we'll loop back and have some of the people that may have registered.

Again, I want to remind you that we're going to limit it to about five minutes for the comments so that you can get the major points out on the table. If I cut you off at the end of five minutes, it's not because I don't think your comments are important, but I want to be sure that everybody gets their opportunity to have their say on the record for today.

And we'll ensure, as I pointed out earlier, that you will have an opportunity to submit written comments to our docket office, and all of the

specifics are in our Federal Register notice.

If time remains at the end, as I say, we can always loop back and do another round of comments.

So again, I would invite you to come up to the microphone, as I call your name, and again identify yourself and your affiliation for purposes of the record.

And the first person I have is Patty Lovera. And I want to apologize in advance if I do violence to someone's name.

MS. LOVERA: Good morning. My name is Patty Lovera, and I work with the consumer group called Food and Water Watch based here in D.C.

I actually just thought of a question on my way up that I should have asked a minute ago, but one was just a little clarification on FDA and their latest thinking on this. Are they here?

MR. TYNAN: Please go ahead and ask.

MS. LOVERA: Yes. I guess the question is we had through Freedom of Information Act received a letter that FSIS wrote to FDA last spring, I think,

asking for their concurrence about changing this to a processing aid, and I was curious if that had happened yet.

MR. DERFLER: This is Phil Derfler. I think Mr. Burke's slide addressed the question. There really hasn't been any further advancement or discussions with them.

MS. LOVERA: So we're still waiting?

MR. DERFLER: Yes.

MS. LOVERA: And will that have to formally happen before you could go ahead and approve this petition?

MR. DERFLER: I don't think I know the answer to that question. I think we need to look at all the facts that we get, and then we'll make a decision on the basis of the evidence that we have before us.

MS. LOVERA: Okay. So now that that's out of the way.

MR. TYNAN: You'll transition to your comments.

MS. LOVERA: Yeah.

MR. TYNAN: Okay.

MS. LOVERA: So Food and Water Watch believes that changing food irradiation to a processing aid rather than its current status as an additive is a major, major change that we shouldn't take lightly, and we also think that it's an inappropriate change due to the historic definition of a processing aid, as something that was a technical effect while you're using it but is not present in significant levels after you're done or doesn't change the food in some way after you're done.

You know, we believe that there's a large body of evidence that shows us that irradiation, even at very low doses, doesn't meet that criteria because it does change the food.

You know, we talked about even if there are minimal vitamin changes, vitamin levels change, lots of other chemical characteristics of the food change, and we know that we see the byproducts like ACBs and other byproducts even at low dose treatment.

So we think that that's significant, that that is material, and that consumers absolutely deserve to know that. And moving this to the category of processing aid where it would not have to be labeled is a huge mistake, and we think that it does a tremendous disservice to consumers.

You know, there are other processes that the FDA requires to be labeled because they think they're material, things like using dehydrated potatoes to make a potato chip. If that's material, using something as controversial as irradiation as a process absolutely is material and that should be disclosed.

We also, just in general, we're not fans of irradiation. I don't think this surprises anybody in this room, that we're not happy about this, but we think there's a lot more to be done to show that this will work at this point in the line.

There's tremendous worker safety issues that have to be dealt with and just appropriateness issues of whether this is a feasible way to deal with *E. coli*, which brings me to kind of the context

of this.

You know, last spring, we were encouraged when FSIS had a two-day meeting on how are we going to tackle *E. coli*? What are we going to do? And the proposals at that meeting talked about, you know, making it an adulterant for primal cuts and boxed beef, looking for it further upstream. These were encouraging prospects that we were happy to see and we supported, and by June, it seems like they were off the table. And that is moving in the wrong direction, and now we get something like this instead, and this is a poor substitute for some of those other changes that we think are necessary to deal with *E. coli.*

One of the questions that came up about what we need to discuss, we think there's absolutely a need to address the potential of, you know, if the stuff gets further irradiated in a later process as a finished product with ground beef. Until that is dealt with, we don't think that there's any way this should move forward.

And then to go back to that letter that we

got through the Freedom of Information Act, the letter was from FSIS to FDA, but at the very end, it had a line where it said that FSIS was going to confer with AMS about their possible concerns about how this interacted with organic, and we think that this shouldn't interact with organic.

There is no role, no place, at any dose, at any purpose, at any point in the line, for irradiation in an organic meat plant. It is a prohibited method under AMS' organic standards, and it needs to stay that way whether you call it an additive or whether you call it a processing aid.

Organic consumers have universally rejected irradiation. It's one of the issues that cause hundreds of thousands of them to comment on the organic standards in the late nineties, and running irradiation anywhere near organic meat is going to cause a major, major, major ruckus, as it should.

And so finally I'll just say that, you know, at this public meeting on *E. coli* last spring, Dr. Raymond, you talked about needing to make bolder changes to deal with *E. coli* and, you know, six

months later, and what we're seeing instead of these bolder changes is a bold step in the wrong direction towards irradiation.

And so we think that FSIS should deny this petition. Thank you.

MR. TYNAN: Thank you.

DR. RAYMOND: I'm going to just respond real quickly. Patty, nothing is off the table when it comes to *E. coli*. To make bold decisions, you can't make them overnight in a vacuum. My opening comments allude to the open transparent meetings. This is a bold initiative. That's why we're having an open meeting.

Some of us in the room just spent two days in Chicago, got home last night, discussing *E. coli* control in beef. Nothing has been taken off the table.

MR. DERFLER: Can I say one thing?

MR. TYNAN: Yes.

MR. DERFLER: This is Phil Derfler, and in the beginning of your statement, you talked about the fact that there's evidence that there are

byproducts that low-dose treatment, and it's really important that you include that evidence with your comments so that we have it in the record.

MR. TYNAN: Okay. Our next commentor is Jeff Barach. Mr. Barach, if you would come up to the microphone, identify yourself and your affiliation.

MR. BARACH: Yes. Thanks very much, Mr. Tynan, for the opportunity to comment here. I'm Jeffrey Barach, Vice President of Science Policy at Grocery Manufacturers Association, the GMA.

GMA represents the world's leading beverage and consumer products companies. The Association promotes sound public policy and helps to protect the science and security of the food supply through scientific excellence.

Now, let me begin my comments with a statement in a report from former Secretary of Commerce, John T. Connor. The report states, "The preservation of food by ionizing irradiation is fast approaching commercialization. Within the next decade, food irradiation will evolve as a major

technique for food preservation and will be utilized by many processors with substantial benefits to producers, distributors and consumers."

Now, this quote is from a 1965 report. This was published more than 40 years ago. Now, how could this be so wrong? Why is a technology that has proven safe, proven to destroy harmful pathogens, proven to have the capability to save human lives and prevent suffering basically been left sitting on the shelf?

GMA believes that food irradiation is a safe and effective process for pathogen reduction in foods.

