

UNITED STATES DEPARTMENT OF AGRICULTURE

PUBLIC MEETING TO RECEIVE)
COMMENTS ON FSIS REGULATORY)
PROPOSAL CONCERNING READY-TO-EAT)
MEAT AND POULTRY PRODUCTS)

Pages: 188 through 323

Place: Washington, D.C.

Date: May 10, 2001

HERITAGE REPORTING CORPORATION

Official Reporters

1220 L Street, N.W., Suite 600

Washington, D.C. 20005-4018

(202) 628-4888

hrc@concentric.net

UNITED STATES DEPARTMENT OF AGRICULTURE

PUBLIC MEETING TO RECEIVE)
 COMMENTS ON FSIS REGULATORY)
 PROPOSAL CONCERNING READY-TO-EAT)
 MEAT AND POULTRY PRODUCTS)

Federal Hall
 The Washington Plaza Hotel
 10 Thomas Circle
 Washington, D.C.

Thursday,
 May 10, 2001
 9:08 a.m. - 2:28 p.m.

PARTICIPANTS

From USDA:

MARGARET GLAVIN, MODERATOR, FSIS
 DR. DANIEL ENGELJOHN, FSIS
 DR. AMELIA K. SHARAR, FSIS
 DR. DAVE PYBURN, APHIS
 DR. HARRY WALKER, FSIS
 PAUL UHLER, FSIS
 FELIX J. SPINELLI, FSIS
 PHIL DERFLER, Animal Science
 STEPHEN CRUTCHFIELD, Economic Research Service

Commenters:

DR. RAY GAMBLE, Agriculture Marketing Service
 BETH BOCKMAN, National Pork Producers Council
 LLOYD HONTZ, National Food Processors Association
 DR. KATHERINE SWANSON, The Pillsbury Company
 BERNARD SHIRES, American Association Of Meat
 Producers
 WILLIAM R. COLE, Techni Cal, Inc.
 JIM HODGES, National Meat Canners Association
 BOB DAIL, Dial Corporation
 DR. DANE BERNARD, Keystone Foods LLC

Heritage Reporting Corporation
 (202) 628-4888

Commenters:

CAROLINE SMITH-DEWAAL, Center for Science in the
Public Interest

CHARLOTTE CHRISTIN, Center for Science in the
Public Interest

KIM RICE, The American Food Institute

STAN EMERLING, North American Meat Processors
Association

P R O C E E D I N G S

(9:08 a.m.)

1
2
3 MS. GLAVIN: Can I ask people to find seats, and
4 may I suggest that because we have a somewhat smaller group
5 today that people might want to move towards the front?
6 This isn't church. You don't have to sit in the back seat.

7 One announcement. I have a green glasses case.
8 Fortunately, there are no glasses in it. If this belongs to
9 any of you, I'll leave it on the table here. Just come and
10 collect it. It's obviously for a prescription pair of
11 glasses. Someone might want to get it back.

12 This morning we have two topics. The first I
13 believe is the Trichina, the changes in the Trichina
14 regulations, so we'll have a presentation on that. My
15 suggestion is we have our discussion on that prior to moving
16 into the second presentation on the canning regulations. Is
17 that satisfactory?

18 I've lost my cheat sheet, so I'm not sure who is
19 leading off on the presentation. Mimi? Mimi Sharar.

20 MS. SHARAR: Thank you.

21 (Pause.)

22 MS. SHARAR: Good morning. Today I'm going to
23 cover the section on elimination of -- for treatment of

Heritage Reporting Corporation

(202) 628-4888

1 Trichina -- . FSIS is proposing a new rule under the
2 provisions for the prescribed treatment of pork and
3 products containing pork to destroy Trichinellosis or
4 Trichina under 761 ready-to-eat and not ready-to-eat
5 products.

6 When this proposal becomes final, prescribed
7 treatments for Trichina will not be necessary because
8 compliance with the performance standards will eliminate all
9 Trichina. At present, the regulations for treating Trichina
10 include freezing, curing, drying, fermentation in salt and
11 curing.

12 For heat treated products, the process achieves
13 the proposed performance standards for Salmonella. The
14 practice should also eliminate Trichina. The time and
15 temperature for eliminating Trichina is lower compared to
16 the time and temperature in the compliance guidelines to
17 achieve the 6.5 log reduction of Salmonella.

18 In salt cured, dried and fermented products, the
19 lethality requirements for Salmonella and also E. coli
20 0157:H7 for fermented products containing beef are achieved,
21 it is likely that Trichina will be destroyed. However,
22 there are no published studies comparing the properties of
23 Salmonella and E. coli 0157 to the destruction of Trichina

1 in those products.

2 Therefore, the Agency cannot state with absolute
3 certainty that the proposed lethality for these products
4 would also destroy any live Trichina. Therefore, the
5 establishment identifies Trichina as the cause of -- . The
6 establishment is to ensure that the process used is
7 effective to eliminate Trichina.

8 The Agency does not prescribe treatment for
9 Trichina in raw products because they are customarily cooked
10 thoroughly for safety at home by the consumer end user.
11 However, there are some raw products where the Agency
12 prescribes Trichina treatment. These are items that are
13 raw, but may appear to have been cooked because they contain
14 ingredients such as wine, other spices and curing agents
15 that mask their appearance. Because of their masked
16 appearance, these products may be eaten rare or under
17 cooked. However, these products are raw and bear the safe
18 handling instructions on their label.

19 Trichina treatment provisions for these raw
20 products are already descriptive and are contrary to HACCP.

21 Therefore, this proposal would provide establishing the
22 flexibility to determine whether -- products eliminate
23 Trichina.

Heritage Reporting Corporation

(202) 628-4888

1 The establishment identifies Trichina as a hazard
2 likely to occur in the process. -- for these products may
3 provide -- , which may be a term in the -- to be cooked or
4 ready to be cooked and offer instructions for fully cooking
5 the products for safety.

6 The Trichina rule was first implemented by the
7 Agency in the early twentieth century. At that time, the
8 most serious foodborne outbreak was due to Trichina. Other
9 bacterial pathogens were not fully characterized or
10 recognized at that time. Therefore, the Agency tests
11 proposed -- has food regulations with regard to Trichina in
12 order to protect public health. Later on, as the bacterial
13 pathogens were characterized and recognized as causes of
14 foodborne illness, the Agency has started making policies on
15 these bacterial pathogens to protect public health.

16 According to public surveillance of CDC, by the
17 Center for Disease Control and Prevention, there is a
18 decrease in reported incidence of Trichinosis from the years
19 1972 through 1997. During the reporting period of 1972 to
20 1987, there were 128 outbreaks due to Trichinosis, which
21 comprised about five percent of the total foodborne
22 outbreaks. In 1988 through 1992, there were ten outbreaks
23 of Trichinosis comprising 0.5 percent of the total foodborne

1 outbreaks.

2 From the reporting period 1993 to 1997, there were
3 two outbreaks from Trichinosis comprising 0.1 percent of the
4 total outbreaks. There were no death cases in all these
5 reporting periods, and an interesting point is, 50 percent
6 or less than 50 percent of the outbreaks were due to
7 ingestion of pork that's undercooked. The other 50 percent
8 was caused by other meat or other unknown sources.

9 Consumer surveys that were sponsored by both the
10 Meat and Poultry Hotline of FSIS and the industry shared the
11 perception that pork may be infected with Trichina continued
12 to be a common food safety concern to American consumers.
13 So FSIS has some confidence that consumers would cook this
14 product thoroughly.

15 Recently, a pilot program for the National
16 Trichina Certification Program was started in August, 2000.
17 This is a cooperative agreement among USDA agencies,
18 meaning APHIS, ARS, CSREES and FSIS. The National Pork
19 Producers Council and pork producers are -- plants. Through
20 this program, pork producers and suppliers can be certified
21 if they identify the risk factors for Trichina infection on
22 the hog farm and they voluntarily adopt management practices
23 that prevent and eliminate Trichina infection in the farm

Heritage Reporting Corporation

(202) 628-4888

1 environment. Dr. Dave Pyburn from APHIS is here, and he is
2 the coordinator for the National Trichina Certification
3 Program. He will give details if you need more details on
4 this program.

5 Establishments must address the hazard of Trichina
6 in their HACCP plant if they know that Trichina is a hazard
7 that might occur. They have to determine for ready-to-eat
8 products if their process achieves a lethality that meets a
9 6.5 log reduction of Salmonella. If they do that, then
10 they'll be able to eliminate Trichina also. They have to
11 determine especially for not ready-to-eat products or the
12 masked products whether they need a Trichina treatment.
13 They have to determine when the pilot project for Trichina
14 certification is in full operation. They have to determine
15 whether Trichina or the pork products come from hogs that
16 are Trichina certified. They have to determine whether
17 aside from safe handling instructions for these masked
18 products whether they need cooking instructions for safety
19 or they need conspicuous labeling in the label.

20 Those are the outbreak cases. These are the
21 provisions that are in the 9 CFR that are related to
22 Trichina that would be eliminated if this rule becomes
23 final. Thank you.

Heritage Reporting Corporation

(202) 628-4888

1 MS. GLAVIN: Thank you. The people who are here
2 supporting Mimi and who also are able to answer questions
3 that might arise are Paul Uhler and Harry Walker from FSIS
4 and, as Mimi mentioned, Dave Pyburn from APHIS. Who is
5 next? Paul, are you? Dave? Dave has a presentation.
6 Thank you.

7 (Pause.)

8 MR. PYBURN: As Dr. Sharar mentioned, my name is
9 Dr. Dave Pyburn. I'm with APHIS Veterinary Services. I'm
10 the national Trichina coordinator. Trichina certification
11 as a project has been ongoing for a number of years, and it
12 is a cooperative project between USDA and the various
13 agencies that Dr. Sharar mentioned, as well as the National
14 Pork Producers Council and the representation that they have
15 for the pork producers of the nation.

16 Something I would like to just start with off the
17 top, and I don't have an overhead for this, is she mentioned
18 a declining prevalence within the industry. Some of the
19 most recent studies are from 1995. A study done on the top
20 19 pork producing states by the Centers for Epidemiology and
21 Animal Health within USDA, basically found that the level of
22 this organism in market hogs and in sows together within the
23 industry today is .013 percent from that study.

Heritage Reporting Corporation

(202) 628-4888

1 In some studies that we have done since,
2 especially in 1997 and 1998 in hogs that came from Iowa,
3 Minnesota and South Dakota, we tested over 220,000 market
4 hogs in this study and did not find a positive. We double
5 tested all of these animals. We tested them both by
6 serology, as well as by the gold standard diaphragm
7 digestion test. We couldn't find any.

8 In 2000, the Centers for Epidemiology and Animal
9 Health is repeating their swine study. They're going to
10 look for the organism again, which the results are not out
11 yet. Quite frankly, though, it won't surprise me if they
12 don't find any this time around just with the way the
13 industry is going.

14 Why would that be? Well, you've got to look at
15 how the industry is today compared to how it used to be when
16 this was an issue. Previous to the 1950s, this was a larger
17 issue. More of the industry was structured in such a way
18 that this organism would most likely find its way or could
19 find its way into swine and into the pork that we eat.

20 In the 1950s, we had the enactment of the Garbage
21 Cooking laws. It wasn't directed at Trichina as an organism
22 to deal with it, but in an indirect way it did because the
23 only way any warm blooded animal can become infected with

1 this organism is they have to eat the live larval cyst and
2 muscle tissue. If it's cooked, if it's frozen, if it's
3 cured, if it's irradiated, the cysts die. It's not at an
4 extremely high temperature or low temperature as far as
5 freezing when the cysts die.

6 Overall within the industry, too, since the 1950s,
7 we've had a reduction of waste feeding operations as well.
8 They're heavily regulated. They have to cook, if they're
9 going to feed waste. There are some states where it is
10 illegal to feed waste to swine. There is no option to do
11 it. When you look at the industry as a whole, it's less
12 than one percent of the commercial industry today, and it's
13 shrinking.

14 Also within the industry when you look at how
15 producers manage their pigs, more so for swine health, but
16 also for safety of their products and economics on the far,
17 we've got much higher biosecure operations today than we did
18 even 15 years ago, and we keep advancing in this area.
19 We're really just now within the industry starting to take a
20 look at some science and research as it relates to
21 biosecurity, so I think you may see even in the next 15
22 years, greater advances in biosecurity that will have an
23 effect on all organisms, including Trichinosis.

Heritage Reporting Corporation

(202) 628-4888

1 Dr. Sharar mentioned some CDC work looking at
2 human cases. There's a graph that I got from Dr. Peter
3 Shuntz at CDC who works with Trichina for them. As you can
4 see from the 1950s forward, a precipitous drop off in the
5 number of human cases.

6 I spoke with Dr. Shuntz about some of the more
7 recent cases, more recent numbers from CDC. On a yearly
8 basis they get somewhere between eight and 15, somewhere in
9 there, the number of individual human cases of
10 Trichinellosis that are reported to CDC. When you look at
11 that, much greater than half of those are not attributed to
12 commercial pork. Usually it's through the consumption of
13 meat from wildlife.

14 I want to just clarify a little bit about the
15 program that's been mentioned in this regulation, as well as
16 by Dr. Sharar. Within this program, we go to the farm.
17 First we go to the farm. We educate producers on the good
18 production practices as they relate to Trichina, and then we
19 come back to the farm.

20 An APHIS accredited veterinarian who has been
21 further trained to do auditing within this program comes
22 back to the farm and looks to see that in fact there are
23 good production practices as they relate to Trichina are in

1 place. Those practices are such that it would be extremely
2 unlikely, if not impossible, for pigs to become infected
3 with the organism if they are in place. They do involve the
4 documentation on the farm to show they have been in place
5 for a period of time and will continue and do continue to be
6 in place on the farm before and after the audits.

7 Also as part of this program, at least in the
8 beginning of this program we're going to verify what we're
9 doing within this program through testing at the slaughter
10 level, taking a statistical sample of the national certified
11 herd at each of the plants that are involved within this
12 program and test those animals for the organism, to be able
13 to back up what we're saying; the fact that these animals
14 are not infected with the organism.

15 I just wanted to put this up to reiterate or to
16 kind of clarify a little bit about the risk factors. The
17 only way that any warm blooded animal -- pigs, humans,
18 whatever it may be -- can become infected with the organism
19 is through the consumption of live tissue cysts that survive
20 in muscle. That is the only way.

21 When you look at individual farms and how we do
22 this within the program, we boil it down to we have known
23 risk factors on the farm, and then how do we intervene. We

1 have known interventions for the producers to put into place
2 on the farm. Our risk factors are, of course, feeding of
3 waste where it's legal, contact with rodents, and in
4 particular for this program, it's really not all rodents.
5 It's more rats than anything else. Exposure to infected
6 wildlife or cannibalism. We have the various interventions
7 that you can see there put into place on the program. We
8 have educational materials on those interventions, and we
9 also have a structured audit to be able to tell that those
10 interventions are in place on farms.

11 As I said, within the program, up front is an
12 educational process for producers. Some of these are
13 inherent good production practices that already are
14 occurring on farms. Some of the documentation and some of
15 the other things that have to occur to support the auditing
16 within the program, maybe isn't so inherent and maybe is not
17 occurring on all farms as of yet, so we have an educational
18 process up front to let the producers know here's what we
19 need to do to control this organism in a pre-harvest
20 fashion. The producer and the herd veterinarian then work
21 to implement good production practices on the farm to
22 decrease the ability of the pigs to become exposed to the
23 organism. The producer then within this program, and this

Heritage Reporting Corporation

(202) 628-4888

1 will be a national voluntary program. The producer then
2 requests that a qualified accredited veterinarian to come
3 out and do an audit to indeed ensure to APHIS and to the
4 public that the good production practices are in place on
5 the farm.

6 Based on the audit then, APHIS grants
7 certification to farms that have all the good production
8 practices in place. Certified pigs then will go to
9 slaughter with identification that they are from a certified
10 site. A certified pig will be processed separately, and
11 their product will be kept separately at the packing plant
12 level if they are taken other than from certified farms.

13 We also have the regular testing, as I said,
14 within the plants to verify what we're saying. We also have
15 an oversight function within APHIS where we have APHIS VMOs
16 and state VMOs that have been trained to be auditors for
17 this program go out and do spot audits on a percentage of
18 these farms that have been certified. I'll be available for
19 questions if there's any further questions on the program.

20 MS. GLAVIN: Thank you very much. Are there other
21 presentations?

22 MR. WALKER: Is here okay?

23 MS. GLAVIN: That's absolutely fine. This is Dr.

Heritage Reporting Corporation

(202) 628-4888

1 Harry Walker from our staff.

2 MR. WALKER: As she said, my name is Dr. Harry
3 Walker. I'm with FSIS Office of Policy, Animal and Egg
4 Production Food Safety Staff. What I'd like to do is
5 continue with what Dr. Pyburn talked about with what we're
6 doing as we're moving from the hog production areas to the
7 slaughter house. That's one of the main functions that I
8 have in Animal and Egg Production. It is mainly a producers
9 type organization, but since this is slaughter we have a
10 little bit of variation of the things that we have to do.

11 The pilot project. We have two packing houses
12 right now that are involved, Swift & Company in Minnesota
13 and FarmLife Foods in Iowa. Pigs from the first Trichina
14 certified sites will be delivered to the plants sometime
15 this summer, and the pilot will continue for at least a
16 year, and longer if necessary, to adequately test the hogs
17 -- and proceedings.

18 If the pilot project is deemed successful, plans
19 are to expand it into a voluntary national Trichina
20 certification program that will be available to all pork
21 producers and processors who wish to participate. In the
22 inspection procedures currently, FSIS does not oversee
23 processors through the process of maintaining certified

Heritage Reporting Corporation

(202) 628-4888

1 status with regard to Trichinosis. With these instructions
2 and the Trichina pilot program, FSIS is adding Trichina
3 certified pork to its inspection procedures for market hogs.

4 There are six points basically to what the
5 inspectors will be doing in the slaughter houses. One will
6 be producer certification. Another will be segregation of
7 market hogs and pork products from Trichina certified
8 production sites. The third one will be validation of a
9 certification program by testing slaughter swine. A fourth
10 will be reporting results of testing. The fifth will be
11 maintaining identity, and sixth will be label claims.

12 Basically on producer certification, the inspector
13 will certify by a number of different methods that the hogs
14 that are coming into the plant are from a certified site,
15 and then on the second point, the inspectors will ensure
16 that the hogs from the inspected sites are segregated from
17 hogs that come from non-certified sites, if that should be
18 the case. I would imagine that most of the plants will
19 probably have only certified hogs, but if they do have both,
20 the provisions are there to keep them segregated throughout
21 the entire process.