We recently completed one phase of our continuing work with the Food and Drug Administration that resulted in the approval of the use of irradiation on fresh lettuce and spinach, and we are pursuing other uses for pathogen reduction such as the treatment for ready-to-eat meat and poultry products.

GMA supports the application of low-dose irradiation on beef carcasses as a potentially

useful process for pathogen reduction. Just as with pathogens in fresh produce, low-dose carcass irradiation is a promising alternative for helping to provide a safer food supply.

The quote I spoke of in the beginning of my comments is similar to quotes throughout the history of food irradiation.

GMA believes there are two main reasons food irradiation has not joined mainstream processing and production in the United States.

First, the requirement for labeling of irradiated foods which is a unique labeling mandate that numerous consumer studies have shown is generally perceived by the consumer as a warning about the safety of the food.

And, secondly, misinformation about the safety of the process and the lack of education and understanding on the part of the consumer about the technology and its benefits.

To assist industry and public in addressing the labeling barrier to commercialization, FDA, back in April of 2007, published a proposed rule

concerning labeling alternatives for irradiation. GMA and others have expressed strong support for the approaches described in the proposal and desire to see this proposal finalized.

The concept of considering low-dose irradiation as a processing aid presented in the petition will also help overcome the labeling challenges that we have. We fully support the approach of carcass irradiation categorized as a processing aid.

We note, as does AMI, that carcasses treated with low-dose irradiation will be subject to further processing by a variety of techniques prior to packaging and sale to the consumers. And therefore, it is appropriate, to view carcass irradiation as a processing aid.

Because processing aids do not require labeling, final products such as hamburger, primal cuts, et cetera, offered to the consumer should not require labeling because of the carcass irradiation treatment.

We bring to your attention, and this

addresses one of the questions at the end of Dr. Burke's presentation, we bring to your attention that the labeling or marking of intact or whole irradiated carcasses as to its irradiation treatment and dose level during manufacturing, would actually be beneficial. This labeling of the irradiated carcass should be conveyed on documentation accompanying the carcass, destined for further processing, so as indicating a treatment has been given, and if further irradiation treatments are applied, such as the irradiation of ground beef made from that carcass, the maximum dose of irradiation which is approved is not exceeded.

In conclusion, GMA strongly supports irradiation technology for pathogen reduction in a variety of foods where beneficial and applicable.

We support the application of low-dose surface treatment of beef carcasses as described in the AMI petition.

We support the concept of using low-dose irradiation as a processing aid, which when used in this manner would not require irradiation labeling

on the finished product.

The food safety outcome of this proposed application of food irradiation technology will be of benefit to the health and well-being of consumers. Thank you very much.

MR. TYNAN: Okay. Thank you, sir. Next on my list is Ms. Nancy Donley. Ms. Donley, come up and identify yourself and your affiliation.

MS. DONLEY: I'm Nancy Donley with STOP, Safe Tables Our Priority.

Dr. Raymond, on behalf of our organization, I want to wish you best wishes for your future, and we hope that it's happy, healthy and safe.

DR. RAYMOND: Don't take that from her five minutes, Robert. She can go on if she wants.

MR. TYNAN: We'll give her another 30 seconds. (Laughter.)

MS. DONLEY: I'd just like to start off by saying that STOP has historically embraced the idea of validated technologies that will better enhance the safety of our food supply. We have long been proponents of continuous innovation and improvement

in development of such technologies.

We particularly embrace that because as representatives of victims of foodborne illness and myself, the mother of a six-year-old little boy who died from O157, we really, really, really try to get behind and support, not individual technologies, but again the idea of improved technologies as a whole.

That said, I want to comment on this petition, and just make a couple of points. And I'm going to limit my comments strictly to the food safety application of these technologies, not any of the organoleptic or other types of shelf life, those types of issues.

The petition was done in 2005 as was brought up earlier, and the question was why was nothing done about it in that period of time. I would like to postulate that perhaps this was not done and FSIS did not approve it because maybe this was the right thing to do because the study to our viewpoint simply does not make the case and that we would submit that the study is flawed and certainly could not be construed by FSIS during these years as

a validated processing aid.

And while I'm not a scientist, I'd just like to bring up a couple of points I noticed in this particular study.

Number one is that the whole support for this petition was a single study, just a single study done by and initiated through the beef industry's Check Off dollars. And the study was not done on actual carcasses, and I understand here, we have a bit of a catch-22 because the industry's saying we don't want to build the technology unless we know that it's going to be validated. So we have a real problem with that.

Number two is that the study that was used, they inoculated with non-toxigenic O157, which the authors themselves said that they have no knowledge of any studies comparing the irradiation sensitivity of such strains to toxigenic O157. So we have a problem with that.

Another thing is that the petition calls for irradiation at the level of 20 mm penetration, but the study was done at 15. So again, we just

don't know. There's an inconsistency there.

And then lastly, I just want to point out that the remaining levels of pathogens present based on the initial inoculation levels, that the case is being made of the remaining levels of pathogens are being based on the inoculation levels and not what the levels that actually are formed after attachment.

So as a for instance, the petition points out that they inoculated with 3.0 which actually after attachment wound up actually at a level of 3.9. It goes on to say that after 48 hours and 120 hours, respectively, that these levels came down to, after irradiation, down to a non-detectable level which actually if you look at where the actual level of the pathogenic level was, you come down to, in the case of the low inoculation, would come down to a 1.0 and 1.3 after 48 hours and 120 hours, respectively.

The same thing with the high inoculation level. It was inoculated at 6.6. It actually wound up growing to 7.6. How can you have a 6.6 log

reduction which is what they're claiming on a 6.0 log inoculation. You have to take a look at 7.6, not 6.0, which means that after 48 hours, you were left with 1.0 and after 120 hours at 1.9.

So I just want to point out these things that to me as a non-scientist, it's not making a whole lot of sense.

That said, I just want to end this with, we would be receptive and listen to again because we want innovations that are going to make people safer, stop the illnesses and stop the death. If industry wants to go ahead and put forward a real true study on this, we would certainly look at it. We do have open minds on this issue, but again, we just can't support this in the manner that it is. Thank you.

MR. TYNAN: Thank you, Ms. Donley. The next commentor I have on the list, and again I will apologize in advance if I do violence to the name, is Urvashi Rangan.

DR. RAYMOND: You must have.

MR. TYNAN: I must have.

DR. RANGAN: I think that gets a prize actually. It beats any telemarketer that's called me. (Laughter.)

Thank you. My name is Dr. Urvashi Rangan. I am a senior scientist and policy analyst with Consumers Union. We're the non-profit publisher of Consumers Reports Magazine. I'm a toxicologist by training. I've worked there for over a decade, including working on our 1993 in-depth project and report on irradiated foods.