22 The inspectors would also be observing the plants
23 as they test the hogs, or a certain percentage of the hogs.

Heritage Reporting Corporation

(202) 628-4888

1 It is designed by a chart so an adequate number are tested
2 to ensure that they are Trichina free. If some problems
3 result, there's a procedure that you are to go back to APHIS
4 and let them know that this certified site is having some
5 problems so that they can be removed from the list.

6 Then, of course, maintaining identity. The IICs
7 in these plants will observe the establishment of records to
8 ensure that for each sample collected plant officials have
9 maintained identity of the sample through the Trichina
10 identification number to the production site from which the
11 market hog originated. Finally, right now on label claims
12 plants cannot make label claims regarding Trichina certified
13 pork on the pilot project. In the future, label claims may
14 be allowed in accordance with FSIS labeling regulations.
15 That's all I have, but I will be available for questions.
16 Thank you.

17 MS. GLAVIN: All right. At this point are there
18 comments or questions with respect to the Trichina
19 provision, the Trichina control provisions in the proposed
20 rule? Yes? Can I get you to come to a microphone and state
21 your name?

22 MR. GAMBLE: My name is Ray Gamble. I have a
23 prepared statement.

Heritage Reporting Corporation

(202) 628-4888

1 MS. GLAVIN: Terrific.

2 MR. GAMBLE: As I said, my name is Ray Gamble.

3 I'm not currently with the government, but I spent 20 years
4 with ARS as a scientist in the Agri-Service Center in
5 Beltsville. During that time, part of my responsibilities
6 were to work in pre-harvest and post-harvest control of
7 Trichinella in pigs.

8 I've done a lot of different things. I've worked
9 on diagnostics. The commercial diagnostic test that's used
10 in this program was developed in my lab. I did a lot of
11 work on pre-harvest control identifying risk factors and
12 validating programs. I've been in from the beginning with
13 NPPC and FSIS. I've done work with FSIS, and I see Carl
14 back there, on processed product regulations as far as
15 curing and did some work with Mimi and others on the
16 freezing and cooking regs as well.

17 I also have some international involvement with
18 Trichina in that I wrote the OIU on regulations governing
19 Trichina and Trichina control on an international basis and
20 worked with AMS currently on their export program for
21 Trichina, which does involve to some extent the regulations
22 that were in place because of -- frozen and freezing
23 processes as far as export to Russia and some other export

Heritage Reporting Corporation

(202) 628-4888

1 markets.

2 Lastly, and I'll mention this just towards the end
3 here, I've worked with a group called the International
4 Commission on Trichinellosis, which has their own set of
5 guidelines for control and in some ways draw from these
6 process regulations, so in fact these regulations haven't
7 really gone away. They're just translated into another form
8 for the international venue.

9 The comments that I had, and I'll read these and
10 hope that they won't be too boring. My experience in the
11 ante-mortem and post-mortem testing of pigs for Trichinella
12 infection from 1981 through the present documents that this
13 parasite is essentially absent from the U.S. pork supply.

14 I have a series of references. I'll turn this in
15 when I leave, but I've referenced the NAHMS test from 1990
16 and 1995, which, as Dave mentioned, found very, very low
17 amounts of infections, and then we have a large body of
18 unpublished work as well testing pigs from 1993 through 2001
19 in which in one case, as Dave again mentioned, we tested
20 about 221,000 pigs. In one study we found no positives. In
21 another study, which is ongoing, we tested about 23,000 pigs
22 and found none positive.

23 In addition to that, this AMS program, which I've

Heritage Reporting Corporation

(202) 628-4888

1 been involved in since about 1990, has tested literally
2 millions of pigs annually. As far as I'm aware, we've not
3 found any positive pigs in recent years from that program.
4 Based on this very low incidence of Trichina in pork, it's
5 fairly clear that there really isn't any longer a need for
6 comprehensive processing regulations relative to Trichina.
7 Therefore, I would certainly support rescinding paragraph
8 318.10 regarding the Trichina in processed products.

9 Again as was mentioned, CDC collects data on
10 outbreaks of human Trichinellosis, and these numbers have
11 been very low in recent years and primarily cases that have
12 resulted from ingestion of infected game meats, so pork is
13 not really a problem as far as cases go to any extent.
14 However, it should be noted that Trichinellosis is a common
15 disease in many countries, and the U.S. was once one of
16 these countries and deserved the reputation as having a
17 problem. Therefore, it's important that we convey to our
18 trading partners in fact that the U.S. has determined that
19 Trichinella really no longer is a threat to public health,
20 although we still need to do some of these processing
21 regulations -- as I mentioned, freezing, for purposes of
22 export to Russia and some other countries.

23 We do have a committee on the International

Heritage Reporting Corporation

(202) 628-4888

1 Commission on Trichinellosis which has published guidelines
2 for control of Trichinae in pork, as well as horse meat,
3 game meats and -- horse meats in Europe. We have a testing
4 program in place for Trichina in horse meat, but this
5 document contains all those regulations relative to cooking
6 and freezing that are in 318.10.

7 As I mentioned, those will go in perpetuity as
8 part of this international guidelines book on Trichinosis
9 that's published by the ICT, and the tables that are
10 included for freezing and cooking are in that document.

11 Now, despite its rare occurrence in pigs in the
12 United States, as Dave mentioned, due to modern production
13 systems, Trichinella does remain a problem. It is possible
14 for pigs to become infected in any area where pigs are
15 raised outdoors and regularly exposed to wildlife. There
16 needs to be an understanding within the industry that there
17 is an occasional risk that pigs can become exposed,
18 particularly in pigs that are raised in outdoor systems or
19 where Trichinae has been reported to be endemic. There are
20 some publications that are cited in here which indicate
21 areas where we found Trichinella to be endemic in pigs.
22 This information should be clearly understood by pork
23 packers and processors, and those who are required to

Heritage Reporting Corporation

(202) 628-4888

1 perform risk assessments should develop a HACCP plan where
2 necessary for this parasite, so we need to discuss that.

3 Related to this action, I wanted to mention
4 another parasite which really has not been discussed to much
5 extent. In the discussion of selection of reference
6 organisms and the relationship of these organisms to other
7 potential hazards, the subject of Toxoplasma has received no
8 more than passing treatment. It was referenced briefly in
9 the proposed rule, but again only briefly.

10 This is surprising considering the fact that, one,
11 the Centers for Disease Control report Toxoplasma as the
12 third leading cause of death due to foodborne illness,
13 behind Salmonella and listeria; two, Toxoplasma is
14 responsible for approximately 20 percent of all deaths
15 attributed to foodborne pathogens; and, three, the CDC
16 estimates 50 percent of human cases of toxoplasmosis are
17 foodborne in origin. I have a citation here for that.

18 Toxoplasma poses a significant public health risk
19 in pregnant women as a cause of birth defects in
20 congenitally infected fetuses and to immuno-depressed or
21 immuno-compromised individuals as a result of acute or
22 chronic latent infections. Human toxoplasmosis in the U.S.
23 is estimated to cost \$5.3 billion annually in medical costs,

Heritage Reporting Corporation

(202) 628-4888

1 losses in personal productivity and costs of special
2 education and residential care. An additional \$100 million
3 in costs are attributed to medical costs of toxoplasmic
4 encephalitis in AIDS cases.

5 Toxoplasma has historically been associated with
6 cats as the main source of infection for humans. However,
7 Toxoplasma can also occur as a contaminant of pork and other
8 commodity meats. Research is again cited and has documented
9 the occurrence of this parasite in pigs. Like Trichinae,
10 Toxoplasma infection rates are higher in pigs raised in
11 outdoor management systems. We have papers cited to that
12 effect. These findings suggest that raw, undercooked or
13 improperly processed pork might be a source of infection for
14 humans, but further research is needed to document this
15 relationship.

16 Nothing is really known about Toxo infection in
17 other meat and poultry, although we do know that Toxo is an
18 important abortifacient in sheep. Additional research is
19 needed to assess the prevalence of this parasite in beef and
20 chicken and the risk it poses to humans from these sources.
21 Despite the claims of the CDC on the relative role of
22 foodborne exposures in human toxoplasmosis, we know
23 essentially nothing about the relative role of meat and

1 poultry versus environmentally contaminated fruits and
2 vegetables in human exposure to Toxo.

3 Methods are needed by packers and processors to
4 assess the risk of Toxoplasma in meat and poultry in their
5 supply chains, and to take subsequent steps to incorporate
6 control in HACCP plans. If surveillance is performed to
7 identify hazards associated with meat or poultry and if
8 Toxoplasma is identified in raw product, the question arises
9 how this product might be handled, particularly if some
10 product is intended for sale as fresh product. FSIS might
11 consider the implications of identifying Toxoplasma as a
12 contaminant of meat or poultry since this parasite has not
13 been previously addressed as a food safety concern.

14 Toxoplasma is inactivated in much the same way as
15 Trichinae when comparing cooking and freezing methods. The
16 information that we present regarding inactivation is
17 relative to Salmonella and the increased sensitivity of
18 Trichina. Toxoplasma would fit in that category as well.
19 In both cases, the absolute thermal death point of Toxo and
20 Trichinella is much lower than reported for Salmonella and
21 E. coli,

22 However, little is known about the effects of
23 curing processes on Toxoplasma. We've done a lot of work on

Heritage Reporting Corporation

(202) 628-4888

1 Trichina, but we know nothing on Toxoplasma, which is a much
2 more deadly parasite. Comparative data on processing is
3 needed for this parasite, particularly if production of a
4 safe product is predicated on meeting performance standards
5 of Salmonella. The assumption cannot be made that
6 processing by curing to meet Salmonella reduction
7 performance standards will have the necessary effect on the
8 inactivation of Toxoplasma. Further research using existing
9 or proposed processing methods is needed to achieve this
10 level of confidence.

11 Basic biological differences between Salmonella
12 and Toxoplasma eliminate the use of certain treatments to
13 achieve comparable results in reducing risk in processed
14 products. Any steps, for example, for surface sterilization
15 to reduce Salmonella numbers to meet performance standards
16 would have no effect on Toxoplasma. The only effective
17 treatments are those that are documented to inactivate the
18 parasite, and those again are cooking and freezing, and then
19 those that would affect the carcass throughout the
20 treatment.

21 Lastly, I just have a couple of recommendations.
22 Again, these are in the statement. The first is to educate
23 packers and processors regarding possible risks for

1 Trichinae in pigs raised in outdoor management systems and
2 take steps to minimize this risk. Certainly the
3 certification program is a major step in that direction as
4 far as minimizing risk. However, there is sort of an
5 assessment whether it would be included in the HACCP plan.
6 I think that needs to be considered from an educational
7 standpoint, but also from a practical standpoint.

8 Support research to estimate the risk of
9 Toxoplasma in pork and other meats and poultry. We've done
10 a pretty good job of that so far for pork, but there is
11 essentially nothing about other meats and poultry, and that
12 really needs to be considered because Toxo can be a
13 contaminant of virtually any warm blooded animal. In
14 particular, support is needed for research on the prevalence
15 of Toxoplasma in retail meats and processes that inactivate
16 the parasite.

17 Third, educate producers and packers regarding
18 possible hazards associated with Toxoplasma in meat and
19 poultry. That again would be a HACCP plan identifying what
20 those risks would be. In particular, it's important to make
21 a distinction that contamination of raw product with
22 Salmonella and other microbes is not related in any way to
23 contamination with Toxoplasma, so the exposure risks are

1 completely different at the pre-harvest level at least.

2 When defining requirements for performance
3 standards, consider the differences between Salmonella and
4 other bacteria and Toxoplasma. Toxoplasma is a tissue
5 dwelling parasite that is not impacted by surface treatment.

6 Therefore, methods to incorporate surface sterilization
7 will not affect Toxoplasma. Lastly, support further
8 research to compare non-thermal processes that inactivate
9 Salmonella with lethality for Toxoplasma in those -- curing
10 methods.

11 MS. GLAVIN: Thank you very much. Do you mind
12 staying at the table just for a minute in case people have
13 questions for you? Are there questions or comments? Mimi?

14 MS. SHARAR: Thank you, Dr. Gamble. Dr. Gamble is
15 one of the leading experts in the field of para-cytology
16 (phonetic), especially in Trichina research. We know that
17 Toxoplasma is one of the pathogens of concern in pork
18 products, but research by Dr. Katula and Dr. Dube from ARS
19 have shown that heating and freezing treatment that is best
20 for Trichina is very effective toward Toxoplasma. As Dr.
21 Gamble said, it's more sensitive to heating and freezing
22 than Trichina, so that will be covered in this proposed rule
23 that we have lethality for Salmonella.

1 In terms of research, we are aware that we are in
2 need of research for this ready-to-eat proposed rule, so we
3 have proposed research comparing the lethality of Salmonella
4 and other pathogens of concern, including Trichina and also
5 Toxoplasma, for ready-to-eat products.

6 MS. GLAVIN: Okay. Any other questions? Thank
7 you very much for that presentation. It was very helpful.
8 Other comments or questions on the Trichina control
9 provisions? Yes, sir?

10 MALE VOICE: Jack -- . Not on the control
11 proposal, but about all regulations that have changed, but
12 as long as you're proposing to change this one --

13 MS. GLAVIN: Okay.

14 MALE VOICE: I think Dr. Sharar's last piece of
15 film up there showed Regulation 310 and other related
16 regulations that would be done away with. However, there
17 are other publications by FSIS that relate to Trichina
18 control and the need for the use of certified pork. There
19 are directives and SID policy numbers on these topics and
20 SID books for products like Chorizo.

21 I would ask that if you're going to change this
22 regulation or change any of the other regulations that you
23 go and find all the other documentation that FSIS has in the

1 field and remove that also. Inspectors now have these FAIM
2 computers where they can just punch in something and a
3 reference will show up. What I've found is that while
4 regulations have been done away with, there are other
5 references that they can go back to, so I would ask if this
6 is done away with that you go through and find all the other
7 references and do away with them, too. Thank you.

8 MS. GLAVIN: Thank you. Very good point.
9 Other comments or questions? Yes? Can you come to the
10 table, please? Thank you.

11 MS. BOCKMAN: I'm Beth Bockman with the National
12 Pork Producers Council, and we will be sending extensive
13 written comments for this particular section. I did want to
14 provide a little bit more background as far as the Trichina
15 certification program and I think really express the
16 appreciation of the pork industry for the efforts that the
17 USDA has shown in helping move forward in food safety
18 certification programs.

19 This program, which is in the pilot stages right
20 now, started in 1993 through a lot of cooperation between
21 APHIS, the Food Safety Inspection Service, the Agricultural
22 Research Service, the Agricultural Marketing Service and
23 Cooperative State Research, Education and Extension Service,

Heritage Reporting Corporation

(202) 628-4888

1 and it has required many pilot projects, many research
2 projects, much -- development, development of tests, and has
3 been a very good example, I think, of the future type of
4 programs that can be developed and then can be adopted by
5 the industry. I just wanted to express appreciation for
6 that work that's been ongoing since 1993.

7 MS. GLAVIN: Thank you. Other questions?
8 Comments? All right. Thank you. Thank you very much for
9 those presentations. We will move on to the section of the
10 regulations or the provisions of the regulations governing
11 commercial sterile canned product. Paul Uhler's
12 presentation is actually the commercially sterile canned
13 product presentation.

14 MR. UHLER: -- products are addressed in two
15 subparts -- . Those subparts are -- address poultry
16 products. Those regulations are -- . -- processes, the
17 forward process -- biological, physical and chemical hazards
18 from developing in a HACCP plan. However, establishments do
19 not have to -- food safety hazards associated with
20 microbiological contamination if the product has -- . This
21 exception is contained in Section 2(b)3 of the HACCP
22 regulations.

23 -- this exception, the Agency recognized that the

Heritage Reporting Corporation

(202) 628-4888

1 -- regulations were based on HACCP concepts to provide for
2 the analysis for food processing systems and controls
3 through -- . However, -- performance standards are
4 finalized.

5 -- to a single category of meat and poultry
6 products is inconsistent with FSIS' other regulatory
7 missions to grant the industry maximum flexibility and
8 define the industry's responsibility and accountability for
9 the safety of meat and poultry products.

10 However, while it may appear that the current
11 exemption for the industry for the flexibility to -- HACCP
12 plant must still comply with the regulatory requirements.
13 Therefore, the change in the standards is no longer making
14 the regulatory language consistent with that -- .

15 FSIS' proposal -- lethality performance standards
16 -- regulatory standards -- . FSIS is also proposing to
17 revise the requirement -- . -- current regulations --
18 requirements and those that overlap the HACCP regulations.
19 FSIS will continue to train -- supervisors. In other words,
20 the proposed changes should not affect current industry
21 practice.

22 The food processing -- commercial sterility.
23 However, commercial sterility addresses both food safety and

Heritage Reporting Corporation

(202) 628-4888

1 non-food safety forms of contamination. Therefore, FSIS is
2 proposing lethality performance standards designed to kill
3 pathogens and prevent growth of pathogens -- in the
4 commercial sterility standard.

5 In the first performance standard, FSIS is
6 proposing a requirement to establish a process for reducing
7 -- . In the second performance standard, FSIS is proposing
8 to require -- factors other than the thermal process to
9 prevent the multiplication of C. botulimon. For these
10 products, -- process reduction of C. botulimon.

11 As additional performance standards, FSIS is
12 proposing a specific requirement that --. This requirement
13 is consistent with the existing commercial sterility
14 definitions in Section -- of the FDA regulations.
15 -- commercial sterility is safe, but it may not be stable.

16 FSIS considers the commercial sterility standard
17 to be appropriate, among other reasons, because the Agency
18 is obligated under the statute to -- . The Agency's current
19 -- regulations are intended to assure -- products are not
20 adulterated.

21 The proposed commercial sterility requirement --
22 commercial sterility. The process delivers -- destruction
23 with the more heat resistant organisms, such as clostridium

1 sporgenes.

2 FSIS is proposing a -- quantitative standard for
3 commercial sterility. -- quantitative standards necessary,
4 such as a 5 log reduction, clostridium sporgenes, just for
5 an example. -- container protects the product -- . If the
6 container -- stable. -- contaminated product. If the
7 product is adulterated and becomes -- , that is an economic
8 concern. C. botulimon becomes a public health concern.

9 For this reason, FSIS considers -- seal
10 requirement. FSIS is proposing that the seal be airtight to
11 protect the contents of the container from the entry of
12 microorganisms. FSIS also recognizes commercial sterility
13 can be achieved other than by the thermal process.
14 Therefore, the definition of commercial sterility has been
15 expanded to include those processes in the definition or the
16 proposed definition of commercial sterility -- added to the
17 current definition.

18 The commercial sterility requirement is the
19 product must be processed to achieve commercial sterility.
20 The container in which the product is enclosed must be
21 hermetically sealed so as to be airtight to protect the
22 contents and the container against injury from
23 microorganisms during and after processing.