Thank you for the opportunity to comment here today on this petition. Consumers Union has a lot of concerns about this petition, and I'm just going to go through them.

First of all, we agree with Patty Lovera that this should not be a replacement for good hygiene on the farm. We really want to see the hygiene standards move upstream because that's where the origin of the problem is. And we think that techniques like this can function as band-aid jobs for a messy system and can actually allow for potentially dirtier and dirtier product to enter in.

In 1993, we looked at chicken tenders before and after they were irradiated at the plant, and we found that the ones that were awaiting irradiation are actually much filthier with regard to *Listeria* contamination than those that were never irradiated that we tested at retail.

It's a snapshot in time observation, but it's an important one to indicate that we don't want the process to get any dirtier.

We also think that this application which is used in the middle of processing does not take into account the rest of processing which can often lead to recontamination of a product during the processing of it. And so it can be somewhat misleading to say that the product has been treated with this, especially for consumers who want to buy irradiated product because processing in and of itself can lead to recontamination.

We also think that this does not qualify as a processing aid because there are unique characteristics that are altered in the food product that aren't taken into account. First of all,

Dr. Thayer never measured these unique radiolytic byproducts in fat, the 2-ACBs. It's a big concern for consumers. There are questions about the safety of it that are still being studied and frankly, that is a unique change that happens in the food and it does seem to happen, some studies demonstrate as low as .1 kGy doses. So that really needs to be taken under consideration here and those measurements need to be made.

We also think that consumers have a right to know what's going on with the products that they buy. If it's irradiated, whether it's irradiated at this stage, whether it's irradiated at the end stage, it's an important technique that consumers want to know about, and without labeling, consumers who want to avoid irradiated products will be misled, but without specific labeling -- that is to say that this can't just be labeled as irradiated. It needs to be labeled as irradiated at early processing step.

Even consumers who want to choose irradiated products will be misled because if they

don't understand where in the processing step this occurred, they may be misled to think that this is indeed a safer product as one that had been irradiated at the very end, and that's important for consumers to know, whether they choose to buy it or whether they're choosing to avoid it.

So thank you. Those are our comments.

MR. TYNAN: Thank you very much, and I apologize for the messing up of the name. But I sincerely appreciate the suggestion for post-retirement career as a telemarketer. (Laughter.)

The next commentor we have is Joseph -- oh, I'm sorry.

DR. HURD: Can I just ask her a question?

MR. TYNAN: Yes, sure.

DR. HURD: Can I ask you a question?

DR. RAYMOND: Dr. Rangan.

MR. TYNAN: Dr. Rangan.

DR. RANGAN: Yes.

DR. HURD: Can I just ask you a question?

DR. RANGAN: Yeah.

DR. HURD: The argument about the product

getting recontaminated, if one of the main purposes of this is O157, and this is more to think about in your comments and stuff like that --

DR. RANGAN: Uh-huh.

DR. HURD: -- and where it's going to get contaminated when they pull the hide or someplace like that, where would the recontamination with respect to O157 occur?

DR. RANGAN: In this case, first of all, as the woman previously mentioned, we don't get to 0 O157 with this technique. So even 1 or 2 CFUs by the way have public health implications, and those bacteria are alive. So as you grind the meat, as you aerate it, as you make the ground beef, the potential to recontaminate or have that bacteria grow and spread is still there all the way until the consumer buys it and cooks that product. So the potential for bacterial contamination or recontamination at that stage is still there.

DR. HURD: Okay. Thank you.

MR. TYNAN: The next commentor I have on my list is Joseph Mendelson. Did I do better on that

one?

MR. MENDELSON: You'd be amazed at what people do to it, though.

My name is Joseph Mendelson. I'm with the Center for Food Safety. We're a non-profit organization that represent consumers across the country.

I'd like to first thank Dr. Raymond for his public service over the years.

And, at the risk of sounding redundant with my colleagues, I'd like to say that our organization does not approve of this change, and it stems from both some of the technical and legal aspects.

Certainly there's a long history over, frankly 30 years, of both FDA and in some instances, FSIS, saying that irradiation is not a processing aid.

And as was mentioned before, this is a petition that has one study and another study on nutrients, but that's not enough to overturn 30 years of what is essentially a legal precedent at the Agency, and I think there needs to be much more

to legally justify that.

A couple quick comments, again, not to be, well, to be redundant but the study certainly does not look at ACBs. As previously mentioned, there are a number of studies that suggest that ACBs and 2-DCB in beef occurs at low levels, below 1.0 kGy. Certainly studies have shown and used 2-DCB to be a detection method as to whether a product is irradiated, and those studies have shown it to be below 1.0 kGy.

Similarly, there's also at least one study that suggests that irradiation of beef at this level can raise trans fat levels. I think both the presence of ACBs and a potential to raise trans fat levels are technical and functional changes in the product and therefore would not meet the definition of a processing aid.

Further, it's been mentioned that, this one slide suggested that there's not organoleptic changes. Certainly we have seen a number of studies show that there are organoleptic changes and, in fact, our organization, Food and Water Watch, issued

a report called "Gross Failure" that goes through a number of those studies.

So what you have is a combination of presence of materials that have never before been in beef which is a functional effect on the end product, possible increase in trans fats from this technology and a history of organoleptic changes. All of those do not meet the definition of a processing aid, and certainly are material changes for the purposes of mandating consumer labeling.

I would add to Ms. Lovera's comments about organic. Certainly if you look at National Organic Program's regulations, and specifically 7 C.F.R. 205.105, 205.270 and 205.301, irradiation, whether it's a processing aid or however you characterize it, cannot be used in any type of handling of organic food and is prohibited.

One last thing, I know certainly that FSIS under regulation is exempt from NEPA. That can change. We know that if the Agency head finds that there is significant environmental impact from a federal action such as this, that NEPA compliance

would be required, and certainly we think there is an environmental impact on this.

As alluded to earlier, there's a moral hazard involved in this technology, and that is because it is allowed at the end process. It insulates people from upstream changes, and those can be issues that certainly affect the environment from husbandry practices, manure management, ground water contamination, something such as the increasing feed of distiller grains to cattle which we know, in several studies, say that O157 increase rates happen because of that.

So we would ask that the Agency also look at the environmental impacts of this and sidestep what is its exclusion from the NEPA process.

So to sum up, we oppose this project, this effort and certainly will be submitting further written comments. Thank you.

MR. TYNAN: Thank you. Dr. Raymond, did you want to --

DR. RAYMOND: Yeah. As Mr. Burke said in his comments, one of the reasons we're having this

meeting is to make sure that we have all the information available to us.

And so, Mr. Mendelson, I would ask you because one other testifier -- no, you don't need to get back up, but one other testifier already said there's only been one study. So we shouldn't make this move with one study. You said there's been multiple studies that showed organoleptic changes. So if those studies are pertinent to this discussion, if they are low-dose, low-penetration irradiation, make sure you get that in your submitted testimony for clarification because right now we have two conflicting comments.

MR. TYNAN: The next commentor we have is Ms. Pat Buck. Ms. Buck, if you would come to the microphone and identify yourself and your affiliation.

MS. BUCK: Good morning. I'm Patricia Buck, and I'm the Executive Director for the Center for Foodborne Illness, Research and Prevention. And, like the other commentors, I want to thank you for this opportunity to express our opinion on what

you are talking about which is low-dose, low-penetration irradiation.

We did our share of research looking at low-dose, low-penetration irradiation, and we have come to recognize, like Nancy Donley, that this is a technology that can, in fact, do something to reduce the level of deadly pathogen on products.

And I am, you know, you think about it, you say, well, that is really worthwhile, but like any other thing that's really good, you have to look how you're going to implement it.

All right. So the technology may in my mind and in CFI's mind be safe, but it then comes down, it always comes down to how is FSIS and how is industry going to put this in place? Because if they put it in place without good management practices, if they put it in place without good husbandry and farming practices, if the Agency thinks they should put this in place without informing the consumers, I don't care who calls it what, I don't care if it's a processing aid that you want to monkey around, is that the name, or if it's

an additive, I have serious problems with the FDA and their announcement that this is a processing aid, low-dose, low-penetration irradiation, and so therefore it doesn't have to be labeled.

Consumers have the right to make a selection as to whether they want to buy an irradiated product or a non-irradiated product, and they also have the right to say, I want to buy a product that has been treated with low dose, low penetration that might reduce the load on the product of pathogenic contamination, in particular for the *E. coli* O157 and the other deadly STECs.

What is it that we feel when we say that? As I said, the good manufacturing practices, the sanitation practices. The technology that puts this in place is going to have to be regulated, and it cannot be regulated by the industry, and it should not be regulated by just anybody. USDA has to have a very strong policy in place of how are you going to oversee low-dose, low-penetration irradiation. How are you going to do it?

These companies are going to spend 1 to 5

million dollars to put this technology in place. What is the proposal? Nobody's talked about that, and that is a problem.

We've talked about the problems that there aren't enough studies. There are a plethora of studies out there, but FSIS is only being presented with one study. So, yes, before you move forward, you have to have more information and some of these other studies should come to you.

We're also concerned that the petition talks about a level of penetration of 15 and now you're talking about 20. I am not a scientist. I don't know if that makes a big difference, but I certainly would want some assurance why there is that discrepancy. Okay.

USDA needs to specify the jurisdiction of who is going to be controlling the oversight of the process. USDA must clearly define what low dose, low penetration is so that there's no confusion. They must clearly define what a carcass is. I don't want later on to find out that this is what we meant a long time ago.

Again, we intrinsically believe that consumers have the right to know. I see labeling as your biggest problem. I see defining oversight over the technology as another major consideration, and I think that there must be some effort made to have some kind of outside study that's going to evaluate if the process is really doing what they said it was going to, and I think that's it. Thank you.

MR. TYNAN: Thank you, Ms. Buck. Next commentor is Ms. Tanya Roberts.

DR. ROBERTS: Hello. I'm Tanya Roberts retired from the Economic Research Service in USDA. And while I was at ERS, I had the pleasure of working on *E. coli* O157:H7 farm to fork risk assessment. And I worked on the slaughterhouse module, and in the slaughterhouse we noted, because this may be of interest to you since you're talking about irradiating carcasses, that 90 percent of the surface contamination on a cow goes into the combo bin that goes into hamburger or processed meats.

In comparison for a steer or heifer, since most of it is turned into steaks and other products

that go directly to the consumer, only 75 percent of the surface contamination that we found for *E. coli* O157 went into the combo bins that are turned into hamburger or processed meat.

So the point here I'm trying to make is that irradiation of a carcass where the contamination of O157 is occurring seems to be a very appropriate place.

What my questions are, have to do with how you're going to test to make sure that the controls for irradiation are actually having the impact that they are. What kind of tests are going to be required for *E. coli* O157:H7? How often are the tests going to be required? And what kind of enforcement actions would FSIS take?

So I would be interested in learning some of these details, if you members of the panel are prepared to answer some of these questions.

DR. RAYMOND: I don't think, Tanya, we're going to be able to answer that yet at this point because right now we're trying to decide whether this is a process, processing aid, an intervention,

that we are going to move forward on based on the comments today and on the submitted comments that will come in, in the next 30 days.

At that point in time, if we do decide to move forward with this, there's many questions that will have to be answered. And we've visited with many people about these.

For instance, if industry would take a look at this as a way to eliminate some of the other interventions, we need to make absolutely certain that there is an improvement in the safety of the beef, not a maintenance of the status quo to change cost or reduce cost.

Your points are well taken, and they are questions that will be addressed at the right time.

DR. ENGELJOHN: This is Engeljohn. I will try to answer maybe perhaps a bit to give you some information to inform your comments as they come in as well. But irradiation generally within the Agency currently is regulated, and we have in place some very prescriptive regulations on the process by which an irradiator would go through to get

approvals to do those irradiations, as well as the type of documentation that has to be present to demonstrate the effect of the treatment.

So in terms of will there be new or different things related to that? The intent here would be if we do go forward with rulemaking, that would be spelled out there.

But in terms of informing your comments, currently we have irradiation of beef in our system. We have a process by which either OSHA, EPA or FSIS, generally all have a role to play in terms of licensing and oversight over the operation, and even though this might be applied as a processing aid, it likely would be handled in the same manner we currently have regulations for the control of the process.

So I think that you should consider that it would be done in the same manner that irradiation of ground beef is done today. It's just the level of application is what's being addressed differently here and the point at which the irradiation process is actually treated for the beef. So there would be

some differences in that application, but in terms of the actual effect, that's what we're talking about for processing aid. It's meant to reduce, not eliminate, the presence of O157 at a point in the process.

DR. ROBERTS: Well, can I have a follow-up comment?

MR. TYNAN: Please.

DR. ROBERTS: I would suggest that you have required, that there be testing done at the end of each shift, that you take some random samples of trim from the most contaminated locations and, you know, the industry knows where that is, and that then would allow you to not only evaluate the irradiation effectiveness but also everything that's happened before, what happened on the slaughter line, what happened on the incoming beef if it was heavily contaminated and whether extra processing steps were added, and what happened in the tiller as well.

So I think you've chosen a good point that would be excellent for testing that would look at

the impact of everything that's happened before in the supply chain, in the supply process, and given the fact that the tests have become much more sensitive and much cheaper, much faster, for O157 and other STECs, it would be an excellent thing to require each and every plant to do each and every shift. I know that sounds like a lot of testing but I also think that testing should be made publicly available to everybody.