Heritage Reporting Corporation

(202) 628-4888

1 Several industry groups and other interested
2 parties have expressed reservations concerning replacement
3 of the existing regulations for fully processed commercially
4 sterile performance standards. The complexity of the
5 process, the condition of the -- have been cited as reasons
6 for maintaining existing prescriptive regulations.

7 Significantly, FSIS is proposing to retain the
8 training requirement for all operators of processing systems
9 for commercially sterile poultry products and it will
10 continue to be issued under the direct supervision of the
11 person who is associated with school instruction. It is
12 generally recognized that it is adequate for the training of
13 supervisors of canning operations.

14 There are many changes regarding the definitions.

15 With the certified product and the time to certify the
16 product, if it's longer than 24 hours it must be validated.

17 In the current regulations, it requires a processing
18 authority to approve a longer time period.

19 Commercially sterile and hermetically sealed has
20 replaced canned product in the current regulation. FSIS
21 specifically invites comments as to whether and in what form
22 the existing requirements for fully processed commercially
23 sterile meat and poultry products should be retained. If

1 the Agency does replace the current requirements, we propose
2 firmer standards and plans to issue a revised version of the
3 current regulations as to requirements for industry. And a
4 copy of these compliance guides is on the table in the
5 lobby.

6 In summary, the proposed rule defines the
7 performance standard for food safety, defines the standard
8 on adulteration, continues the training requirement,
9 encourages flexibility and motivation, -- the requirements
10 and removes overlap with HACCP requirements. Thank you.

11 MS. GLAVIN: Thank you very much. Lloyd, did you
12 want to make a comment at this point?

13 MR. HONTZ: I did have --

14 MS. GLAVIN: Do you want to give your name for the
15 reporter, please?

16 MR. HONTZ: Lloyd Hontz with the National Food
17 Processors Association. I do have some prepared remarks I
18 would like to give, but maybe it's appropriate to ask some
19 questions about the information that was just presented, and
20 the Preamble discussion.

21 MS. GLAVIN: All right. That's fine. That's
22 fine. Are there questions for Paul Uhler at this point on
23 the presentation he has made on what is included in this

1 proposal? You had one. Now there's a method to your
2 madness.

3 MR. HONTZ: Lloyd Hontz with the National Food
4 Processors Association. Paul, I was looking at the Preamble
5 discussion of commercial sterility. Let me tell you that in
6 the discussion it talks about current practice, but on some
7 occasions in delivering the thermal process, the times and
8 temperatures to achieve commercial sterility may not be
9 attained, but indeed the heating time is more than enough to
10 protect it from -- I'm talking here about a practice in some
11 cases of incubating some product under those conditions to
12 determine if the product is stable and then allowing the
13 product to be released.

14 Later in the Preamble discussion where it states
15 that the proposed commercial sterility requirement -- there
16 is something that says, would have to ensure a reduction or
17 inactivation of foodborne organisms sufficient to guarantee
18 commercial sterility, if there's even an intent here that
19 processors would no longer be able to operate under the
20 current practices, which would allow release of product
21 which might not have met commercial sterility requirements,
22 but has indeed exceeded the minimum health requirements.

23 Another question or an observation is that in many

1 cases the thermal processing authority, which we believe is
2 a very, very integral part of the current regulations, the
3 processing authority would be experienced in the background
4 and in many cases has and will continue to make
5 determinations that products which may have only slightly
6 failed to meet the commercial sterility requirement would
7 not even need to be incubated before it could be released.
8 I was wondering if the proposal suggests any different
9 strategy for this area of thermal processing?

10 MR. UHLER: For the processing -- processing
11 environment -- and the need for certain poultry products
12 -- . That preceded the implementation of HACCP in all
13 establishments, so it's similar -- . The process has to be
14 validated, so --

15 MR. ENGELJOHN: This is Engeljohn. Just to follow
16 up on what Paul said, I would say there is no limitation
17 within the proposed rule that would restrict the use of a
18 processing authority and that authority providing
19 documentation to the plant, which would be part of the
20 record so that the plant would keep documenting wider
21 processes that were safe and validated.

22 MR. HONTZ: Lloyd Hontz again. My question is
23 whether you're utilizing the process and whether there's an

1 intent by the Agency to disallow the marketing of product
2 that may not have met the commercial sterility requirements,
3 but is above the minimum health requirements.

4 MR. ENGELJOHN: This is Engeljohn again. Could
5 you give me maybe a little more background on what the
6 product would be that doesn't meet commercial sterile today,
7 that's released into the marketplace? Does it have
8 refrigerated statements on it? What exactly does it say
9 today in those situations?

10 MR. HONTZ: It would not require anything like
11 that. It would be your typical canned meat product, which
12 perhaps has a certain commercial sterility -- . It's
13 discussed in the Preamble language. It says a product that
14 is -- processing and necessary to protect health, but less
15 than necessary for commercial sterility is safe, but it may
16 not be safe.

17 It talks about in certain cases the processor
18 might distribute that product for some period of time in
19 containers, which could indicate economic standards of the
20 product. They would not be appropriate for marketing. They
21 would be used and discarded, but the remainder of the
22 product would be released into the marketplace. It would be
23 processed and delivered at somewhat less than required for

1 commercial sterility.

2 MS. GLAVIN: Did you want to jump in?

3 MS. SWANSON: Yes, just to provide a
4 clarification. This is Katie Swanson. For example, you'll
5 have a stated time process that the plants are supposed to
6 produce against, and perhaps they have a processing --
7 associated with that. The process that is given to the
8 plant is supported by data that the thermal processing
9 authorities have in hand. They might look at the deviation
10 that was submitted to them, do a very technical assessment
11 as to whether or not it still provides the assurance that
12 they need that we're not producing and sending product out
13 that's going to provide extensive spoilage in the
14 marketplace. So it might be something less than the
15 authorized process given to the plant, but more than the
16 likes of their data suggests would present a problem.

17 They might take that information, couple it with
18 -- detection tests, incubated samples or even 100 percent
19 sort and say we have seen no spoilage that is evident other
20 than that related to a canning defect. Based on that
21 information, we'll release it. We're not talking about
22 shipping product that we think is going to spoil in the
23 hands of the consumer. It's just that the assumptions that

Heritage Reporting Corporation

(202) 628-4888

1 they make when they develop those processes are under worst
2 case situations -- the highest fill, the lowest head space,
3 the greatest viscosity, et cetera -- and that is not the
4 average. If you put all of that together, it's not
5 something that you can clearly delineate in your HACCP plan
6 with regard to corrective action. It's something that takes
7 a highly competent, trained processing authority who's been
8 working on this for years to make that judgment.

9 Under what we have under the guidance of HACCP,
10 that flexibility seemingly disappears; albeit maybe not
11 intended to have that happen, but it very well could
12 disappear. I think that's the crux of what you're talking
13 about.

14 MR. HONTZ: That was very helpful.

15 MR. ENGELJOHN: This is Engeljohn. I would say
16 that there was nothing in the proposed ruling intended to
17 change the status quo on that issue. If there are language
18 issues with regard to the way we've written the standard
19 that would make that more clear so that it would continue to
20 provide that. We would clearly like to have some guidance
21 on what language that would be, but I would say there was no
22 intention to change those provisions.

23 MR. DERFLER: Let me just ask Mr. Hontz a

Heritage Reporting Corporation

(202) 628-4888

1 question. Is there a provision in the current regs that
2 specifically authorizes what you're talking about, or is
3 this a process that's kind of grown up under the regs?

4 MR. HONTZ: Lloyd Hontz again. I believe it's
5 just practice. It's through practice.

6 MS. SWANSON: In some respects -- Katie Swanson --
7 it might be industry practice, but there is a need for a
8 thermal process authority, and the thermal process authority
9 is the one that has to review these deviations. That is
10 covered.

11 MS. GLAVIN: In the regs.

12 MS. SWANSON: In the regs.

13 MR. DERFLER: Okay.

14 MS. SWANSON: So it is current. That's the need
15 for a thermal process authority provision.

16 MS. GLAVIN: Okay. From the nods I'm getting over
17 here, I assume that that will be in your written comments?

18 MS. SWANSON: Yes. It already is.

19 MS. GLAVIN: Okay. Other clarifying questions
20 before Lloyd makes his comments? Yes?

21 MS. SWANSON: Related to the thermal process
22 authority concept, is it the intent of the new regulations
23 to negate the need for a thermal process authority? There

1 are currently thermal process authorities there, but there
2 are people who might think they're one, but might not be,
3 and so are the regs as intended supposed to allow for other
4 people to be able to make these technical changes?

5 MR. ENGELJOHN: This is Engeljohn. I would say
6 the intent of the reg is to make it as flexible as it can be
7 with regard to what the establishment will use to validate
8 or provide the validating documentation for the safety of
9 their process. If that requires them to have a processing
10 authority that they will get services from, that is what
11 they can do.

12 It doesn't limit their activity, but it also
13 doesn't require one, which would be what would be the
14 current reg. It doesn't limit that, but it certainly would
15 allow for the use of processing authorities as the
16 supporting role for the plant's HACCP plan.

17 MS. GLAVIN: Okay. Thank you. Someone over here?
18 Yes? Could you state your name when you come to the
19 microphone? Thanks.

20 MR. SHIRE: Bernie Shires. If you want to have a
21 processing authority standard, what other types of
22 individual organizations would you be thinking about since
23 you propose to remove this from the regulation? Process

Heritage Reporting Corporation

(202) 628-4888

1 authority.

2 MR. ENGELJOHN: The intent of the proposal was to
3 allow the establishment to establish their HACCP plan and to
4 have the adequate documentation to show that they have a
5 validated system, so that would be a determination that the
6 plant would use as to what rigor they would employ to assure
7 that.

8 MS. GLAVIN: Other questions before we move on?
9 Yes?

10 MS. SWANSON: I have a question related to
11 requirements for validation. Under the current HACCP regs,
12 frequently when validation is done it is done with the
13 specific hazard of concern or the pathogen of concern. With
14 regard to thermal process validation, this is not the case.
15 Clostridium botulimon is not put into containers of product
16 and tested to assure that they are inactivated.

17 My question is how will the Agency assure that or
18 is it the intent of the Agency to require those validations,
19 and how will they assure that if they don't want to
20 specifically require the use of C. bot validations how will
21 they be able to communicate this as a difference from other
22 parts of the HACCP regulation?

23 MR. ENGELJOHN: I would say that the Agency's

1 intention in terms of proposing this performance standard
2 based rule would be that the establishment would need to
3 have on file what its documentation would be, how they've
4 identified their hazards and what it is that they're going
5 to do to ensure that the product is safe. I don't view that
6 differently than what they do today. If you could give me a
7 little more clarity as to what you're seeking on that, maybe
8 I could respond to that.

9 MS. SWANSON: Well, frequently if we get requests
10 to demonstrate some of the time, temperature and activation
11 studies, and they want to make sure -- the inspectors might
12 want to see Salmonella or how many strains of Salmonella did
13 you use, and those kinds of studies. When we discussed the
14 lethality standards for Salmonella just earlier in this
15 presentation, very pointed questions about well, did you use
16 Scot-A for listeria or, you know, how many strains were
17 there and how many times did you replicate. That is part
18 and parcel of validating lethality studies for many of the
19 microbial systems.

20 That is just simply not the case for Clostridium
21 botulimon. We tend to develop processes based on what you
22 need for commercial sterility because it far exceeds
23 Clostridium botulimon, yet the regulation is to control

1 C. bot.

2 I have somewhat of a concern that once a change is
3 made to something that has been in place for many, many
4 years that it's so different than the approach that HACCP
5 has used in other situations, people will start looking for
6 similar types of data, and they just don't exist.

7 Additionally, and I'm getting comments so I'm
8 going to ask some questions here, but additionally current
9 HACCP regs require reverification of the HACCP plan on an
10 annual basis or with every verification. The processors are
11 validated extensively when they're set up, but they're not
12 revisited on an annual basis from a thermal process
13 perspective.

14 We review changes as they come along and make a
15 technical judgment as to whether or not there is an impact.
16 But something as simple as changing from one starch supplier
17 to another, at the same percentage, can change the impact on
18 those products.

19 I just want to make sure that the Agency
20 understands the magnitude and the complexity of the things
21 that they're trying to change in light of the fact that a
22 very effective system has been in place for years and has
23 demonstrated a lack of -- .

Heritage Reporting Corporation

(202) 628-4888

1 MR. SHIRES: Katie mentioned something that
2 sparked a little bit of an idea here in terms of, if we
3 transition from where we are now to a "HACCP" and
4 performance standard mode on canned foods, there are
5 frequent formulation changes, et cetera. Processes may
6 change. For example, one may have five processes on the
7 same product as alternatives.

8 I'm curious as to how you would envision that
9 fitting into HACCP. You may be setting up a system which is
10 much more burdensome in trying to make it more simple. Your
11 paperwork burden is going to go way up in terms of
12 reassessment of the plans for each process that is now a --
13 process or each -- .

14 I hadn't thought of that aspect of this before,
15 but that could be very cumbersome. That's just a comment.

16 MR. ENGELJOHN: I would respond just particularly
17 to the comments that you submit when you flush that out as
18 to some of those issues. I would in part compare this to
19 what occurs with irradiation processes in which there
20 currently is defined, there are requirements for defined
21 criteria that have to be there.

22 Now, within the irradiation regulations that we
23 have in place today we have seen more prescriptive

1 requirements there than what we do for general processing
2 categories. So if there are similarities between existing
3 irradiation regs and the canning regs, that would be
4 something I think we'll go back and look at to see the
5 additional requirements that we put there which involve more
6 clarity as to specifying any changes and so forth through
7 required certain activities.

8 We've gone in this proposal to the very general
9 performance standard statement without considering some more
10 prescriptive provisions other than requiring that a person
11 be trained, which is one of the components for irradiation.
12 There may be a need to look at some added descriptive
13 requirements to this performance standard. If you could
14 maybe flush that out a little more as to the specifics, that
15 would be very helpful to us.

16 MS. GLAVIN: Any immediate questions? I'm not
17 trying to shut this down, believe me. What I'm going to
18 suggest is that if there are a few more questions we get
19 those on the table now and before we move on to the
20 presentations, because there are a number of people signed
21 up, we take a short break. Questions?

22 MS. SWANSON: One more question, and that's
23 related to thoughts in the Agency on prerequisite programs.

Heritage Reporting Corporation

(202) 628-4888

1 I know that that's not something that is frequently
2 addressed within USDA. Would some of the provisions related
3 to the equipment that is used for thermal processing is a
4 very good example of the need for a prereq program. When
5 you're establishing a process it's specific to the line.
6 You do temperature distribution studies within retort
7 (phonetic) vessels, for example, to determine where the cold
8 spots are.

9 This is not something that is easily captured
10 within a HACCP plan because it's not done every day. It's
11 done at a certain point in time and then when equipment
12 changes are made. When you remove the equipment portions
13 and requirements from the regs, all of a sudden those
14 requirements seemingly disappear, and they are essential to
15 delivering the process that you need on each and every can
16 that goes through. Is there a consideration that you might
17 have some recognition of the prerequisite program?

18 MR. UHLER: Won't the equipment be covered in the
19 validation system -- wouldn't that be covered?

20 MS. SWANSON: It would be covered during that
21 initial validation, but the ongoing check is not something
22 that would be able to -- that's easily amenable to doing in
23 your HACCP plan.

1 MS. GLAVIN: Question?

2 MR. DERFLER: This is Phil Derfler. The only
3 thing I'd add is we have pending before the Agency a
4 petition from the industry. One of the issues that it
5 raises is the issue of prerequisite programs. The petition
6 --

7 MR. COLE: -- someone who spent 25 years in the
8 Food and Drug Administration as an investigator, who spent a
9 lot of time on the plant floor doing inspections of food
10 processors, both national and international.

11 I think the concern that Katie and Roy and Dane
12 are voicing here is that if you transfer a regulation, okay,
13 which has a very clear cut definition of commercial
14 sterility, and by definition of commercial sterility it
15 mandates destruction of bot. It mandates the destruction of
16 *Clostridium botulinum* right now by definition.

17 You're going to have an awful lot of work that
18 needs to be performed on the basis of the annual
19 reevaluation of the HACCP plan whereas today the situation
20 in the plant is that a lot of work goes into basically
21 establishing the schedules and the processes and validating
22 the recording systems through temperature distribution
23 studies. Then a careful eye is kept, or supposed to be kept

Heritage Reporting Corporation

(202) 628-4888

1 on the process by plant management to make sure, A, nothing
2 changes with respect, okay, to the process itself.

3 Katie mentioned the example of going from one
4 starch supplier to another starch supplier. There are a
5 myriad of different issues that are involved here. On the
6 weak -- side, if you have a plant engineer who runs out of
7 gate valves on the vertical scale retort side, and decides
8 to replace it with a globe valve, not understanding, you
9 know, the significance of what that means in a line, okay,
10 so this is basically the way this is controlled today.

11 They do not redo the -- on an annual basis. They
12 do not do the temperature distribution on an annual basis.
13 Basically it has not been necessary. It does become
14 necessary, as David said, and there should be control
15 provisions in place for that.

16 If the process is being thought to be changed,
17 you're supposed to contact the process authority. If you're
18 thinking of changing something to your retorting system,
19 you're supposed to contact the process authority. If this
20 moves to HACCP, it looks like what's going to have to be
21 done, regardless of whether it's necessary or not, on an
22 annual basis. I think this is the source of a lot of
23 concern here.

Heritage Reporting Corporation

(202) 628-4888

1 MS. GLAVIN: All right. I declare a break. Let's
2 try to keep it to about ten minutes. Thank you.

3 (Whereupon, a short recess was taken.)

4 MS. GLAVIN: All right. What I will suggest is
5 that we start moving into some of the comments that people
6 are prepared to make and intersperse that with questions,
7 since I suspect the presentations will trigger additional
8 questions and discussion.

9 Lloyd, sometime way back earlier this morning I
10 offered you the opportunity to make a presentation. Would
11 you like to proceed?

12 MR. HONTZ: Yes, I would.

13 MS. GLAVIN: Thank you.

14 MR. HONTZ: Thank you, Maggie. I am Lloyd Hontz
15 from the National Food Processors Association. I do have
16 some prepared remarks. They will take about five minutes to
17 cover, and I promise to cover them in less than half an
18 hour.

19 MS. GLAVIN: Thank you.

20 MR. HONTZ: Thank you for this opportunity to
21 comment on one important element of the FSIS proposed rule
22 setting performance standards for ready-to-eat food. For a
23 host of reasons, the National Food Processors Association

1 vigorously approves of the FSIS plan to remove the existing
2 canned regulations from the Code of Federal Regulations and
3 to replace them with performance standards.

4 In our reading of the Preamble to this ruling, we
5 find no discussion of a public health basis for this change.

6 This is not surprising since the existing regulations have
7 been exceptionally effective in minimizing public health
8 problems associated with canned foods. In that regard, I
9 noted at the end of Mr. Billy's opening remarks from the
10 technical conference on Tuesday, the desire for science
11 based processes with proven performance. If I remember
12 correctly, Mr. Billy also said that the one true measure of
13 success of regulatory food safety methods is the reduction
14 of foodborne illnesses. If this is so, then the FSIS canned
15 food regulations have been truly successful.

16 Unlike some of the other ready-to-eat food
17 categories in which new approaches for enhancing food safety
18 are still being developed, we do not believe that the
19 proposed changes to the canned food segment of the meat and
20 poultry industry will yield public health benefit. In fact,
21 we fear that a very opposite result can occur.

22 I would also note that the proposed changes appear
23 to be very likely to require significant economic

Heritage Reporting Corporation

(202) 628-4888

1 expenditures for validation of those processes that are
2 already exceedingly conservative and whose adequacy has been
3 validated by many, many years of production of safe
4 products. Again, we would note that no public health
5 benefit would accrue from such expenditures.

6 Before going further, I would like to offer a
7 brief review of the origin of the canned regulations, which
8 have had the strong support of the canning industry for more
9 than 30 years. I will show how the change surely would
10 introduce unnecessary competition for processors who also
11 produce FDA regulated canned foods and/or export their
12 products to other countries. As was suggested, the proposed
13 changes could adversely impact the very envious safety
14 record of this food industry segment.

15 Following a food poisoning incident in 1971 in
16 which the failure to properly apply a heat process to
17 commercially canned product led to fatal consequences, the
18 National Cannery Association, now the NFPA, petitioned the
19 FDA to publish new regulations to address the problem.
20 Elements of this major new program were designed to control
21 the primary food safety hazard associated with canning
22 operations; that being the survival of scores of Clostridium
23 botulinum which could then germinate and produce the deadly

Heritage Reporting Corporation

(202) 628-4888

1 botulism toxin in the anaerobic environment of the -- can.
2 Consumption of even small amounts of this potent toxin in
3 the absence of practical administration of antitoxin can
4 quickly lead to paralysis and death of any consumer, not
5 just those who might be immuno-compromised or in some other
6 special risk category.

7 In addition to new emergency -- requirements that
8 provided FDA with a basis for enforcement, the plan called
9 for good manufacturing practice regulations applicable to
10 formerly processed low acid foods packaged in hermetically
11 sealed containers. These PNPs were published and made
12 effective in January of 1973.

13 At a time long before hazard analysis and critical
14 control point became a household term, these canning
15 regulations were based upon HACCP principles. Utilizing
16 knowledge gained over a period of more than 60 years as the
17 art of canning was converted into a science, experts from
18 the NCA and its member companies carefully analyzed the
19 various steps in the canning process and identified those
20 whose proper performance was essential to the manufacture of
21 safe product.

22 In a cooperative effort with FDA, the most
23 important features of various retorting systems, the

Heritage Reporting Corporation

(202) 628-4888

1 essentials of thermal process establishment by recognized
2 processing authorities and special parameters for container
3 closure were identified as mandatory requirements to
4 document that, as denoted as shells in the regulation.
5 Monitoring and record keeping requirements to document that
6 factor is critical to the final process, and prescribed
7 procedures for corrective action when process deviations
8 occurred were also required elements of the regulation.

9 In addition to the mandatory requirements, other
10 advisory or recommended practices intended to ensure
11 compliance with the required features were included and
12 specified in the regulations as "shoulds." This strategy
13 allowed industry flexibility to achieve a desired goal by
14 alternative approaches.

15 Meanwhile, several incidents and one death from
16 commercially canned meat and poultry products occurred in
17 the early 1970s. FSIS procured a canning regulation of its
18 own in 1976, but never went further with it. In September
19 of 1981, the NFPA petitioned FSIS to establish further
20 manufacturing practice regulations that prescribe detailed
21 thermal processing requirements for canned meat and poultry
22 products which would enhance consumer protection, reduce the
23 cost of inspection, achieve consistency in the FDA

Heritage Reporting Corporation

(202) 628-4888

1 regulations and ensure fair and predictable enforcement by
2 USDA. NFPA urged the Agency to abandon its earlier proposal
3 as it had significantly mis-marked for comparability with
4 the original FDA ruling, which had been modified itself in
5 1979.

6 On April 12, 1984, FSIS published their proposed
7 ruling in response to the NFPA petition. I find some of the
8 Preamble language to be informative to our discussions
9 today. The Preamble stated that the decision to pursue the
10 proposal was in consideration of our petition and, I quote,
11 "the Department's desire to provide maximum consumer
12 protection by the most efficient means possible."

13 Later in the Preamble it was noted that among the
14 several alternatives available, the option to develop
15 comprehensive canning regulations, and I quote, "was
16 selected because it would accommodate advanced technology
17 and would strengthen controls over canning operations to the
18 degree deemed necessary to provide increased assurance of
19 safety and sterility of canned products.

20 "Also, the development of regulations which are
21 not -- the proposed CODEX Elementarius Code of Hygienic
22 Practice for Canned Foods and which closely parallel
23 existing FDA regulations would serve to promote

Heritage Reporting Corporation

(202) 628-4888

1 standardization and unity in national and international
2 regulations."

3 Finally, it was noted that the requirements and
4 recommendations -- in the proposal are generally recognized
5 by the industry as essential to good canning operations, and
6 they have been widely adopted. When FSIS published its
7 final rule for canning establishments in December of 1986,
8 they included a Preamble statement that, "This regulation
9 will reduce the risk of public health hazards associated
10 with improperly processed canned product." It became
11 effective six months later.

12 To conclude the historical perspective, the
13 canning regulations promulgated by FDA and FSIS resulted in
14 a unique cooperative effort between the canning industry and
15 the sister agencies to address a very serious public health
16 concern, Clostridium Botulimon. These HACCP based
17 regulations are widely regarded as the first and perhaps the
18 most successful application to date of the principles of
19 HACCP.

20 The FSIS proposal to remove the from the Code of
21 Federal Regulations these industry supported regulations and
22 to replace them with abbreviated performance standards seems
23 to overlook this unique background. While NFPA and its

1 members are certainly supportive of appropriately designed
2 and achievable performance standards, we believe that the
3 severity of the hazard addressed by the existing canning
4 regulations justifies their continuance. The primary
5 justification for the proposed change is to make the
6 requirements for this industry segment consistent with those
7 for other meat and poultry products. Overlooked is the fact
8 that it would create disharmony with the requirements of the
9 FDA and the recommended Code of Practice of the CODEX
10 Elementarius Commission. As previously noted, these were
11 significant reasons for publishing comprehensive regulations
12 in the first place.

13 Most of our members who manufacture canned meats
14 and poultry products also produce FDA regulated canned
15 foods. We argued long and hard for consistent regulations
16 between the agencies as the requirements for the production
17 of safe canned goods are the same for both types of
18 products.

19 Another stated justification for the proposed
20 change is to provide greater flexibility for industry to
21 produce safe product in the most efficient manner. While
22 the original FSIS canning regulations were indeed somewhat
23 restrictive, over the past 15 years many changes have been

Heritage Reporting Corporation

(202) 628-4888

1 made both at the request of industry and of the Agency's own
2 volition, to eliminate unnecessary requirements such as
3 those that require approval of alternative procedures that
4 can be documented scientifically to achieve the same end
5 result.

6 Indeed, the Agency has eliminated the many
7 requirements in the original rule for a mandatory prior
8 approval of partial quality control or PQC programs -- .
9 After a lengthy effort, we were able to gain regulatory
10 alternatives to the HACCP incompatible requirement for
11 mandatory ten-day incubation of canned products. While a
12 few additional changes along this line could be made, these
13 can easily be accomplished with minor amendment to the
14 existing regulations. The drastic action proposed by the
15 Agency was certainly not required for this purpose.

16 We note that the Agency very recently released its
17 proposed version of guidelines for industry. While we
18 haven't had the opportunity to carefully compare these with
19 the existing regulations, it appears that the sole change
20 has been the conversion requiring "shalls" to recommended
21 "shoulds." Just as we objected when the initial FSIS
22 proposal converted many of the FDA's recommendations to
23 requirements, we find this proposal to make all of the

Heritage Reporting Corporation

(202) 628-4888

1 provisions advisory to be unconfirming.

2 Indeed, in those guidelines they would not be
3 suitable for regulatory enforcement nor compliance purposes.

4 Processors, especially new ones or very small ones, would
5 have no basis for knowing which of the requirements are
6 essential in CODEX and which are merely examples of
7 acceptable practices. Such a situation would seem to us to
8 invite problems.

9 On the other hand, if inspection personnel are
10 finding fault with the procedures of a processor who did not
11 follow all of the provisions of the guidelines, the industry
12 could rightfully argue that the Agency was attempting to
13 enforce a guideline, a practice to which we have frequently
14 objected in the past.

15 One of the most troubling elements of the Agency's
16 proposal is the elimination of the codified provisions for
17 developments by processing authorities, which in our mind
18 introduces the possibility of inappropriate processes and
19 procedures, especially once again by new or small
20 processors. Our recommendation is for the Agency to delete
21 the canning regulation from the rest of the regulatory
22 proposal. At a later date and within a separate docket if
23 it could, undertake some relatively minor refinements out of

Heritage Reporting Corporation

(202) 628-4888

1 the existing regulations. Certainly the Agency could
2 combine and recodify the current separate requirements for
3 meat and poultry into a single section.

4 Other modifications to eliminate any lingering
5 restrictive requirements along the lines of the document we
6 shared with the Agency in 1997, could also be considered at
7 that time. Indeed, we believe that it is time for us to
8 take another look at those recommendations provided four
9 years ago with an eye toward making sure that they reflect
10 the current situation. This would be in addition to our
11 request of a further extension of the comment period on this
12 proposed rule.

13 As we have aptly demonstrated over the past 20
14 years, we are more than willing to work with the Agency to
15 ensure the continued safety of the products in this food
16 industry segment. I appreciate this opportunity for
17 comment. We intend to provide more input in written kind at
18 a later date. Thank you.

19 MS. GLAVIN: Thank you very much. What I'd like
20 to do is if anybody has any questions for Lloyd to raise
21 them now, but to hold the discussion until we have maybe two
22 other proposed comments prepared. Are there any questions
23 at this point for Lloyd? Okay. Jim? Jim Hodges?

Heritage Reporting Corporation

(202) 628-4888

1 MR. HODGES: I think it would be our preference
2 that Bob go ahead, and then I'll finish up our testimony.

3 MS. GLAVIN: Okay. Bob Dail?

4 MR. DAIL: My name is Bob Dail, and I work for the
5 Dial Corporation. We make the Armour brand of canned meat
6 and poultry products. We are the second largest producer of
7 canned meat and poultry products in the U.S. The Armour
8 brand first appeared in the marketplace in 1867, and our
9 first canned product was placed in the marketplace in 1879.

10 Product safety is our highest priority in this business,
11 and the reason for that is that we believe that Clostridium
12 botulimon is in a class by itself among food pathogens. You
13 don't have to be elderly, immuno-compromised, an infant, for
14 bot toxin to be fatal. None of the other organisms listed
15 in this proposal represents this level of threat to the
16 public health.

17 At the request of the industry, the current USDA
18 canning regulations are very similar to those promulgated by
19 FDA in the early 1970s. Together, these regulations have
20 been spectacularly successful at protecting the public
21 health from botulimon fatalities. The Agency states a part
22 of its motivation for proposing the performance standards is
23 the recent incidence of foodborne illness caused by

Heritage Reporting Corporation

(202) 628-4888

1 adulterated meat and poultry products. None of these
2 incidents was caused by adulterated canned foods.
3 Consequently, we see no public health basis for including
4 the canning industry in this proposal.

5 The Agency states that additional motivation for
6 the proposal was its desire to move away from command and
7 control type regulations. While we generally support this
8 philosophy, in this instance we think it is inappropriate
9 because its threat to public health is so significant. I
10 tell the management of my company that this is like making
11 injectable drugs. You cannot make a mistake.

12 Further, to provide a modified form of the current
13 regulations solely as guidelines with a selection of
14 critical control points left to the processor potentially
15 invites disaster. We think this is particularly true for
16 smaller processors that do not have in-house technical
17 people.

18 While most of the food products that the Dial
19 Corporation produces are regulated by USDA, we do make some
20 FDA regulated products. Right now when we comply with one
21 set of regulations, we are essentially complying with the
22 other, and we are also in compliance with the recommended
23 Code of Practice and the CODEX Elementarius for our

Heritage Reporting Corporation

(202) 628-4888

1 international sales. To us, it makes no sense for all these
2 regulations and recommendations to have the same
3 philosophical basis.

4 The Agency also states that it has a need to have
5 objective, measurable pathogen reduction. Our
6 interpretation of this for the canning industry is that
7 microbial destruction genetics obtained by a thermal --
8 testing will be required because this is the only real way
9 to scientifically demonstrate that you have a 12 log
10 reduction of Clostridium botulimon spores.

11 We view this as burdensome and unnecessary for the
12 following reasons. First, the alternate processes used for
13 low acid canned foods utilize FO values that significantly
14 exceed 12-D. The reason for this is a requirement that
15 spores and all thermal heat resistant organisms be destroyed
16 to prevent economic spoilage.

17 Consequently, the need to know the process level
18 which scores 12-D is only useful in the event of process
19 deviation, and even then it's not required because we're
20 allowed to rework or reprocess the product. Therefore, we
21 find the requirement to define and -- the specific 12-D
22 levels for a wide range of meat and poultry products to be
23 unnecessary.

Heritage Reporting Corporation

(202) 628-4888

1 Second, there are very few places the industry can
2 turn to generate -- data because the handling of Clostridium
3 botulimon spores requires licensing by Centers for Disease
4 Control and Prevention. Also, the equipment and the
5 expertise required to do the testing is unique, which makes
6 it quite expensive.

7 Because this adds little or nothing to ensuring
8 product safety for the reasons just given, we view it as
9 burdensome. To summarize this point, the requirement to
10 validate measurable pathogen reduction will require an
11 expenditure of money, time and human resources with no added
12 safety benefit for the consumer.

13 In regard to listeria testing, there is simply no
14 scientific basis for including the canning industry in the
15 proposed rule and listeria testing provisions. There is no
16 chance that any vegetative organism can survive a retort
17 process, and listeria is not a first process contamination
18 organism for canned foods. Therefore, we think the canning
19 industry should not be included in this requirement.
20 Otherwise we will be forced to rewrite our HACCP analysis to
21 include listeria as a hazard reasonably likely to occur,
22 which would then be destroyed in the retort process, along
23 with all the other vegetative organisms, which the whole

Heritage Reporting Corporation

(202) 628-4888

1 thing would become nothing then but a paper exercise. So
2 the rhetorical question is why make us do that?

3 The Agency has requested whether and in what form
4 the current regulations should be retained. From all of the
5 discussion provided above, we think it makes the most sense
6 for the thermal process commercially sterile foods to be
7 excluded from this proposal and to remain under the current
8 regulatory structure. Changes made over the past few years
9 to eliminate prior approval requirements have made the
10 current regulations less restrictive. Speaking as a
11 representative of the second largest producer in the United
12 States, we are quite satisfied with them.

13 We think changing for the sake of consistency with
14 other FSIS regulatory initiatives is insufficient reason for
15 change, given the current regulations have been so effective
16 in an organism this virulent. We strongly urge the Agency,
17 as strong as we can, to adopt this viewpoint as well. Thank
18 you for hearing our comments.

19 MS. GLAVIN: Thank you. Before we move on to
20 Jim's concluding comments on that presentation, are there
21 questions for Bob? Okay. Jim?

22 MR. HODGES: Thank you, Maggie. I am Jim Hodges,
23 and today I'm representing the National Meat Cannery

Heritage Reporting Corporation

(202) 628-4888

1 Association. The National Meat Canners is the national
2 trade association representing processors and suppliers of
3 shelf stable meat and poultry products.

4 NMCA was founded in 1923 to promote the interests
5 of the canned meat industry in the United States. NMCA
6 members include companies of all sizes from regional
7 processors to large, multi-client operations. Our members
8 were instrumental in helping USDA develop the current
9 canning regulations that are in place today. Therefore, the
10 proposed rule to replace the existing regulations for
11 thermal processed commercial sterile products with the
12 performance standards has a direct and substantial effect on
13 our members and the industry.

14 NMCA, like MFPA, opposes the section of the
15 proposed rule that would significantly change the manner in
16 which thermally processed commercially sterile products are
17 regulated. NMCA sees no compelling reason or rationale or
18 need to make the wholesale changes described in the proposed
19 rule.

20 The existing rules and procedures for canned foods
21 have been remarkably successful in protecting the public
22 health against the threat of foodborne illness and death
23 caused by *Clostridium botulinum*. The Preamble to the

Heritage Reporting Corporation

(202) 628-4888

1 proposed rule states that FSIS action is compelled by the
2 recent outbreak of foodborne illness related to the
3 consumption of adulterated RTE meat and poultry products.
4 However, none of the referenced foodborne illnesses involved
5 thermally processed shelf stable products, which is a
6 testimonial to the efficacy of the current regulations in
7 assuring the safety of these products.

8 Furthermore, Clostridium botulimon toxin is one of
9 the most lethal foodborne toxins known. The virulence of
10 the Clostridium botulimon organism is unparalleled.
11 Therefore, it is entirely appropriate and desirable that
12 detailed regulatory requirements such as those currently
13 codified in the Code of Regulations are necessarily
14 prescriptive to control this significant public health
15 threat.

16 We applaud the Agency's desire to provide the
17 industry with more regulatory flexibility, but the
18 production of commercially sterile shelf stable food
19 products presents unique challenges that require specific
20 procedures and controls to prevent a potential catastrophic
21 outcome.

22 FSIS cannot justify replacing the existing
23 regulations simply on the belief that the current rules are

Heritage Reporting Corporation

(202) 628-4888

1 inconsistent with other FSIS regulatory initiatives. The
2 existing canning regulations have been validated over time
3 as effective in safeguarding public health. Replacing these
4 proven regulatory standards with an untested regulatory
5 approach based on performance standards cannot be justified.

6 Protection of the public health should be FSIS'
7 first priority. Replacing the existing canning regulations
8 with less prescriptive performance standards, potentially
9 threatens public health by creating unnecessary confusion
10 and uncertainty in the industry.

11 Section 430.5 of the proposed rule describes the
12 performance standards an establishment must meet to achieve
13 regulatory compliance. But the proposal is silent regarding
14 the nature and scope of documentation a plant must have to
15 demonstrate compliance with that performance standard.