And I know that industry doesn't necessarily want to do that, but that would be something that I would like FSIS to consider as a possibility and use irradiation to kind of further the assurance to the American public that there is no O157 or it's in very, very limited reductions in the amounts that are in the food supply. Thank you.

MR. TYNAN: Okay. Thank you, Ms. Roberts.

DR. ROBERTS: I'm interested in any other comments you had on that, too.

MR. TYNAN: The next commentor I have is Randy Huffman. Randy, if you'd come to the microphone, identify yourself and your affiliation.

DR. HUFFMAN: Thanks, Robert. I appreciate the opportunity to be here today, and I guess I'm partly to blame for us being here this morning. I appreciate the Agency taking the time to hold this public meeting and gather input.

And, Dr. Raymond, I had the pleasure of being at your first public meeting about three years, three months ago, and I'm glad to be at the last one, and I've enjoyed working with you. I hope you enjoy your time away from Washington.

As stated, my name is Randy Huffman, and I'm speaking to you on behalf of the American Meat Institute and our member companies. I'm President of the AMI Foundation, which is the research, education and information arm of the AMI, which is the oldest and largest trade association representing meat and poultry packers and processors in the U.S. AMI, our member companies, process over 90 percent of the meat and poultry products manufactured in the U.S., and we appreciate having the opportunity to speak to you on this petition, and we appreciate the action that FSIS has taken.

The beef industry has made significant progress in enhancing the safety of beef products during the last two decades. The industry has invested tens of millions of dollars in research aimed at developing new technologies that will reduce microbial hazards, that are inherent in the processing of raw agricultural products. Implementation of the most effective of these technologies has occurred and has contributed to the reduction in pathogens such as *E. coli* O157 that we've seen on raw beef products.

However, clearly there's a need for more technologies and more effective technologies, and that's what the basis of our petition is.

The AMI Foundation strives to fund exploratory research in cooperation with other food safety funding entities to discover, evaluate and validate solutions-based microbial interventions that can be made freely available to the meat industry as a whole.

Since 2000, the AMIF research program, which is funded entirely with voluntary

contributions from our member companies, has directly sponsored over 60 food safety research projects at leading universities and public labs, totaling well over $6.5 million in direct research costs. So our industry is strongly committed to funding food safety research.

We're also cooperate closely with other groups that provide research funds such as the National Cattlemen's Beef Association and the Cattlemen's Beef Board, and the fruits of this research cooperation can be found in the underlying science that supports the petition that's under consideration today.

AMI and our industry partners have a vested interest in developing safe and effect technologies that can make a real difference in enhancing beef safety. We profit from selling safe food.

The proof of concept research underlying the petition was conceived, designed, and conducted using a multifaceted team of researchers and experts in beef processing, including microbiologists, engineers, biochemists, and meat and sensory

scientists.

The project was initiated to evaluate the possibility that this unique application of electron beam energy could be an effective intervention at a point in the process where unintended contamination is most likely to occur on the surface of the carcass.

AMI agrees with the position of the FSIS that low-dose, low-penetration electron beam applied to the surface of a chilled beef carcass is a processing aid and, accordingly, that the process need not be labeled or any products derived from the carcass be labeled.

The information contained in the petition demonstrates that the process under consideration would be used as a processing aid. The data clearly show that it could be remarkably effective as an antimicrobial on the carcass surface, but in no case has FSIS ever required the labeling of an ingredient merely because of its antimicrobial properties at time of treatment.

In the case of this process, it has no

other technically functional effect on the carcass or the products derived from the carcass. The petition demonstrates the process has no significant effect on the organoleptic properties, the shelf life or nutritional properties of the carcass, or the products derived therefrom.

In addition, we submit that this lack of any technical effect demonstrates that the process is insignificant in terms of the products of the carcass.

The key unique difference of this proposed application of irradiation, compared with other approved methods or final product irradiation, such as with ground beef, is that it is low dose, it's low penetrating, and it's only an e-beam application. And it results in an insignificant portion of the carcass actually receiving e-beam exposure, and most of the edible portion of the carcass would not receive any e-beam exposure at all.

The external surface of the carcass is largely used in ground beef manufacturing where it

constitutes about 5 percent of the ground beef blend. Much of the carcass surface is covered by adipose tissue which is inherently self-limiting as a component in ground beef blends.

Indeed, we submit it would be misleading to mandate the labeling process or any beef derived from the carcass since those products would evidence no characteristics of being irradiated products.

FSIS posed a series of technical questions that were considered by the research team, and the appropriate research studies were conducted to address these questions. The specific questions and the detailed research results are contained within the petition.

And I would point out that the primary component of the petition includes a public peer-reviewed study. So I submit based on some of the comments made earlier, that the recognition that the research was peer reviewed and in the published literature, in the Journal of Food Protection, I think establishes the validity and veracity of that research, and it shouldn't be questioned here at the

-- in this meeting. Certainly, additional research is needed, but the research that's in this petition is valid and appropriate.

The series of questions and conclusions from those questions are summarized in the petition. The proposed application surface applied low dose irradiation would be exceptionally effective at reducing *E. coli* O157. Number two, the application would not have any effect on organoleptic properties or appearance of the products. The proposed application would not have any lasting effect on the shelf life. And, four, the proposed application would not produce significant losses of either macro- or micro-nutrients.

These data provide an initial evaluation of the potential effectiveness and the needed data to support a regulatory decision on label. AMI and its member companies recognize clearly that it is simply the first step in a long process of developing and validating this potential food safety tool. There's a lot more work and research that needs to be done. Engineering studies will need to be conducted and

prototype units for applying this technology in a plant setting will need to be constructed.

Worker safety and FSIS inspector safety procedures must be established and properly implemented. Process control techniques would need to be developed and implemented to ensure proper dose application and the penetration and to ensure that the minor dose on the surface would be accounted for at any subsequently irradiated products.

A prototype system must be validated under real world operational conditions, and ultimately processing plants, if all these issues are properly addressed and the technology still is promising, processing plants would likely require significant reconfiguration and incur significant capital expenditures.

These issues are significant to our industry, but I don't see them, and our industry does not see them as insurmountable.

The key issue at hand today is that a regulatory decision is being contemplated based on

sound scientific data which will allow the industry to further study this potential food safety tool and potentially take advantage of its pathogen reduction capabilities.

So, in summary, based on the data and analysis referenced in the petition, we submit that the proposed process of e-beam to treat the surface of a chilled beef carcass would meet the USDA FSIS definition of a processing aid and would result in significant reduction of pathogens such as *E. coli* O157, while causing no meaningful change in the organoleptic properties, the shelf life, or the nutritional profile of the products derived from the carcass.

We appreciate your action on this request, and I look forward to working with you as we move forward. Thank you.

MR. TYNAN: Thank you very much. The last commentor I have on my list is David Plunkett.

MR. PLUNKETT: I will submit written comments.

MR. TYNAN: You're welcome to have some

oral comments or -- no.

MR. PLUNKETT: I'll submit them.

MR. TYNAN: All right. Thank you. Mr. Plunkett has yielded his time at this particular point.

I would invite then since we still have time on our agenda, if there are some other folks that have comments that would like to do so at the time, I'd like you to come to the microphone, identify yourself and your affiliation, and we'll include those in the oral comments.

MR. GOODSIR: I'll add a little to my former introduction.

MR. TYNAN: And if you could state your name and --

MR. GOODSIR: Graeme Goodsir is my name, originally from Australia, just to explain the accent, and I've lived in the United States 36 years and am a U.S. citizen now.

I've been in the livestock and meat industry all of my career, and as I mentioned, I do work for the British industry for liaison purposes

which doesn't directly affect irradiation.

In my former trade activities, I've had my consultancy 20 years. Before that, I had other roles. I was Chairman of the Meat Importers Council of America and dealt a lot with industry issues and have kept very much involved especially with *E. coli* O157.

I took a special interest after the Jack-in-the-Box outbreak in 1993 and have done so ever since on a private basis. I talked a lot with the industry people and others. I totally sympathize with Nancy Donley, and if I had lost a child like she did, I would never forgive this industry until we addressed the issue in a totally responsible manner and came up with the best possible solution.

And I believe we're close to that today. We've been trying a long time and spent a lot of money as Randall just said.

I also want to add that I've got a great respect for Dr. Randall Huffman, and his father was a notable meat scientist, and I think he's looking at the total integrity of this issue.

And one point I'd like to make at the outset, I've been disturbed all along by the adversarial nature of the attitudes between consumer groups and the industry, and I think there's a great need, and I hope USDA can help as a mediator, to sit down and show respect for each other and really go through these issues without emotion. We have a lot of irradiated food already. We have spices, for example, that often go into meat products. Most of them irradiated, and it's not an issue of controversy at all. The procedure is acceptable.

We've heard other terms for irradiation. I remember Hormel and, Dr. Raymond, your predecessor in Food Safety, while she was at Texas A&M, was a great advocate of irradiation, and together with Hormel they were promoting the concept and I thought in a very admirable way, but they were totally shot down by consumer advocacy criticism without ever having started the dialogue, and Hormel retreated I believe. I can't speak for them, but I believe they retreated because their brand name would have been in danger of a lot of injury if they really pushed

this, but that's the problem we have to overcome.

I just want to comment a little bit on the practical aspect.

No, first if I can take a minute as a consumer, I buy irradiated ground beef in Pennsylvania where I live from the Wegmans Supermarket, very high profile and in my belief, top integrity. And they advocate this in their fliers. They explain it. They've sold it for a number of years, and I think it's good. And they use the SureBeam process.

And the other product I can buy where I live is from the Schwan Group that goes door to door selling irradiated ground beef among other products frozen. But on the labeling, on their package, they do recommend that you cook that product still to 160 degrees, which is almost telling me that maybe I can't have total confidence in the irradiation. I've still got to follow the USDA recommendation for safety, and they're doing it to protect themselves from legal liability I'm sure, but it's a confusing label, and we've got to show very careful attention

to labeling and make sure consumers fully understand all of the aspects.

I meant to say that Texas A&M and Hormel, I remember, advocated a term of electronic pasteurization. Whether that can be considered as a legitimate description, I'm not sure, but I'd like it to be considered because there's no question, irradiation sparks alarm and danger.

How do we explain milk being pasteurized? It's the same problem of farm contamination having to be corrected. We did it years ago with a lot of controversy but now it's not even a talking point. We're looking at a similar thing to protect meat the same way that we protect milk.

And I just want to comment briefly on the practical aspects of looking at this. My studies in the last, what, since 1993, 15 years, have persuaded me, and I'm not a scientist, but persuaded me that the hazard lies with the hide of cattle. We don't have any problem with pork. I never heard of *E. coli* with pork because at the end of the line, we put it through a high temperature flame procedure

that eliminates contamination if it's there.

We can't do that with cattle, and I believe that contamination is on the hide, and I believe with the hide puller, the mechanical process that pulls the hide off, and at the end it snaps off with a lot of friction, and if there's any manure on that hide, it's going to dissipate into the atmosphere and those particles could fall anywhere along the line before that carcass leaves the slaughter floor, and that's where I think we still have that risk. With all the interventions that we try to eliminate, I think it's all those particles still falling down that give us that odd contamination.

And we've got to investigate and explain, this is the reason we need to have an intervention like irradiation at the end, and I'd like to know where it would be, at the end of the slaughter line or just before going into the cooler. But it's got to be at that point, not after it leaves and gets scattered around, like SureBeam tried to do, irradiating ground boxed beef, ground beef in boxes in different parts of the country.

MR. TYNAN: Not to impose a time limit on you --

MR. GOODSIR: Okay.

MR. TYNAN: -- but if you could maybe --

MR. GOODSIR: Thank you. Just one more point.

If irradiation comes into slaughter plants, we heard it could cost millions of dollars to install, very expensive, and I worry about how that affects the small and very small processor.

I want to make this point that I believe the contamination is on the hide and on the mechanical hide remover with those particles.

I think if a small processor does not use that mechanical hide remover and does the removal of the hide by handwork and knife work, he should be allowed not to have irradiation. That should be subject to a whole lot of testing to be sure that he or she is capable and does not have that risk of contamination. Thank you. I didn't mean to say so much, but I'm inspired today that it triggered. Thank you.

MR. TYNAN: I lost track of the time. I got so engrossed in your comments.

Is there anyone else that would like to make a comment before we conclude? I'm sorry. Mr. Waldrop, if you want to come up, identify yourself and your affiliation.

MR. WALDROP: Chris Waldrop, Consumer Federation of America.

At the beginning of his remarks, Dr. Raymond mentioned that he just envisioned this as just being another intervention step, and Randy Huffman from AMI said the same thing, that this is an intervention step. That seems to be how FSIS is considering it.

I think consumers need reassurances that if it is an intervention step, that it doesn't result in the decrease use of other interventions, or if that's the case, then that we are receiving the same or actually better protection as Dr. Raymond said. And so consumers need reassurances if that is going to be the case. We don't want it to just be put in there as another intervention step and then left

alone. So we need FSIS' oversight on that to make sure that that happens.

In terms of the study that was presented to support the petition, I believe, and I forgot to look at it just quickly, but I believe that was done on individual pieces of meat and not on entire carcasses in order to determine reduction in *E. coli*, and I think that that's something that we need to look at before we go ahead and approve this.

Can we get a uniform dose on a carcass? All carcasses are different. It's not the same thing. Can we get a uniform dose on a carcass? If so, USDA needs to validate that, and consumers expect USDA to be validating that.