16 Presumably, FSIS will make the final determination
17 regarding regulatory compliance based on the evidence that a
18 company presents to the Agency, but the company will not
19 have the benefit of knowing the threshold of proof required
20 by FSIS. This regulatory approach that requires an
21 establishment to prove that it is producing products that
22 are not adulterated places the industry in an untenable and
23 precarious position. Less industry guidance and more Agency

Heritage Reporting Corporation

(202) 628-4888

1 discretion is a prescription for creating, not solving,
2 problems.

3 Additionally, the proposed rule adds new
4 burdensome requirements by mandating producers to thermally
5 process commercially sterile products and address food
6 safety hazards associated with microbial contamination under
7 HACCP plans. Presently, establishments producing canned
8 meat and poultry products do not have to address microbial
9 hazards in their HACCP plan if the product is produced in
10 accordance with the existing canning regulations.

11 This exemption is permitted because sufficient
12 microbial lethality is achieved to assure product safety.
13 NMCA does not support the notion that performance standards
14 should replace the existing canning regulations and requests
15 that the current exemption be retained.

16 Finally, the proposed rule is incompatible with
17 regulations applicable to the production of thermally
18 processed commercially sterile foods other than meat and
19 poultry products. Several manufacturers produce products in
20 the same plants that are regulated by FSIS and FDA. FDA
21 regulations codified under 21 CFR, Part 113, govern the
22 production of thermally processed low acid foods packaged in
23 hermetically sealed containers other than meat and poultry

Heritage Reporting Corporation

(202) 628-4888

1 products.

2 These regulations are very similar to the existing
3 regulations codified in 9 CFR, Part 318 and Part 381, that
4 govern meat and poultry products. The proposed rule would
5 significantly alter the rules for producing meat and poultry
6 products, thereby creating two vastly different regulatory
7 regimes for foods that have virtually identical food safety
8 hazards. FSIS has provided no rationale to justify this
9 regulatory disparity.

10 In summary, the proposed rule to change the way
11 thermally processed commercially sterile products are
12 regulated is unnecessary, burdensome and not justified based
13 on the exemplary food safety record of the industry. As you
14 have heard in my testimony and in comments previously given
15 prior to mine, the canning industry is unanimously opposed
16 to promulgating the rules that have been published in the
17 Federal Register. We believe the proposed wholesale changes
18 to the existing regulations are unwarranted and respectfully
19 request FSIS withdraw sections of the proposed rule that
20 pertain to thermally processed commercially standard
21 products. We appreciate the opportunity to comment on this
22 important proposal. Thank you.

23 MS. GLAVIN: Thank you. Are there other people

Heritage Reporting Corporation

(202) 628-4888

1 with prepared comments at this point? I have Dr. Gamble's
2 name on this list, but I believe he made his comments on the
3 Trichina. I suspect that was his intention. Okay. We're
4 open for questions and further discussion. Dane?

5 MR. BERNARD: Thank you. Dane Bernard, Keystone
6 Foods. At this point you're probably what you did to
7 deserve this verbal barrage. Let me from my perspective,
8 having been associated with canned foods for most of my
9 career, try to explain a little bit about why the response
10 is what it is. I noted to Dr. Engeljohn earlier that it's
11 as if you've touched the Holy Grail.

12 MS. GLAVIN: Or the third rail.

13 MR. BERNARD: Or the third rail --

14 (Laughter.)

15 MR. BERNARD: -- as the tag line goes. It's
16 almost like changing a line in the Bible talking about
17 changing this rule. Why is that? It would seem that we
18 should welcome the opportunity for more flexibility and less
19 rigidity in our world, but I think part of the reason is
20 canned foods are pretty much boilerplate. It's easy. You
21 just put it in a can and seal it right, cook the heck out of
22 it, and it's okay.

23 Despite the fact that it looks like a fairly easy

1 thing to do, it's a relatively sophisticated technology, and
2 the reason we don't have a record of recent problems is
3 because of the factors that need to be addressed in
4 successfully implementing this technology are addressed in
5 those rules.

6 The difference between, for example, a gate valve
7 and globe valve -- they both work. You can drain a retort
8 with either one, but the flow characteristics of those two
9 valves are different, and the reason that one is prescribed
10 and the other not is because you need to know how they
11 function. It's those nuances that are addressed in the
12 regulation that I think people fear would be lost if we
13 change those rules. The successes that we have are the
14 result of basically hard won battles.

15 One of the projects that I'm working on is the
16 history of food safety. And with Dr. Turps (phonetic) from
17 CDC, my contribution is an investigative review of the
18 history of canned foods, so I've been digging back through
19 some of the old literature. It's surprising how a lot of
20 what we have arrived at today in the regulations basically
21 came about and people paid for it, unfortunately, with their
22 lives to learn some of those hard learned lessons, which has
23 all been distilled down into those regulations.

Heritage Reporting Corporation

(202) 628-4888

1 I began my career before final implementation of
2 FDA's canned food rules, but after they were finalized.
3 They were adopted, but not yet implemented. A lot of people
4 who are here remember those early days of implementation.
5 It was tough getting a lot of this up and running and
6 getting it successful. With the publication rule and
7 implementation rule, we were not successful for years after
8 that rule was published. As a personal note, being the
9 laboratory person at the time about all we did when I
10 started with that organization, which was then National
11 Canners, was examinations on spoiled canned goods trying to
12 find out why.

13 Over the next ten years after finalization of that
14 rule, that book of business, if you will, of spoiled canned
15 goods went down. I personally relate that to the success
16 over time of understanding those regulations to the point
17 where they became steady state and common practice. The
18 industry understood what was in those rules, and the
19 inspectors in the field understood what was in those rules,
20 and were able to inspect according to those rules and get
21 good results. And the industry was able to understand and
22 comply with those rules.

23 These were not easy times. They were difficult

Heritage Reporting Corporation

(202) 628-4888

1 times, but we've forgotten now that we did have problems
2 with canned goods at one time. I think what you're hearing
3 now as a universal response is that people who were part of
4 that were, and I think rightly so, proud of their successes
5 and feared that the problems that we had are only asleep and
6 that they could be back.

7 We've seen an erosion, I think, of commitment to
8 safety of canned goods. FSIS at one time had a canning
9 group, which is no longer. FDA's expertise in canning is
10 probably gathered in this room. That's how few people there
11 are left because we haven't had problems, and we all know
12 money follows problems.

13 I think there's a fear that changing the rule
14 itself will be a further erosion of the fabric that supports
15 the safety of this technology. I think as an emotional
16 issue, that's kind of what you're hearing. We've heard a
17 lot about what we don't like about the rule, what changes
18 might bring, but at a gut level, we're talking about looking
19 at successes that we've had, why we've had them and fear
20 that we may be further undoing the reasons for that success.
21 Thanks.

22 MS. GLAVIN: Thank you. That was very helpful.
23 Other comments or questions? Thank you. My helpers are

Heritage Reporting Corporation

(202) 628-4888

1 over here telling me that there's someone behind me.

2 MR. COLE: William Cole with Techni-CAL again. On
3 the advice of my colleague, Mr. Bernard, I switched to decaf
4 during the break. I think one of the things that you're
5 hearing from the people that made the presentations today
6 more than anything else is that low acid canned foods as we
7 generically refer to them are not your typical ready-to-eat
8 foods. They are in an extremely unique category. Let me
9 give you an example from my FDA career of how unique at
10 least the Agency looked at this class of foods as being. I
11 was initially trained in a two-week course on HACCP
12 inspections, most of which was in the performance of low
13 acid canned food inspections, in 1973 under those
14 instructors who worked for the Pillsbury Company. Pillsbury
15 was early into this type of food safety control.

16 Okay. Once a certain core of investigators like
17 myself were trained, we went out, and we did inspections of
18 the low acid canned food industry. Something that is also
19 not known to a lot of people, is that we had a voluntary
20 HACCP program involving six different categories of frozen
21 heat-and-serve type foods.

22 For a number of years our investigators such as
23 myself got more and more experience basically in evaluating

Heritage Reporting Corporation

(202) 628-4888

1 the basic principles behind the establishment of the thermal
2 process, behind delivery of the thermal process,
3 documentation of delivery, as well as container entitlement.

4 Now, the uniqueness of this was pointed out by
5 virtue of the fact that when the FDA upgraded their program,
6 their compliance program, for the inspection of store
7 pharmaceuticals, they realized that they didn't have a very
8 large base of trained investigators to go in and actually
9 look at the processes that would be -- from the standpoint
10 of the establishment of those processes.

11 They actually sent in initially investigators who
12 had been trained to do canning inspections because they had
13 this basic background. So there was a recognition on the
14 part of the Food and Drug Administration at that particular
15 point in time, I think, of the uniqueness of the canning
16 industry. I think before FSIS decides that they want to
17 shift thermally processed low acid foods over into the rest
18 of the category of ready-to-eat foods, you need to take a
19 look, a very hard look, at the uniqueness of this industry
20 and the potential problems that can occur by considering it
21 to be a category of foodstuffs like any other ready-to-eat.
22 As I said, I think some of the comments that have been
23 presented today more or less voice support to this and

Heritage Reporting Corporation

(202) 628-4888

1 demonstrate I think a real concern.

2 MS. GLAVIN: Thank you.

3 MR. DERFLER: It's Phil Derfler. Let me ask the
4 question that Bill's comment raised. When I was at FDA,
5 everybody talked about the canning regs as the HACCP regs.
6 You know, that was the first model for the HACCP regs before
7 we moved into HACCP for seafood and infant formula and a
8 couple other places.

9 The question that I have is we're really not
10 talking here about necessarily moving the canning provisions
11 into other ready-to-eat foods. We're talking about
12 integrating the canning provisions into the HACCP rule
13 because there's the exception in 417.2. My question is if
14 this is essentially a HACCP program, and that's kind of I
15 think what Bill just talked about, why is it so hard to do
16 that?

17 MS. SWANSON: Katie Swanson. I'll take a stab at
18 answering that. Because we do have facilities that have
19 HACCP regulated products and not HACCP regulated products.
20 We at Pillsbury look long and hard at how we can capture the
21 information that we currently gather for thermally processed
22 products in a HACCP format. There was a desire by some to
23 have consistency within the company, more the types of

1 things that you're talking about, and it is based on the
2 same thought process to define what can go wrong and how can
3 you prevent it.

4 As you define the processes and products that we
5 produce, the format that you envision for HACCP where you
6 have the seven columns with all of these things delineated
7 across, just aren't amenable to documenting all of the
8 things that you have to do with thermally processed
9 products.

10 Because of that, we have captured HACCP as a
11 prerequisite program within Pillsbury because it's not just
12 here's the step, here's the process, here's the hazard,
13 here's the control. It's more all of that is done, and
14 here's your authorized process, guys. Here's the particle
15 size you need to do. Here is the time, the temperature, the
16 pressure, et cetera, all on one page. It's just a heck of a
17 lot easier to communicate to the plant, the expectations and
18 requirements if you do it in that format. And there's all
19 of that underlying don't change the valves on the retorts
20 and make sure you have your heat penetration done. It's
21 just a more effective way to manage it.

22 MR. DERFLER: Let me just ask you to clarify
23 something that you said. You said HACCP has a prerequisite

1 program. Do you mean low acid canned foods is a
2 prerequisite?

3 MS. SWANSON: No. Yes. Thermal process is a
4 prerequisite program --

5 MR. DERFLER: Okay.

6 MS. SWANSON: -- under our HACCP program for those
7 plants that can products.

8 MR. DERFLER: Okay.

9 MS. SWANSON: We have products that are FDA
10 regulated. We have seafood products that are in a can on
11 the same lines that do USDA products. So we've got to
12 manage all those things.

13 MR. DERFLER: Thank you.

14 MS. GLAVIN: Jim?

15 MR. HODGES: Phil, it might help to answer your
16 question in a very simple way. If you look at almost all of
17 the regulations in USDA prior to the publication of the
18 canning rules, they related to a finished product standard
19 of some form, in some form or another. When the canning
20 rules were published, that was the first time that we
21 started to try to regulate the process, not the product, and
22 that's the reason that they're called HACCP regs because
23 we're regulating the process, not regulating the product.

1 MR. DERFLER: Thank you.

2 MS. GLAVIN: Charlotte, did you have a question?

3 MS. CHRISTIN: Yes. Hi. Charlotte Christin from
4 CSPI. I had a question for Katie, and actually it is in
5 regards to, if things are regulated or done through
6 prerequisite programs, our concern would be whether the
7 Agency has access to documentation. Could you address the
8 issue of Agency access to documentation?

9 MS. SWANSON: Katie Swanson. With regard to
10 thermal process regs, yes. They have access to the records.
11 If they ask for anything with regard to our thermal process
12 records, we give them the records.

13 MS. CHRISTIN: Charlotte Christin again from CSPI.
14 One of the concerns with prerequisite programs that we have
15 is the Agency's access to documentation and I guess the
16 concern about if this were managed under a prerequisite
17 program such as the issue with the rest of the HACCP
18 program. I mean, one of the things that the Office of
19 Inspector General said in his report last June was that he
20 was concerned that the Agency didn't have access to all of
21 the information that might be included in the Prerequisite
22 Program, and a concern about things being left outside of
23 HACCP.

Heritage Reporting Corporation

(202) 628-4888

1 MS. SWANSON: But with regard to thermally
2 processed products, they are covered by the regulations, by
3 different regulations. Because of that, that issue does not
4 exist. They are accessible.

5 MS. GLAVIN: Dane?

6 MR. BERNARD: Dane Bernard, Keystone Foods. I'd
7 like to comment on that as well. We don't have that issue
8 if the canned food rule stays in place. You have that issue
9 if we transition HACCP. Let me give you a good example.
10 The canned food rule requires seam examinations. This is
11 when you cut the can down you make various measurements, and
12 you make a judgment call as to whether that seam
13 construction -- this is more in terms of whether it is
14 accessible.

15 Where that falls if we transition to HACCP, I
16 mean, it's covered broadly, but whether it lands in a HACCP
17 plan or whether someone wants to call it a prerequisite
18 program I don't know, and that's assuming we're going to
19 put can seam examination in as a critical control point.

20 I don't know sitting here what kind of critical
21 limits I would put on that because of the judgment of what
22 is a good and bad seam is an expert operation because there
23 are several measurements that we can make on a judgement

1 call judgement call to say this is okay. There are
2 guidelines, but there are nothing that I recall as critical
3 limits.

4 You're also required to add a germicide to the
5 cooling water, and there are guidelines on how much. There
6 is nothing I would call a critical point in that. So by
7 transitioning this into HACCP there are several of those
8 issues that now become what I would call the -- that I'm not
9 sure we would like to open that Pandora's Box.

10 MS. GLAVIN: Thank you, Dane. As usual, you cut
11 to the heart of the matter. Thank you. Okay. Are there
12 questions or comments on this section of the proposal? We
13 will close with that comment.

14 Our next area to cover, which is scheduled this
15 afternoon, but I suggest we move ahead as we thought we
16 might, is the economic impact of the proposed regulations
17 and the cost benefit data needs that the Agency has with
18 respect to moving to a final regulation.

19 I'd like to ask Phil Spinelli from our Office of
20 Policy, Program & Development Evaluation to present this
21 issue. Phil was the lead on putting together the economic
22 and cost benefit information for the proposed regulation.

23 (Pause.)

Heritage Reporting Corporation

(202) 628-4888

1 MR. SPINELLI: Is the microphone on? Everybody
2 can hear me? Very good. My name is Phil Spinelli. I'm
3 currently with the Agency, and I have the pleasure to try to
4 assemble as much information as I could as to the regulatory
5 impact assessment for the proposed ready-to-eat rule.

6 What I would like to cover today is five topics.
7 I'll first give you a brief overview of the regulatory
8 impact analysis and impact assessment framework where this
9 information fits into the regulatory framework. I'll spend
10 most of my time on the preliminary estimate on the industry
11 costs, particularly the impact of the higher performance
12 standards and the mandatory testing of the listeria species.

13 I'll try to break those costs down to give you
14 some idea of the cost impact on small entities, and I'll
15 spend a fair amount of time on the preliminary estimate of
16 social benefits and then finally compare those industry
17 costs with possible social benefits.

18 Moving quickly to the purpose of the regulatory
19 impact assessments, there are three -- as I see them; the
20 estimate of potential social benefits and costs, the
21 proposed options. We also identify and assess regulatory
22 alternatives. This material is in the proposed reg and
23 economic impact material, and what I will be going with and

Heritage Reporting Corporation

(202) 628-4888

1 presenting also in the appendix of that proposed rule.
2 Hopefully this provides a framework for public comment and
3 further improvement.

4 Now, along these lines, what I have tried to do is
5 I tried to take some of the comments that were made
6 yesterday, and I recognize that there are people that are
7 particularly motivated to look into the assumptions that
8 were made. This is a means to better flush out some of the
9 data needs whereas our particular need in this analysis, and
10 I've worked with my colleagues in FSIS and other agencies to
11 try to get a better handle on this thing. As you can
12 imagine, it was quite an effort, and it will continue to be.

13 I have a limited number of copies, but for those
14 that are particularly motivated I would like you to follow
15 along. What I did is also provide in my speaker notes a lot
16 more detail that you might be able to respond to.

17 Just to finish off on some of the bigger picture
18 here of the regulatory impact analysis, one job really is to
19 try to establish a baseline of the industry's behavior and
20 also on the benefits side, the consumer side, and then try
21 to forecast or estimate to the best of my ability the
22 regulatory induced changes in industry practices that might
23 come about with the proposed rule, and create a scenario

Heritage Reporting Corporation

(202) 628-4888

1 which incorporates this impact of the changes in the
2 industry and the health benefits, and then compare those
3 two.

4 In that light, I'd even like to refine that or
5 boil that down into even simpler jargon that I would like
6 you to view as a focusing device. Hopefully I'm going to
7 take the material that I've gleaned here in the last two or
8 three days, and other material, and try to focus that so our
9 policy makers can make a more informed judgment and policy.

10 I would like you to follow along as best as you
11 can and focus on any comments that you can make that would
12 help me better identify how to clarify any of the materials
13 I present in the larger framework and then the specific
14 estimates; any clarifying comments on those two points, the
15 general framework and then my general estimates.
16 Afterwards, I'd like to open it up then for others and
17 myself, if appropriate, to address your concerns, your
18 comments on maybe better estimates that I might be able to
19 use, more informed data, knowledge, information.

20 In that light, let me go right into the
21 preliminary assessment of the performance standards. On the
22 impact of the performance standards, as well as on testing,
23 the general framework is I look at the direct cost, and then

Heritage Reporting Corporation

(202) 628-4888

1 I look at indirect costs. The indirect costs are more the
2 unintended consequences of the rule, the economics that
3 cause spill over effects, or extraneousities. These aren't
4 intended. We need to recognize them, the possibility. We
5 need to quantify those as best as we can.