Can irradiation get into the folds and the crevices of all these carcasses in the way that steam pasteurization or other methods cannot? And if so, USDA needs to validate that that's the case.

So again, reassurances that this is going to be done properly and that any further studies that are needed, USDA is validating them and not just accepting them on their face.

Finally, on the labeling issue, FSIS needs to look at the labeling issue very, very carefully. There's been a number of comments about it. Consumers do have a right to know that this process is being used. It's different than other processes. You can't just educate consumers and say, look, it's great. We have this great technology. Just trust us, you know, don't worry about it, everything's fine. Consumers have valid concerns, and those need to be addressed. Consumers have a right to know about this.

And they also have a right to know to avoid this process if they want to. This gentleman before me said he seeks it out. That's great. That's good. It's an option that is out there in the marketplace, but some consumers want to avoid it. So FSIS needs to think through the labeling issue on that.

We also don't want to mislead consumers and say that just put irradiation on the packaging because it's been done at an earlier step, and if you start mixing that product in with other product,

all of a sudden the irradiation doesn't hold in the same way that it does if you're doing it at the very end of the line.

So these are very critical issues, and FSIS needs to think through them very, very carefully. Thanks.

MR. TYNAN: Thank you, Chris. Any other comments from the audience?

MS. RANGAN: One point I just wanted to bring up, it's Urvashi Rangan from Consumers Union, is to encourage the panel to take a look at Dr. Thayer's data. One point I forgot to mention in my comment that I'll definitely include in your written ones is that the data do not, in fact, conclusively support the assertions being made.

The fact that AMI has asserted that there are no organoleptic changes is simply not demonstrated by the data, and I encourage you to take a look at Table 5 in Dr. Thayer's report. While aroma and flavor only saw statistical differences when you did 100 percent of the cut in the ground beef, and there was only a statistical

difference there, tenderness, juiciness did, in fact, show that there were statistically significant differences even when 5 percent of the irradiated or 10 percent of the irradiated parts were used.

So the assertion that there are no organoleptic changes based on this validated data doesn't stand, and it's extremely important to take a look at the science that's been presented to you because the assertions that are being made are not upheld in the data. Thank you.

MR. TYNAN: Okay. Thank you. One last call. Ms. Buck, I saw you leaning in that direction.

UNIDENTIFIED SPEAKER: Should we just line up? Would that be easier?

MR. TYNAN: Well, you could do that if you'd like to.

MS. BUCK: Yeah, this is Pat Buck from CFI. I have a comment to make, and basically I'm directing it to FSIS and to the industry. There's almost nothing else that a person does that is as intimate or personal as eating food. I mean, you

are actually taking it into your body. I mean, this is stuff that really involves importance to people.

I see this irradiation to some degree as a trust issue. Most consumers have very little knowledge of the science behind all of this. So they're looking toward their government agency to make sure that you have shown complete due diligence in your research efforts and in your gathering, and I think this meeting, of course, one of those efforts, but you need to continue at that, and if any consumer group in this rank over here has a concern about the study, that has to be looked at thoroughly, and more studies may have to be conducted.

Again, it's a trust issue. This is a new technology. The American consumer has a right to know that it's being used, and I really in all deference to what you said earlier, I truly believe that it would be to the business' advantage to say this has been used to reduce the pathogen load on beef carcasses.

The other thing I would like to mention

which I didn't mention before is that that Radura symbol, when it's put onto the package, to some consumers, that means that that product is now sterile. As the gentleman pointed out to me, that's not 100 percent the case.

So you have to have clear, concise messages to the consumer on this label that you will develop that safe food handling must be applied because really you have only conducted a partial treatment of irradiation because, as Mr. Huffman pointed out, most of the product is not irradiated.

The last thing that I forgot to mention is that we are very concerned about that small processor, and the small processor should not have to necessarily follow and do irradiation. He may have a different way of handling his contamination control that he wants to use or that he can afford to use. We think that small processor should not be put in a position where it has to use irradiation as part of their processes.

All right. Those are my last comments. Thank you.

MR. TYNAN: Thank you, Ms. Buck. Ms. Roberts.

DR. ROBERTS: Yes. Actually I have a Ph.D. in Economics. So I suppose I should call myself Dr. Tanya Roberts. I'm just not used to using that label because in the Government you tend to just call yourself by your name and not have a lot of fancy titles.

But I had a question that's not really an economic question at all in nature, but it has to do with the physical process of irradiation. And my interpretation of slide number 3 where the way that the irradiation works is by damaging the DNA of I assume the *E. coli* O157 organisms and destroying them, in that process, you're creating free radicals and oxidants, and that is the procedure that actually allows the O157 to be killed.

And I guess my question is, is that true? And the question is antioxidants have recently been shown in the literature to be increasingly important in consumer health. And so with this antioxidant and free radicals, is that a consumer health issue?

I'm not a scientist. I don't know how to answer that.

MR. BURKE: When the electron beam hits, you know, hits the product on that, a lot of, depending on the energy going in there, depending on what is actually done to different organisms and the tissue and such, it has different resistance to that. In other words, you're coming in and you're slamming an electron into the product, and it's breaking, you know, like the DNA, specifically *E. coli*, and we haven't gotten into any of the issues you were talking about at this time exactly how all the organism are affected on this. That's one of the things we're going to have to look at.

DR. ROBERTS: Any other comments?

(No response.)

DR. ROBERTS: Then my last question has to do with I'm not really up to date on what the current regulations are by FSIS for testing shipments of combo bins for *E. coli* O157. Is every shipment required to be tested, and if not, why not?

DR. RAYMOND: Tanya, I'm just going to have

to jump in here and say, you know, this is a listening session for us to hear comments about low-dose irradiation --

DR. ROBERTS: Okay.

DR. RAYMOND: -- not to discuss the entire beef industry.

DR. ROBERTS: Sure.

MR. TYNAN: Mr. Mendelson, I'm going to let you be the last commentor for the day.

MR. MENDELSON: Thank you. I'm honored. (Laughter.) And I won't make people stay in this room for much longer.

I just actually had a question. Joseph Mendelson with the Center for Food Safety. I know FDA has a proposal out to address certain labeling requirements and certainly labeling is discussed briefly in, in this proposal. I was wondering if there was any discussions on how this dovetails with FDA's proposed labeling changes and if there's a sense on when FDA would be completing that and how the timing of a decision on this petition may intersect with that?

MR. DERFLER: This is Phil Derfler. I think we see ourselves proceeding on two different tracks, and I mean, we're going to make our decision on the basis of the comments and what we learn in response to the notice and our evaluation of the petition and our evaluation of our statute. And ultimately we're going to proceed in communication with FDA, but we're going to proceed separately and make a decision on the basis of the evidence that's in the record of this proceeding.

MR. TYNAN: Ms. Donley, I see you'd like to make a comment, and I take it back, Mr. Mendelson.

DR. RAYMOND: You can get back up if you want.

MR. TYNAN: Yeah, you can get back up.

MS. DONLEY: Thank you very much. I appreciate it. It's really one of going forward. It's kind of a strategic question. Although I do have to just make one kind of response to something that was said is I think, you know, that, Graeme, and I've been working with you, beside you, across from you, 15 years as well on this issue, and I

think one thing I'd just like to say, I think it's good, it's necessary that we keep these tensions going here. We need to because otherwise we're going to become stagnant and not get anything done. You can't be too cozy. These things are actually good. These types of debates are positive and I think a very, very good thing.

I would also like to kind of respond to the fact of questioning science at this microphone and, you know, again that's a positive thing in that it's keeping everybody on their toes, and we're not just going to swallow and stomach something that's been put forward to us by a self-sponsored study. We're just not going to do it.

That said, I really hope that the industry, that AMI goes forward and builds one of the things, gets it done, puts in front of us and let's take a look at it. I'm all for that.

So now to my procedural thing is, and Phil started talking about this. I just question is this a yes or no situation here where you assess these comments and our written public comments or if you

could kind of elaborate a little bit more on the next steps. Thank you.

MR. DERFLER: Well, I don't think I've ever answered a question yes or no in my life. (Laughter.)

MR. RAYMOND: Not the last three years.

MR. DERFLER: You know, we're going to evaluate the comments. We're going to evaluate the science. We're going to evaluate the law. There is a possibility we can decide that we can treat it as a processing aid in which case there would be some sort of public announcement of our decision, but we would not necessarily have any further process based on that.

There may be a possibility that we decide that there is a basis, there is something here on which we think we can proceed, but we do think because of the nature of the regulation that we have in place already on irradiation, we're going to need to amend that regulation, and so we would have a public process to do that.

Or, there is I guess some possibility on

the basis of the science and the information that we receive in comments that we decide that there really is no reason to treat type of irradiation any differently than the way we're already treating irradiation, and we leave the regulation standing and not proceed any further with this particular idea.

I think all those things are open. I think we're having this meeting because we felt on the basis of our analysis of the petition that there was some promise here in light of how we treat processing aids.

There is some possibility here that there's something that we need to look at a lot more closely. And so that's why we're here today, but we really are interested in comments and additional public input and stuff like that so that we can make our decision.

MR. TYNAN: Before I turn it over to Dr. Raymond for maybe giving us closing comments, since this is his last public meeting, we ought to give him the last word, I just want to remind

everybody that we are accepting written comments. So if you were not able to get all of your thoughts conveyed today, and I know there was quite a bit of dialogue, and I appreciate the effort that all the commentors put into their thoughts, we will be accepting written comments through the 18th and the Federal Register notice kind of outlines how that should occur. So the different methods of submitting the comments.

In addition, we'll have a transcript of this public meeting that we'll probably receive within 10 to 12 days, Keith?

Yeah, about 10 to 12 days, and we will post that on our website, and that will be available so that you can review some of the comments that were made today and formulate based on that, your thoughts a little bit more carefully.

And with that, I would also mention that I think we'll have Mr. Burke's presentation up on the website as well. So all of the information will be available for you to fashion the comments that need to be submitted by the 18th.

And with that, I want to thank you again personally for your thoughts and comments today. I'm going to turn it back over to Dr. Raymond.

DR. RAYMOND: Thanks, Robert. I won't say much about the process down the road since I won't be here to try and guide it, but a couple things that had come up in the discussion this morning that I think I can boldly try to respond to.

A couple of people mentioned small establishments, and they should not have to do this. I don't think there's any intent on the Agency to make this a requirement for anybody. The intent is to consider making this a possible intervention that can be used at the industry's desire, personal desires.

I agree with the comments that the processes of removing the hide are different in the small slaughter establishments versus the larger establishments. There is no question about that either, and the small establishments are represented here today by one of their associations, and they're here probably to make sure that we don't make this

mandatory for small establishments. So that's not our intent. That's not our intent at all.

Secondly, Chris, I think it was, made the comment about the study was done, he thought, maybe on muscles rather than carcasses, and I think that's correct. And industry, when Mr. Huffman was up, he made the comment that there is more studies that need to be done. Industry just isn't willing to invest millions of dollars unless there's an indication that this can be an intervention that they can use, and so I think the studies we have seen are preliminary studies. And if they are good enough to open the door for further studies, I think probably that's kind of what AMI petitioned us for.

It isn't to say let's just put this in all the plants willy-nilly. It's like we want to move forward but are unwilling to invest the money unless there's an indication that it will be a tool that we can use to make beef safer.

So you're right in your question, and I think you're right, and I think that's why I say at least this would be just another intervention in the

series of interventions rather than the be all end all to the problem because with the crevices in the carcasses, you're exactly right. The level of radiation is going to differ, and that's why when the study shows, you know, this huge log reduction on a muscle, that doesn't mean that's what we get on a carcass, and I think we all agree with that comment. Your concerns are our concerns.

I wish we could say it was better. I wish we could say it was almost 100 percent like Wegmans says versus Schwan's because Wegmans, their advertisement is if you like pink hamburger, buy this irradiated product. I mean, they're willing to tell you that you can eat it pink, and I love pink hamburger, used to, you know. (Laughter.) But I cook all my hamburger to 160 degrees and just so I don't spend the extra money at Wegmans and buy the irradiated beef, I'm still going to cook it to 160. I've certainly learned that in three years.

And my last comment is, and I think Pat is the one that says we need clear, concise messaging. To quote, "We need clear, concise messaging so the

consumers know what was used in the processing of this meat." I wish we could get consumers to acknowledge our clear, concise messaging that ground beef needs to be cooked to 160 degrees because we're not going to turn this thing around with low-dose irradiation, with vaccines, with bacteriophages. This is just another step, but another huge step is that end processor, the consumer. And so we can try our darndest for clear, concise messaging, but to some people it doesn't register. To others it's extremely important, and that's part of this thing that these guys, we're going to have to determine from the input of this meeting and the 30-day comment period is clear, concise messaging necessary or not necessary, and like I said, I'll be gone. So it will be somebody else's problem to determine that.

But that said, thank you again for being here today. Randy, what was the first public meeting? You said you were at the first one. I don't even remember.

DR. HUFFMAN: You spoke to the

international boundaries in meat science and technology --

DR. RAYMOND: Okay. Well, thank you for remembering that. I hope --

DR. HUFFMAN: It was very memorable.

DR. RAYMOND: I don't know that I had -- comments yet, but thank you all for being my friends during these three plus years and look forward to seeing you again. Thanks.

(Whereupon, at 10:58 a.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:

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

LOW DOSE IRRADIATION IN BEEF

Washington, D.C.

September 18, 2008

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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DOMINICO QUATTROCIOCCHI, Reporter

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