6 The first thing we do with the impact of the
7 performance standards is we try to estimate how many firms
8 might be potentially affected by this provision and in what
9 ways. In direct costs, there might be some one time initial
10 costs in validating the processes in order to assure that
11 the performance standards are being met. They might also
12 include any equipment costs in processing those food items,
13 cooling them down, whatever. Then there's also some
14 recurring costs that might directly impact the firm in
15 additional processing, longer times, higher temperatures,
16 other processes, irradiation and what have you.

17 The number of firms in this industry that I have
18 identified that might be potentially affected are roughly
19 one-third of the firms in what I classify as the Group 1,
20 Subgroup 1, and Group 1, Subgroup 2 and 3. Those are the
21 fermented dry and summer sausage producers, salami, dried
22 beef and pork product producers, salt cured country hams and
23 one-third in the sausage and meat and poultry patty

Heritage Reporting Corporation

(202) 628-4888

1 industry.

2 The reason I say that is because assuming that the
3 other folks producing similar products are already complying
4 with the roast beef rule, and that's why that assumption was
5 made. What that does in the analysis is cuts the number of
6 establishments down to roughly 50 in the first group and 25
7 in the second group. You can see that in your notes as you
8 go through that. That would be data need number one. If I
9 could particularly address some data concerns, that would be
10 a valuable piece of information. I would welcome your
11 comments later.

12 You'll see in Section 2 down below there we have
13 to get the number of products that these folks are going to
14 produce and how many potential production processes might
15 need validations to see if they're obtaining the performance
16 standards. To do that, there is a whole host of assumptions
17 as well.

18 The large firms in Group 1, Subgroup 1, produce 30
19 items, small produces ten items, and the very small firm
20 category five. You'll see similarly down in Group 1,
21 Subgroup 3, similar assumptions. Somewhat different, but we
22 figure that \$5,000 cost to validate those processes. That's
23 how we arrived at the first year -- cost.

Heritage Reporting Corporation

(202) 628-4888

1 The first year recurring costs again in 75 firms
2 through census date estimated that they produce roughly 441
3 million pounds, and another crucial piece of information I
4 assumed was these processes would amount to about a one cent
5 per pound additional cost on each product. That would
6 include all equipment costs for higher temperatures and so
7 forth.

8 I said there were direct, and then there's going
9 to be indirect costs, too, in the general framework. In the
10 indirect HACCP performance standards, I would like to know
11 more about the potential impact on short- and long-term
12 rejection rates. These firms expect that their rejection
13 rates will go up after an increase in time and temperature
14 or whatever new processes, but in the long term maybe those
15 rejection rates would go down and be a benefit.

16 Speed lines. I would be interested in knowing if
17 a lot of these meat patty plants have a stainless steel
18 conveyor belt. Would they be required to slow down those
19 speeds, as opposed to increase temperatures or a combination
20 of both? What would that do to their annual production
21 level? This would be an unintended effect that would reduce
22 their profits, their volume of production and thus their
23 profits.

Heritage Reporting Corporation

(202) 628-4888

1 What would be the impact of recalls? Product
2 quality. Product shrinkage. You can see in the speaker
3 notes there, one example that was submitted to us was the
4 potential shrinkage in meat patties. That might be a
5 sizable loss for particular products.

6 In summary, the direct costs, and I believe the
7 previous slide said at this time there are no indirect cost
8 impacts that were estimated. I simply did not have enough
9 information to base any of those on. I would welcome any
10 comments along those lines.

11 We have right now a preliminary direct cost impact
12 first year, -- costs in the validation process of those
13 processes is \$2.72 million with an annual recurring cost of
14 \$4.41 million for a total first year impact cost of a little
15 over \$7 million. That's just on the performance standards
16 alone.

17 Now going back to the testing provisions, as Dr.
18 Engeljohn explained yesterday it's an either/or proposition.

19 We look at the decision by a firm to go and elect to go
20 modify their HACCP plan to incorporate a critical control
21 point addressing Lm contamination or instead go with the
22 actual testing of product contact surfaces.

23 The way I went about trying to get a handle on

1 this component of the reg, to the best of my information --
2 NFTA did a survey last year, and we did our survey
3 assessment about a year ago -- putting together some
4 thoughts and making some assumptions as an economist, and
5 I'm allowed to do those types of things.

6 Currently 50 percent of the large establishments
7 have a CCP incorporated into their HACCP plan that addresses
8 Lm concern. What I propose is that or forecast is that 100
9 percent of those plants would like to develop and
10 incorporate a CCP addressing Lm in their HACCP plan. I'll
11 show you in a minute what my logic was there. There again,
12 that's another critical piece of evidence that I would like
13 to have, as well as these other assumptions. For small, I
14 assume right now about a third of the firms currently have a
15 CCP addressing Lm contamination. That would go up to 50;
16 very small ten, and that would go up to 20 percent.

17 If you do the math with the number of firms that
18 I'm dealing with, it appears that we would have and switch
19 over, and that's in your speaker notes as well, 257 firms
20 that would elect to take this option. Again, I used roughly
21 a \$5,000 estimate to modify their HACCP plan. That might be
22 high. It might be low. I saw estimates ranging from \$2,000
23 problem to \$20,000. Any comments that you might have

Heritage Reporting Corporation

(202) 628-4888

1 concerning that estimate would be helpful.

2 Again, some of the logic that I used, and I
3 welcome any suggestions here. As I looked at the
4 requirements that are applied with the proposed rule, if you
5 look at the large plants with six lines per establishment is
6 what we estimated or thought would be representative of
7 large firms times the four times per month requirement to
8 test, 24 tests per month. We have a cost for testing that
9 we could do in our little survey was \$35 a test, not \$6 or
10 \$8. As Dr. Tompkins was saying it would be as an in-house
11 test, so there's another piece of evidence that would be
12 very helpful. If you multiply that out, the \$35 times 24
13 tests per month times 12 months a year, that would impact
14 large firms a little over \$10,000 an establishment. Again,
15 their option as opposed to that, they would be looking at
16 \$5,000 to incorporate a CCP into their HACCP plan.
17 Similarly with the requirements times the cost that I used,
18 and that's also in your speaker notes in the handout. Those
19 are what it would imply for small and then the very small
20 establishments.

21 In total, when you have the number of plants and
22 deduct the 257 that would foreseeably go into the HACCP plan
23 modification, that leaves 835 that would be open for

Heritage Reporting Corporation

(202) 628-4888

1 testing. Those testing costs over the industry would be
2 \$1.75 million a year.

3 Now comes some of the more interesting items, some
4 of the things that were touched upon yesterday. I must say
5 I gained some insight yesterday and particularly on Tuesday.
6 But we're interested also in identifying the indirect costs.

7 In the testing area, they're very similar to the
8 performance standards, rejection rates, impact on recalls
9 for quality. Perhaps the testing would not affect line
10 speeds and shrinkage as much, but we were concerned, as was
11 commented on yesterday, on the potential impact of increased
12 testing and detection of Lm and what that may imply for
13 testing all occurrences, disposal of product and the storage
14 capacity question.

15 Unfortunately, I did not have a lot of data on
16 these sorts of things. I was wondering what the audience
17 member who did a -- envelope calculation and what he thought
18 it would cost his plant for just a small increase in the
19 number of tests on hold kind of occurrences. This would be
20 very valuable information. Particularly with small
21 operators and very small operations, this would be a
22 particular concern.

23 There was one indirect impact, though, that I did

Heritage Reporting Corporation

(202) 628-4888

1 venture out to try to quantify, and that had to do with the
2 need for production adjustments in order to eliminate any
3 listeria species contamination that would have been detected
4 by the increased amounts of testing.

5 These production adjustments are along the same
6 lines as much of the discussion on Tuesday; increased
7 sanitation efforts, redirection of the processes, these
8 sorts of things that firms can do. All the way up to the
9 last speaker today talked about actually incorporation of
10 post-lethality treatments for products.

11 One of the basic assumptions here is that I would
12 assume that a large number of plants will not incur any
13 additional costs due to the testing. I would imagine they
14 would not have a serious contamination problem. Now, why
15 did I assume that? I assure you that what I tell you now is
16 previous knowledge of what Dr. Tompkins said yesterday, but
17 it is amazing how similar some of the numbers are. I never
18 talked to him before, never met him before yesterday.

19 He did give me an estimate of about 85 percent of
20 the plants for the two years of data that he had that of the
21 plants that he had looked at about 85 percent of the plants
22 did not have an occurrence of more than two consecutive
23 positive Lm finds.

Heritage Reporting Corporation

(202) 628-4888

1 That stuck in the back of my mind because one of
2 the first things I did when I came to the Agency was I
3 looked at some of the microbiological survey data, and for
4 the one year that I looked at, and this is alternatives, and
5 I'd like to further explore this. I looked at the initial
6 positive finds, and then I also looked at the firms that
7 were found to get a negative within five consecutive time
8 period tests after that period of time, in what's called a
9 follow up test.

10 Looking at that data, it appears that about 85
11 percent of the ones that had an initial one or two follow
12 ups in our microbiological survey data, about 85 percent of
13 the plants it appeared, cleared up their listeria problem
14 promptly. So different data but roughly similar kind of
15 magnitudes.

16 Why is this important? I'm going to have to try
17 to predict on if you have had increased testing what's the
18 likelihood of finding a firm that's going to have a chronic
19 problem and what's their most likely remedy sources and
20 what's that going to cost them.

21 This is a post -- . Roughly 85 percent I assume
22 would not incur any additional cost. And from the tentative
23 data from the FSIS microbiological survey data it appears

Heritage Reporting Corporation

(202) 628-4888

1 that another seven percent will have a number of follow up
2 tests, and they would most likely run into some important
3 modifications that would cost them some money.

4 To the best of my knowledge, the type of increased
5 sanitation, the operation of sanitation efforts, this sort
6 of thing, I estimate about \$2,000 per line cost. Seven
7 percent of those firms or of the industry I think works out
8 to be 104 -- it's on your speaker notes there -- would incur
9 those kinds of costs.

10 Another seven percent would incur one-tenth of one
11 percent of gross sales. They would have a more serious Im
12 problem and maybe have to realign drains, production
13 processes, these sorts of things. That cost estimate came
14 out of the literature in the early 1990s and is documented
15 in the preamble or the appendix.

16 That leaves roughly one percent then that would
17 have a chronic listeria problem and would elect to drop out
18 of ready-to-eat production. This is something that you
19 should note on the general framework. The numbers --or if
20 this framework is faulty, I would like to get comments on
21 those.

22 If you multiply those numbers out, we have a
23 one-time production adjustment cost. Those are the firms at

Heritage Reporting Corporation

(202) 628-4888

1 seven percent and the additional seven percent. They would
2 need to fix their plant. They would have to take steps to
3 clean up their listeria contamination problem to the tune of
4 about \$2.5 million.

5 Add that also to the one-time cost to the folks
6 that modify their HACCP plan at \$1.2 million, as we talked
7 earlier. The subtotal for one-time costs is \$3.78 million,
8 and then they have this recurring testing cost. On the
9 testing program, we have a first year impact of \$5.53
10 million.

11 The total impact of the performance standards and
12 the testing, if we add those two together, to validate the
13 performance standards is \$2.72 million; to modify your HACCP
14 and put a critical control point addressing Lm
15 contamination, \$1.29 million. The production adjustment we
16 just talked about. You get a subtotal of \$6.5 million.
17 That's the way it's broken up between the two provisions.
18 We have to add onto that a return cost, the increased
19 processing cost related to the performance standard of \$4.41
20 million, in addition to the testing cost of \$1.75 million.
21 So your total first year cost impact is \$12.66 million about
22 evenly distributed between the two provisions.

23 Similarly, the cost impacts. The first year, all

1 the costs, \$5.53 million related to testing; performance
2 standards, \$7.13 million. Again, that total is \$12.66
3 million for the first year, and the recurring costs then
4 thereafter are \$6.16 million per year.

5 Over the two years I established a baseline. I
6 explain that in the appendix. In today's dollars, \$68.1
7 million. Over ten years as taking those future values and
8 bringing them to the present, \$48.3 million.

9 If you haven't had a chance to look at the
10 appendix and the impact on small entities, this might give a
11 little bit of a flavor in the aggregate what those costs
12 translate into and the incidents on the different size
13 firms. There's also quite a bit of data in the appendix on
14 the specific product groupings that were used so you can get
15 a better idea perhaps on a particular industry's particular
16 product type.

17 Just for a real global snapshot, we have 32
18 percent of the plants that, since we're using census
19 definitions and numbers, would be classified as very small
20 plants employing less than ten, ten or less employees. They
21 may absorb 15 percent of the total impact. The number of
22 small firms are a large chunk of the folks in the industry.

23 Fifty-nine percent of the firms absorbed roughly 54 percent

Heritage Reporting Corporation

(202) 628-4888

1 of the impact that I've identified up until now with mostly
2 direct costs. Large firms. Nine percent of the firms, but
3 they absorbed 31 percent of the impact.

4 That makes perfectly good sense when you look at
5 the processing, the additional processing that's associated
6 with the performance standards as item based. When you look
7 at the testing, for the most part that's item based as well.

8 There is some additional data in the speaker notes
9 here and what that might imply for a typical small firm,
10 very small firm and large firm, from each of the provisions
11 that might pertain to their situation. Basically with the
12 performance standards, the potential impact on those 75
13 firms, those very small firms within the group, roughly
14 \$40,000 a year, small firms a little under \$90,000 a year,
15 and the large firms \$630,000 a year just on the performance
16 standards. It's very difficult to get some of these bigger
17 picture type numbers out to you. I know it probably would
18 be more meaningful, but given the diversity of the products
19 and size of the plants and what might pertain to them, it's
20 difficult.

21 I think I've made quite a bit of comments there on
22 what kinds of data and data gaps exist on the cost side.
23 I'd like to look now on the demand side, the consumer side.

Heritage Reporting Corporation

(202) 628-4888

1 I want to specifically limit this. My benefits discussion
2 at this time is really limited to the improved food safety
3 that's possible and spurred on by the verification testing
4 for Lm. I would be welcome to receive any comments from
5 you.

6 The logic on the testing benefits that I'll be
7 discussing are simply that increased testing hopefully and
8 theoretically would imply that we would have a decreased
9 probability of contaminated product going out through the
10 commercial channels, less contaminated product and fewer
11 instances and deaths.

12 We have to ask ourselves some very, very tough
13 questions, and I know there was a lot of discussion in the
14 last two days about a lot of these topics. They're very
15 difficult ones to address. Be that as it may, they're
16 important for any kind of analysis.

17 This is very preliminary, and I want you to keep
18 that in mind. I would very much like to receive any
19 comments on any specific estimates, but particularly when we
20 move to the comments on maybe perhaps better estimates for
21 other ways for going about this thing. I'd be particularly
22 interested to hear your comments.

23 The best thing that I've come across and most

Heritage Reporting Corporation

(202) 628-4888

1 people in the industry use is Dr. Mead's study from CDC.
2 He's estimated about 2,500 listeria cases were associated
3 with about 500 deaths from all sources in the U.S., so
4 therein lies the first major hurdle of what is attributable
5 to the consumption of meat and poultry products. A \$64,000
6 question. In fact, it's been such an inflationary time
7 since that was first said, it's probably worth a whole lot
8 more than that.

9 Also, once you've established that, what is
10 attributable to actions at the plant? What could actually
11 be feasibly reduced at the plant by actions taken at the
12 plant? What's the impact of other measures? We've heard
13 lots of other measures. This would be private sector
14 initiatives, as well as regulatory induced or facilitated.

15 We heard some scientists talking about the
16 incorporation of additional secondary inhibitors in certain
17 products, these kinds of things, so we would want to try to
18 adjust and account for those, the benefits of those other
19 measures.

20 If we know those first three, are we confident
21 then? Do we know enough about the effectiveness of the
22 measures that will be taken by the plants in response to
23 increased listeria testing?

Heritage Reporting Corporation

(202) 628-4888

1 There are some other questions on the rate of
2 beneficial impact. Do you get this impact overnight? Is
3 there a flood of benefits over time? There's the whole
4 question of how to monitor all these benefits. We have an
5 additional speaker to address those issues from the Economic
6 Research Service this afternoon.

7 Let's first try to address that first issue. We
8 have two estimates linking meat and poultry products to
9 Listeriosis. The first one is the recent draft of the FDA/
10 FSIS risk assessment, and they ranked relative risk across
11 many food products.

12 While we feel there is an FDA/FSIS risk
13 assessment, when I started in on this project, I had to
14 piece together two independent studies by Dr. Mead and Dr.
15 Olson down at CDC. Linking those two studies I feel will
16 give a little about perhaps cases and deaths, but we have to
17 recognize that I've made some tenuous assumptions in order
18 to do that, and I hope to be very clear and transparent how
19 that came about so I don't give any false impressions of
20 precision or anything like that. I don't want to do that.

21 All right. Let's look at the FDA risk assessment,
22 the FDA/FSIS risk assessment. If you'll look at that data,
23 it would suggest or it does suggest to me anyway that over

1 65 percent of the cases and deaths are attributable to
2 ready-to-eat meat and poultry products. A huge proportion,
3 over 90 percent of that proportion, was attributable to deli
4 meats. The remainder was attributable to deli salads, hot
5 dogs, pate, -- and sausages.

6 So the bottom line on the FDA/FSIS risk assessment
7 is if you apply those estimates to Dr. Mead's numbers you
8 get roughly 1,660 cases of Listeriosis resulting in 331
9 deaths per year. That would be directly attributable to the
10 consumption of meat and poultry products.

11 Dr. Olson had made another study earlier on, and
12 she looked at the transmissions of different diseases,
13 Listeriosis being one of -- excuse me; total foodborne
14 diseases and attributed eight percent of total foodborne
15 diseases to the meat and poultry products, so if you can
16 make that leap from total foodborne diseases, Listeriosis,
17 which is a jump, and apply those to Dr. Mead's number of
18 annual cases and deaths, you get 167 cases and 35 deaths per
19 year, roughly a tenfold decrease. The FDA is a tenfold
20 increase.

21 Okay. Now, if you have the notes there's quite a
22 bit of assumptions, quite a few assumptions that go into
23 this slide. I'll try to walk you through it as best I can

1 so you'll know what's involved in the numbers.

2 The unadjusted Mead-Olson and draft FDA/FSIS risk
3 assessment study. The FDA/FSIS study are the higher range
4 and the Mead-Olson. A combination of those two studies are
5 on the left. Remember, I had on the other slide that we
6 have to identify some kind of a reasonable assumption on the
7 flow of benefits. In your speaker notes, you'll see I
8 assume a five percent benefit accruing the first year, ten,
9 15. Additional comments on this estimate would be helpful.

10 If you apply those numbers then to both sets of
11 raw data you come up with average annual cases over ten
12 years at 87 to 863 possible case reductions, cases that
13 could possibly be reduced from the testing provision, given
14 those initial numbers and the benefit stream. That implies
15 a death reduction that would be possible of 18 to 173.

16 Now, what I did is I tried to then be as
17 conservative as I possibly could and address those for some
18 of those factors that I've identified that we don't have
19 very good estimates of and that we would be particularly
20 interested in getting your opinion on. I adjusted those.
21 This adjustment is for what can be controlled at the plant.

22 I made an estimate that about 60 percent of what occurs
23 could be possibly controlled at the plant. I can go into

Heritage Reporting Corporation

(202) 628-4888

1 that. I can clarify that if you need what was that based
2 on. That might perhaps elicit more clarifying comments on
3 your part that could clarify this part of the analysis.

4 If you accept that, to develop a feasibility set
5 then one could say how many cases then could you reasonably
6 reduce from actions taken by the plant. The total pie
7 that's possible is 50 to 496 cases that could possibly be
8 reduced, and that implies about a ten to 99 death reduction
9 per year average over the ten years. Now, that's the total
10 pie. We all know that the internal combustion machine, what
11 you put into it you don't get that transmitted 100 percent.

12 There's all kinds of losses. We would assume the same
13 thing. A benefit is not going to be 100 percent effective.

14 I failed to come across in the literature what kind of
15 reasonable assumption could be made on the percentage of
16 that feasible set that could be reduced due to program
17 effectiveness.

18 For illustrative purposes, this is 50 percent.
19 Even if you assume that 50 percent of that bigger pie could
20 be reduced, then you'll come down with a possible case
21 reduction of 25 to 248. Associated with that is five to 50
22 death reductions. You may want to keep in mind that five to
23 50 death reductions per year.

Heritage Reporting Corporation

(202) 628-4888

1 Let's summarize what we have on the cost side and
2 on the consumption side here. First, your costs are a
3 little under \$13 million. The recurring costs, annual costs
4 of increased production, processing and testing to the
5 industry, \$6.16 million. The cost over ten years is a
6 little shy of \$7 million.

7 Benefits in lives saved. When you have a five to
8 50 on an average annual basis over ten years, that is your
9 five to 50 deaths avoided. That's highly dependent on your
10 assumption of what is the percentage of total Listeriosis
11 cases and deaths attributable to meat and poultry products,
12 the percent that is attributable to plant actions or what
13 could be effectively reduced at the plant, the impact of
14 other regulatory actions and other actions that are spurred
15 on through the private sector to better address listeria
16 contamination. And then the effectiveness of the measures
17 that would be taken by clients in response to the testing
18 provisions.

19 You can see that my focusing tool is that general
20 framework, and I'm trying to pick up pieces of information
21 from everywhere I can. If you were sitting here the last
22 two days, I think you can appreciate some of the ranges on
23 the cost side and on the benefits side that I have to put

Heritage Reporting Corporation

(202) 628-4888

1 through this viewer in order for our policy makers to
2 capture the essence of the impact both on the cost and the
3 benefit side.

4 When I summarize the major costs and benefits of
5 the rule, and I don't believe my colleague from ERS is here
6 right now, but this afternoon he may be able to put more of
7 the benefit side, the cases and deaths avoided, more into a
8 better focus and the monetary side. But from my preliminary
9 data it would suggest that the benefits far exceed the
10 costs.

11 Of course, you have to recognize that this is
12 preliminary, particularly on the indirect cost side that
13 we've really heard much about the last two days that we've
14 been aware of that we would like to quantify, as well as
15 qualify. We know these things exist. These would be
16 important pieces of information. Of course, we seek
17 additional data and comments on costs and benefits.

18 I would open up the comments, and if I could move
19 down then to comments that would pertain to your need for me
20 to clarify the framework that I presented in the material?

21 MS. GLAVIN: Phil, I'm going to suggest that given
22 that it is 12:15 and that we have an ERS presentation that
23 will also be of use for a discussion, that we break at this

1 point unless somebody needs to ask a question right now.
2 Let's try and keep it just to a couple of questions and then
3 discussion when we have more information on the table.

4 MS. SMITH-DEWAAL: Maggie, it's Caroline Smith-
5 DeWaal from CSPI. I appreciate you recognizing me. I have
6 to go. I've been asked to give a briefing to the House
7 Appropriation Committee members at 1:00 p.m., so I won't be
8 here this afternoon.

9 MS. GLAVIN: Okay.

10 MS. SMITH-DEWAAL: This is my one shot.

11 MS. GLAVIN: Okay.

12 MS. SMITH-DEWAAL: Of course, Charlotte will be
13 here all afternoon.

14 MS. GLAVIN: She will eagerly represent you.

15 MS. SMITH-DEWAAL: Very well. The one thing I
16 will need clarification on perhaps after lunch is the issue
17 of the Olson study. I have never seen an assessment that
18 says that meat is only responsible for eight percent of
19 foodborne illnesses. I have notes of the CDC outbreak data
20 that has outbreaks linked to food sources, so it doesn't
21 include outbreaks where there are unknown food sources. In
22 that listing, 20 percent of the outbreaks are linked to meat
23 and poultry products.

1 Now, I can do another assessment -- I don't have
2 it with me, and I'll include it in our comments -- that
3 includes the case percentile linked to meat and poultry
4 products linked to outbreaks. But I will get you that data.

5 I've never seen anything so low. We also believe that 20
6 percent figure is low compared to FoodNet data on
7 Campylobacter. That is just one point.

8 The other thing is, in the indirect impacts, you
9 haven't thought about lawsuits. The reality here is that
10 these illnesses are terribly devastating. When they occur,
11 about 90 percent of the people are hospitalized, and 20
12 percent die.

13 I have, and I will submit for the record, the
14 *Washingtonian* magazine article from July, 2000, in which a
15 woman with no high risk who didn't meet any of the high risk
16 criteria ended up with bacterial meningitis and with chronic
17 effects, with very severe effects. Two other women, both of
18 whom have independently called me, had miscarriages as a
19 result of that pate outbreak.

20 I'd like to submit this statement of Lisa Lee, who
21 lost twins as a result of the Sara Lee outbreak. Her babies
22 she lost 20 weeks into the pregnancy, and they were named
23 Andrew and Alicia. And Mary Winkerstorff, who also lost her

Heritage Reporting Corporation

(202) 628-4888

1 pregnancy at four and a half months. I would like to submit
2 these as actual examples.

3 The thing that I need hopefully for you to think
4 about is the issue which is very much -- it may not be part
5 of what the economists think about, but it's certainly what
6 the lawyers think about when they see cases like this.

7 There are issues around when a life is lost due to
8 listeria, it is not only an economic detriment to the person
9 who died. It is a serious tragedy for the people who
10 survive. There is loss of companionship issues, for a
11 miscarriage loss of potential, the potential child, the
12 potential life that was going to be. This is a tragedy for
13 the family, and in legal terms we talk about issues of pain
14 and suffering that accompany that kind of a loss. That also
15 goes to if you survive, but you have a chronic outcome.

16 I think you should consider this. I can see this
17 is not complete because this is the first time I have seen
18 one of these cost/benefit analyses where there are no
19 benefits enumerated. I mean, you talk about them, but
20 there's no number. We can debate the cost of a life. I
21 mean, you know, there's lots of vehicles for doing that, but
22 I think you need to add in one more thing. There is a
23 benefit to the industry to not have these very devastating

Heritage Reporting Corporation

(202) 628-4888

1 lawsuits and loss of corporate reputation.

2 I mean, we know what happened with Bill Marr and
3 the Sara Lee Corporation, but that can happen to many other
4 companies. Cargill recently experienced a similar recall.
5 I think that there are benefits on the corporate side, and
6 you need to consider in addition to the economic value of
7 the life that is lost, the loss to the family. That should
8 be an additional consideration.

9 We would be happy to ask the many women and
10 families who have contacted us following losses like these
11 to submit letters talking about what that pain and suffering
12 is like if you would like to go through that analysis as
13 part of your analysis, but I think without that, I mean,
14 it's clearly something that's going to come up if this reg
15 isn't implemented, if things continue as they are and if the
16 companies get sued. They are going to pay pain and
17 suffering losses every time they have to settle one of these
18 cases or when they go to Court. These can be huge. I think
19 that's a real gap in your analysis so far. Thank you.

20 MS. GLAVIN: Thank you for that, Caroline. I'm
21 sorry that you will not be able to be here for the rest of
22 the discussion. We will return at 1:30 to complete our
23 discussion on this topic.

Heritage Reporting Corporation

(202) 628-4888

1 (Whereupon, at 12:30 p.m. the meeting in the
2 above-entitled matter was recessed, to reconvene at
3 1:30 p.m. this same day, Thursday, May 10, 2001.)
4 //
5 //
6 //
7 //
8 //
9 //
10 //
11 //
12 //
13 //
14 //
15 //
16 //
17 //
18 //
19 //
20 //
21 //

Heritage Reporting Corporation

(202) 628-4888

A F T E R N O O N S E S S I O N

(1:37 p.m.)

1
2
3 MS. GLAVIN: We're getting down to the hard core
4 attendees at this meeting. What I propose to do is ask
5 Steve Crutchfield from Economic Research Service to make his
6 presentation because I think that will inform the discussion
7 of both Phil's and Steve's presentations. I think that
8 would be the most useful way to do that. Steve, are you
9 ready?

10 MR. CRUTCHFIELD: Sure. I'm Steve Crutchfield,
11 and I'm an economist from the USDA's Economic Research
12 Service. I'm head of the Diet Safety and Health Economics
13 Branch. What our group does is we look at a variety of
14 issues related to food safety, diet and health issues. Our
15 task is basically to put numbers on things.

16 The sort of work that we do and have done over the
17 years has been to look at in the case of foodborne illnesses
18 looking at what sort of costs foodborne illnesses impose on
19 society. When people get sick from things like listeria,
20 E. coli 0157:H7 and so forth that imposes a cost on society,
21 and our group has been working actively for a number of
22 years to measure what some of those costs are.

23 The second part of my job is to work with agencies

Heritage Reporting Corporation

(202) 628-4888

1 like Food Safety Inspection Service. When a rule is
2 proposed, or some action is taken designed to address a
3 public health issue such as listeria in ready-to-eat
4 products, what we do is take some of our economic analysis
5 tools and answer the question, what are some of the benefits
6 associated with these rules, because ideally what we want to
7 have in the end is a situation where the government society
8 expends resources to address a problem, in this case
9 listeria. We want to ensure that the benefits of whatever
10 we do are at least hopefully greater than the cost of
11 whatever it is we're trying to achieve. I'll give a brief
12 overview, and I apologize for not being here this morning to
13 hear Phil's remarks. I had an advance peak at his slides.

14 The issue here is a new RTE rule to prevent
15 premature death from listeria. What we did at ERS is we
16 started with some of the assumptions that were given to us
17 by FSIS that I understand Phil ran through this morning.
18 Estimated cases prevented at 25 to that should be I believe
19 248 rather than 48, estimated deaths prevented between five
20 and 50, and an estimate of some of what the costs of this
21 rule might be at \$68 million over ten years, which is \$48
22 million is present value terms. This is what the cost of
23 this proposed rule might be.

Heritage Reporting Corporation

(202) 628-4888

1 What we were asked to do is address what some of
2 the benefits of the rule might be. I'm an economist. I
3 have a Ph.D. from Yale, and I cannot start a talk without
4 going 'assume the following.' Economists are very fond of
5 making assumptions, and much of what I'm going to be talking
6 about today will depend and flow directly on the assumptions
7 we made during this analysis.

8 Running through them in no particular order, the
9 first is that all of the cases of Listeriosis that are
10 associated with this rule, the cases prevented from this
11 rule, will require hospitalization. I checked with my
12 experts, and we just don't have any good idea of the total
13 round of cases of listeria, how many end up in the hospital,
14 so we're assuming that all of these cases of listeriosis
15 will require hospitalization. We will be assuming that five
16 percent of the cases are moderate and 95 percent severe.
17 This is data that we got from working with the Centers for
18 Disease Control and their FoodNet active surveillance
19 system.

20 The third assumption is we're only going to be
21 considering adult illnesses and death, not perinatal or
22 maternal deaths. What I'm saying here is the economic
23 analysis is not going to include an analysis and benefits of

1 preventing deaths of unborn children. Economists get very
2 squeamish and squishy when asked to put a value on the
3 premature death of an unborn child, so for the sake of not
4 getting into that moral and ethical quandary we're only
5 going to be considering adult illnesses and deaths. Keep in
6 mind that's going to mean that some of our benefit estimates
7 are going to be lower than they otherwise would be if I as
8 an economist have a good way of dealing with that issue.

9 Finally, the last assumption is the effectiveness
10 of the rule in preventing cases will increase over a ten
11 year period. It's not realistic to assume that if the rule
12 were enacted say on July 1 that a year from now the rule
13 would be 100 percent effective and all of the deaths and
14 illnesses that we're talking about here would be immediately
15 prevented. So in our analysis we phased in the benefits of
16 the rule by accounting for the fact that it will take some
17 time for the rule to take effect.

18 There are two types of benefits we're going to
19 consider here. One is just the out-of-pocket medical costs
20 associated with cases of listeriosis. As I said, we assume
21 that 25 to 248 cases require hospitalization, and of those
22 20 to 198 cases the patient will survive.

23 Based on estimates done partly by Tonya Roberts at

1 ERS and also by my colleague, Paul Franzen, who is at ERS,
2 we're setting the medical costs associated with
3 hospitalization from listeriosis. For mild cases it's about
4 \$10,300; for severe cases \$28,300.

5 For the medical costs of the cases prevented, if
6 we take 20 cases and again go through this each year for ten
7 years, just if you add up ten years it's \$4.4 million in
8 nominal terms. In present value terms, accounting for the
9 fact that future dollars ten years out are worth less than
10 they are now, \$2.9 million in present value terms. For the
11 more severe assumptions that there would be 248 cases of
12 listeriosis prevented by this rule, the benefits would be
13 \$44.2 million in nominal terms or \$29 million in present
14 value terms.

15 Again, the assumptions we're working with are the
16 large numbers of cases of listeriosis come from an FDA risk
17 assessment. The small numbers of illnesses and deaths
18 prevented come from some work that's been done by the
19 FoodNet people, Paul Mead at Centers for Disease Control,
20 and extrapolating from that to what prevention of illness
21 might be associated with this particular rule.

22 The next issue we have to deal with is what is the
23 value of a life. In my Agency and the economists I work

Heritage Reporting Corporation

(202) 628-4888

1 with and economists generally have spent a lot of time
2 worrying about that particular issue. How do you put a
3 value in dollar terms on somebody who dies from any cause,
4 whether it's a foodborne illness, a traffic accident, an
5 unsafe product or what have you?

6 The approach economists have taken is they've
7 looked at the wages which are paid to high risk workers.
8 The idea here is if you pay people enough money, they will
9 voluntarily undertake risks to life and health in exchange
10 for money.

11 The predominant research in this area is kept
12 exclusively at Harvard University. What they've done is
13 they've looked at high risk occupations -- bridge builders,
14 tunnelers, perhaps fishermen in the Gulf of Alaska and what
15 have you -- and they've looked at the amount of extra money
16 that has to be paid for people to voluntarily undertake
17 risky occupations. Based on statistical analysis of the
18 data, they found that if you pay these people enough money,
19 between \$5 million and \$6 million, that will pay the extra
20 wages that these people in these high risk occupations have.

21 It results in an expectation of one extra premature death.

22 If you look at enough people in these risky
23 occupations and you have an expectation of one premature

1 death, you have to pay them \$5 million to \$6 million. In
2 the literature it's been called the value of a statistical
3 life. This \$5 million to \$6 million figure has been used
4 throughout the federal government to look at the benefits of
5 regulations which prevent premature death. It's been used
6 by the Consumer Product Safety Commission, the Environmental
7 Protection Agency to look at health risks from pollution.
8 It has been used by the Department of Transportation to look
9 at prevention of deaths from traffic accidents and so forth.

10 One of the problems that we at ERS have with this
11 particular approach, though, is you look at the people whose
12 values were considered; predominantly middle-aged, healthy
13 construction workers, predominantly males. They would
14 expect to lose about 36.5 years of life from these fatal
15 accidents from on-the-job injury.

16 That may not be particularly relevant for
17 foodborne illness cases because some of the susceptible
18 populations, for example, might be elderly people who would
19 only lose a few years of life or very young people who might
20 lose more than 36.5 years of life. We've developed a
21 procedure which adjusts this \$5 million to \$6 million figure
22 downwards for deaths that occur later in life and upward for
23 deaths that occur earlier in life.

Heritage Reporting Corporation

(202) 628-4888

1 For the sake of expediency and time, I'm going to
2 go through this very quickly. The two scenarios we dealt
3 with were five premature deaths prevented and 50 premature
4 deaths prevented. Cost per death when you account for the
5 age at which death occurs, and we do this by using data on
6 the percentage distribution of people who die from
7 listeriosis. There's a fairly large clump in the elderly
8 range and a fairly large clump early in life. Again, I'm
9 not dealing with premature death from unborn children.

10 We have a clump of deaths out there later in life,
11 which is why the cost per death is \$4.8 million rather than
12 \$6.1 million is the average the EPA uses now. If you look
13 at this over ten years and again phasing in the
14 effectiveness of the rule so that the benefits start
15 accruing in the out years and not immediately, the ten year
16 total is \$55.1 million in nominal terms or \$36.5 million in
17 present value terms for the low estimate of premature deaths
18 prevented and about \$500 million present value for the
19 larger estimate of 50 premature deaths prevented.

20 At this point, if you put this in the context of
21 the cost estimates that were presented earlier I believe it
22 was \$48 million present value terms over ten years so the
23 bottom line is do the benefits of this rule exceed the cost?

Heritage Reporting Corporation

(202) 628-4888

1 Well, it depends, as always, on the assumptions you make.

2 The low estimate of \$36.5 million for the five
3 deaths prevented per year over ten years is a little bit
4 less than the expected costs of the rule. If you believe
5 that the rule would prevent more deaths, if it would prevent
6 50 premature deaths again stretched out over ten years, the
7 benefits of the rule are \$500 million compared to \$48.2
8 million for the cost.

9 At this point, the question is do benefits exceed
10 cost? My guess as a professional economist is probably yes.

11 I would suspect that the benefits of the rule would likely
12 be greater than the costs, and that's for two reasons. One,
13 as I said, I'm not attaching any benefits to prevention of
14 deaths of unborn children. If you believe that has a
15 non-zero value, which I ethically believe that it does --
16 I'm just not prepared to estimate it yet -- then that means
17 the benefits would be greater than I presented here.

18 Also, to be consistent with the cost analysis
19 which was stretched out over ten years, I limited myself in
20 this analysis to just looking at benefits over ten years.
21 One would presume that the rule is going to stay in place
22 longer than ten years. If we start looking at years outward
23 past year ten, the benefits stream from years ten through 20

1 is greater than the cost stream in years ten through 20. So
2 as the rule progresses past ten years in implementation,
3 then the benefits grow faster than the costs. So I think in
4 the long run, again, there's evidence that the benefits in
5 the proposed rule would be greater than the costs. I
6 believe that is the end of my discussion.

7 MS. GLAVIN: Thank you very much.

8 MR. CRUTCHFIELD: Would you like me to take
9 questions now, comments?

10 MS. GLAVIN: What we've been doing, and you may
11 choose to stand there if you want, but we've been being
12 informal and being at the table and letting people comment
13 and ask questions as they like.

14 Questions either for Phil Spinelli or for Steve
15 Crutchfield on their presentations, what they included in
16 their work, what their assumptions were, where they came
17 from? Any questions? Charlotte?

18 MS. CHRISTIN: Charlotte Christin from CSPI. The
19 first question I have would be, did I hear you correctly
20 that EPA uses an estimate of \$6.1 million?

21 MR. CRUTCHFIELD: I believe that's correct. The
22 reason I'm a little hazy here is that originally what
23 happened with these labor market wage studies is there was a

1 range of \$4 million to \$7 million, and Congress a number of
2 years ago picked a midpoint.

3 The original studies where this methodology was
4 thought up were back in the past. The actual dollar depends
5 upon picking up and updating for inflation, so I apologize.

6 I did not check with my colleagues at EPA to see what exact
7 value they're using, but I believe it's around \$6.1 million
8 to \$6.5 million.

9 I believe this approach is also used in the
10 arsenic in drinking water rule. I'm not going to comment on
11 that. I know that's -- . That shows you that this approach
12 has been used elsewhere to value health risks.

13 MR. DERFLER: Phil Derfler from Animal Science.
14 Maybe you explained this, but you only talk in terms of
15 deaths, and maybe that's -- , but what about illnesses
16 prevented even if you don't quantify them by the rule?

17 MR. CRUTCHFIELD: I'm sorry. I closed down the
18 presentation. Earlier in the presentation I did present an
19 estimate on the hospitalization costs associated with the
20 cases of listeria, and that was around \$4 million.

21 MR. DERFLER: But that wasn't enough to push the
22 benefits, even the lowest of the benefits, over?

23 MR. CRUTCHFIELD: You're talking about \$10,000 to

1 \$30,000 per case, and you're talking at most 248 cases.

2 MR. DERFLER: Isn't it 2,500 cases?

3 MR. SPINELLI: I didn't hear the question.

4 MR. CRUTCHFIELD: The question was why are the
5 benefits just associated with measuring the cost of treating
6 the illnesses, forgetting the value of death. They appear
7 to be fairly low since we used 248 cases as a maximum
8 number.

9 MR. SPINELLI: Right. Right.

10 MR. CRUTCHFIELD: You multiply that by \$30,000 per
11 case, and it's not very large.

12 MR. SPINELLI: Yes. I guess I wanted to clarify
13 one thing, something that might be confusing. On page 17,
14 the estimates on that page is \$55.1 million. The cost
15 that's associated with just the -- is \$21.3 million. The
16 \$68.1 million over ten years represents both the cost -- and
17 the performance standards.

18 As I said, I am open for comment as to how to
19 better quantify the benefits from the performance standards,
20 but at this time there were no benefits that were quantified
21 at this time. I would welcome any suggestions or comments
22 on how to better quantify those benefits.

23 MS. CHRISTIN: This is Charlotte Christin from

Heritage Reporting Corporation

(202) 628-4888

1 CSPI. Is there any way you can look back at the analysis
2 you used for the HACCP rule and perhaps get some values for
3 Salmonella reduction from that?

4 MR. CRUTCHFIELD: Salmonella reduction? This
5 was --

6 MS. CHRISTIN: I'm speaking in terms of the
7 Salmonella performance standard. If we only are talking
8 about benefits from reductions in listeriosis deaths among
9 adults, there are lots of issues, but one of them being why
10 are we not talking about benefits from reduced illnesses due
11 to Salmonella and 0157:H7 specifically in fermented beef?
12 I mean, if the rule is much larger, why are we not looking
13 at the benefits of the larger rule?

14 MR. CRUTCHFIELD: If somebody were to give me
15 estimates of how many cases of Salmonella or E. coli 0157:H7
16 cases would be associated with this particular -- , we could
17 do a similar sort of analysis that would make the benefits
18 greater. I was just strictly addressing myself to the issue
19 of listeria.

20 MS. CHRISTIN: Okay. So you are looking for data
21 on Salmonella and 0157:H7?

22 MR. CRUTCHFIELD: Yes. The analysis that I
23 presented here for listeria we have done for other illnesses

1 caused by other pathogens. If you go to our website, which
2 is www.ers.usda.gov, and look for food safety, we have a
3 number of presentations where we've gone through exactly
4 this sort of approach to measure the costs associated with
5 0157:H7, Salmonella and other pathogens as well.

6 In theory, here's a request for information. If
7 somebody can give us information as to how this rule could
8 potentially reduce cases of Salmonellosis or 0157:H7 then we
9 could do this sort of analysis for those pathogens as well.

10 MS. RICE: Can we get a copy of your presentation?
11 Is that going to be available on your website?

12 MR. CRUTCHFIELD: I can't promise when it will be
13 available on the website. Probably the quickest thing would
14 be just send me an e-mail, and I'll send it to you.

15 MS. RICE: Okay. The second question is to follow
16 up on the last one. Have you done anything on perfringens
17 or bot; Clostridium perfringens as it relates to this
18 particular rule and the products associated with it?

19 MR. CRUTCHFIELD: Not associated with this
20 particular rule. We've done some research in the past on
21 Clostridium. That information is available on our website.
22 It's an older publication. We have not updated that cost
23 estimate in the last few years. What was the other one?

1 MS. RICE: Perfringens, Clostridium perfringens
2 and clostridium botulimon, both associated with these
3 products.

4 MR. CRUTCHFIELD: Not associated with these
5 particular products, no.

6 MS. GLAVIN: Bernie?

7 MR. SHIRES: Bernie Shires from AAMP. We're going
8 to be making comments in written form on some of these
9 issues after today, but I just wanted to direct something to
10 Phil. You asked for a lot of information that may not be
11 there. I guess one thing I'm wondering about a little bit
12 would be the number of plants that you've taken into your
13 sample. I'm not sure if, for example, plants that are under
14 state inspection, equal to state inspection programs, have
15 been figured in as part of this because they also have to be
16 involved in this if and when this rule is passed.

17 Now, most of the figures we've seen, I guess
18 there's about 6,500 federal establishments more or less,
19 maybe a few less than that, and about 2,500 state inspected
20 establishments in 27 states. These are plants that are
21 under what we call equal to inspections, so they carry out
22 the same regulations that the USDA does.

23 Most of these plants, virtually all of these

Heritage Reporting Corporation

(202) 628-4888

1 plants, are I'd say small or very small establishments. Of
2 that percentage, a good percent of them are very small. Of
3 all those, a higher percentage are involved, and I don't
4 have the figures with me now, but a higher percentage of
5 those kinds of plants are involved in processed products
6 production because of what they do, making large numbers of
7 products. I wonder if they were taken into account when
8 these plant numbers were estimated because I just get the
9 feeling that with the number of plants that you're talking
10 about it may be on the low side in terms of plants that are
11 going to be affected by the rule.

12 MR. SPINELLI: I will definitely agree. They are
13 certainly on the low side. The reason I used the figures
14 that I did is that it was the best available -- and it came
15 from the Census, so 1630 firms in total, are FSIS internal
16 data -- at least the products that I identified.

17 -- maybe 6,500, so any kind of data that you have
18 or any source of data that I could get my hands on that
19 would identify the number of plants, the type of products
20 that they produce and their volumes would be very helpful.

21 MR. SHIRES: Yes. I don't want to give an
22 incorrect impression. When I said 6,500, I think that's the
23 number of USDA plants under USDA inspection. That's not to

1 say that all of them make processed products.

2 MR. SPINELLI: Right.

3 MR. SHIRES: Especially when you get to the small
4 and the very small, the numbers may be higher. At the same
5 plants, having been factored into this obviously, a high
6 percentage of that would relate to processed products.
7 That's going to have to be part of this as well.

8 MS. GLAVIN: I think Phil's point is that to the
9 extent that you can provide him data that he can use, that
10 would be terrific.

11 MR. SHIRES: That's what we plan to do.

12 MS. GLAVIN: You're more likely to have that data.

13 MR. SHIRES: Yes. We'll give you that data.

14 MS. GLAVIN: Great.

15 MS. CHRISTIN: Charlotte Christin from CSPI. Do
16 you have any data to address the cost to industry from
17 recalls from litigation, from costs of attorney's fees
18 associated with outbreaks or recalls?

19 MR. CRUTCHFIELD: Not with this particular rule,
20 but I -- responding. We have just completed a report, which
21 is being released either today or tomorrow, which looks at
22 product liability and cases of foodborne illness and does a
23 statistical analysis trying to establish a relationship

Heritage Reporting Corporation

(202) 628-4888

1 between the nature and severity of the food poisoning or
2 foodborne illness case and the result of a jury verdict and
3 jury award. If you want to meet up with me afterwards and
4 give me your card, I'll arrange to mail you a copy, or it
5 will be available on our website within a few days.

6 MS. CHRISTIN: That would be great. Thank you.

7 I also will put a copy in the record of a *Food*
8 *Processing* magazine report that talks about some of the
9 costs associated with the Sara Lee outbreak. They spent \$76
10 million just to cover the cost of the recall. Thorn Apple
11 Valley spent between \$1 million to \$7 million on its recall.

12 The only reason those costs were lower or one of the
13 reasons the costs were lower was because the products were
14 already code expired.

15 As you can see, there are some real costs
16 associated in addition to loss of goodwill. It really does
17 benefit industry to have a strong regulation in place
18 because a lot of times consumers aren't going to remember
19 the name of a specific company, but they're going to
20 remember the type of product.

21 It inures to the benefit of industry to have a
22 strong regulation in place, and I think that it will
23 strengthen this proposal to have an accounting for those

Heritage Reporting Corporation

(202) 628-4888

1 costs in the economic analysis.

2 MR. SPINELLI: That's a good point. I appreciate
3 it.

4 MS. GLAVIN: Other questions and discussion?

5 RON: Ron -- . Just a point of clarification.
6 Steve, I believe you were looking at the benefits. You were
7 looking at the reduction in listeria illnesses and deaths
8 associated with the testing provision in the rule. Is that
9 correct?

10 MR. CRUTCHFIELD: That's right.

11 RON: Right. Okay. But when you were comparing
12 that with costs, the costs covered all the provisions in the
13 rule?

14 MR. CRUTCHFIELD: Yes.

15 MS. GLAVIN: Does everyone now understand how
16 these people do their analyses? Charlotte?

17 MS. CHRISTIN: I'm sorry. I didn't want to hog
18 the mike, but I guess I will. A question about your
19 inability to estimate the cost of fetal death. Tonya
20 Roberts from ERS had done some important work in the early
21 1990s, and she was able to place a value on that. Are you
22 able to incorporate some of her earlier analysis into this
23 analysis?

1 MR. CRUTCHFIELD: Tonya Roberts works for me, so,
2 yes, I'm aware of that. The work that she had done I
3 believe was in the case of Toxoplasma -- , although there
4 may have been some others.

5 MS. CHRISTIN: listeria?

6 MR. CRUTCHFIELD: listeria as well.

7 MS. CHRISTIN: Yes.

8 MR. CRUTCHFIELD: Let me give you a little bit of
9 the philosophical debate about this. When we were going
10 around updating some of our estimates and costs associated
11 with all foodborne pathogens, the question is how do you
12 place a value on a premature death.

13 There have been some economists who have argued
14 that the premature death of an unborn child does not have a
15 cost because that was never a person and that if the family
16 wanted to replace that, they could have another child, as
17 one economist put it to me in a Toxoplasma conference.

18 We could go through and assume that the death of
19 an unborn child would be statistically equivalent in cost
20 terms to the death of say a one-year-old or somebody who
21 would expect to lose 73 point something years of life. But
22 it's just the procedures among economists is that there is
23 no universally acceptable approach for that particular moral

1 or ethical issue of how you handle the fact that the child
2 was unborn at the time the fetal death occurred.

3 Another thing we're doing at ERS and trying to get
4 a handle on this is looking at not only deaths of unborn
5 children, but what happens when you have learning
6 disabilities or severe mental retardation. In earlier
7 approaches we valued that in terms of long-term acute care,
8 giving extra education costs. In other words, we're
9 recognizing these costs exist, and if we were to prevent
10 deaths of unborn children then there would be a benefit
11 associated with that.

12 In the past, Tonya and I kind of argued about
13 whether or not we should include these costs. Basically
14 because I spent some time looking at this, I just felt
15 uncomfortable professionally standing up and saying here's
16 exactly what the cost of the death of an unborn child is
17 because the economics profession hasn't really come to any
18 closure on the appropriate use of that value.

19 MS. CHRISTIN: Do you think that your new research
20 on the values placed at time of litigation would perhaps
21 give you some costs that you could use in this?

22 MR. CRUTCHFIELD: From what I recall of the report
23 that I mentioned earlier, I don't know. I'd have to check.

1 I don't think there's more than two or three cases that Dr.
2 -- looked at in her study where the nature of the lawsuit
3 was that an expectant mother contracted a foodborne illness
4 and then lost her unborn child. There may be some cases in
5 there, but I don't think that there would be enough evidence
6 from the data to make a reliable inference.

7 The other thing I'll caution about using sort of
8 litigation case studies from the legal profession is one of
9 the things that Jean Wesby found in her research is that
10 when a defendant company has a particularly weak case; that
11 is, they may face a non-zero probability condition in having
12 to pay both compensatory and punitive damages, they tend to
13 settle out of Court. What happens is, a lot of times it's
14 when these cases are settled out of Court we as economists
15 have no way of knowing what the settlement was because in
16 many cases the parties are bound to confidentiality.

17 That was one of the problems that we had in that
18 particular research project. A lot of the cases were
19 settled out of Court, so we didn't know what the jury
20 verdict would have been, and we didn't know what the
21 settlements actually were. I hope that answers your
22 question.

23 MS. CHRISTIN: I do think that it's difficult in

1 the time of a Republican Administration to think that there
2 might not be a value placed on a lost life, and I think that
3 other agencies do look at issues such as this. I think that
4 for companies that face these problems, they have to have
5 their own experts help them make decisions about the values
6 of these lives when they think about litigation strategies,
7 when they think about settlements. I understand it's not an
8 easy question. I understand there are a lot of assumptions
9 involved. I do think, however, if we're going to truly be
10 able to evaluate this rule it's important that we include
11 those things.

12 I also think we do have fetal deaths, but we also
13 have newborns who survive and face meningitis and other
14 serious illnesses. I'm not sure why we don't have more
15 information about that included in the analysis.

16 MR. CRUTCHFIELD: That's a good question. I'll go
17 back and as the final rule making goes forward, see if we
18 can come up with some more information to provide as the
19 final rule goes forward.

20 MS. CHRISTIN: We'll try, you know, with whatever
21 we can find. We will be sure that --

22 MR. CRUTCHFIELD: Again, if you have information
23 or know of sources of information that would help us, please

1 let us know.

2 MS. CHRISTIN: Great. Thanks.

3 MS. GLAVIN: Other questions? You wanted to make
4 a presentation?

5 MR. SHIRES: Yes.

6 MS. GLAVIN: Thank you.

7 MR. SHIRES: Bernie Shires with AAMP. I just want
8 to make a few brief comments. As I indicated before, we're
9 going to be submitting detailed written comments about the
10 proposal, including answers to a lot of questions that we've
11 been asked to provide answers to over the last three days.
12 We plan to do that in the spirit of helping this process
13 along.

14 I'll just say briefly that AAMP, the American
15 Association of Meat Processors, is an international trade
16 association. We have members in all 50 states, Canadian
17 provinces and several foreign countries. Our members
18 include meat and poultry processors, slaughterers,
19 wholesalers, retailers, caterers, as well as suppliers and
20 consultants to the meat industry.

21 While we have a few large establishments as
22 members, most of our members are small and very small
23 businesses. A high percentage of them are family owned and

Heritage Reporting Corporation

(202) 628-4888

1 operated establishments. In addition, there are 35 state
2 meat processing associations affiliated with us, and most of
3 their members, virtually all of their members, are small and
4 very small businesses as well, so we represent a fairly
5 large segment of the small and very small meat and poultry
6 processing industry.

7 As I said, we're going to be submitting detailed
8 comments, as well as answers to questions that you raised
9 during these discussions. But from talking to our members
10 and doing some preliminary survey work, we can say now that
11 if small and very small processors of ready-to-eat products
12 would have to follow this rule as it was written today, it
13 would probably force many of them out of the ready-to-eat
14 business or at least to consider getting out of that
15 business.

16 As you know, many small and very small processors
17 make a wide variety of products, especially in this
18 processed products area. For those who are not convinced
19 that they might be better off giving up making these kind of
20 products, many might, on the other hand, be forced to take
21 another attack; that is to stop making that wide variety of
22 products and limit themselves to only a few.

23 Unfortunately, this would greatly hurt the

Heritage Reporting Corporation

(202) 628-4888

1 strength of these processed product small manufacturers
2 because their strength in marketing, their strength in their
3 markets, really comes from the diversity of products that
4 they do, as well as specialty and ethnic type products.
5 Their strength is the niches they work in. For this to be
6 taken away from them would cause these businesses obviously
7 serious harm.

8 In listening to the discussion over the last
9 couple days, we see great problems with finding meaningful
10 HACCP plans, including critical control points, that small
11 and very small plants can afford and then implement. A lot
12 of this I think came from the discussions, the excellent
13 discussions that were held on Tuesday, which was more of a
14 scientific discussion. Those discussions and the
15 possibilities that were pointed out, many of these
16 possibilities would carry very large price tags. At this
17 point, we don't see how a lot of these small folks would be
18 able to do this.

19 In my discussions that I've had with colleagues in
20 other trade associations, similar problems exist, and other
21 problems, for that matter, exist for large establishments.
22 The specter of -- HACCP plans has been raised several times,
23 plans that would fulfill regulatory compliance, but not

Heritage Reporting Corporation

(202) 628-4888

1 really do anything as far as solving the problem with
2 listeria. Obviously that's not something that industry or
3 USDA wants to get into at all.

4 We're also concerned about what we don't see, I
5 guess would be the way to put it, as viable corrective
6 actions that could be taken as part of a HACCP plan to
7 control listeria by small plants.

8 The alternative SSOPs, the testing, will cost a
9 great deal of money, and we feel more than what has been
10 estimated in the estimates that have been in the rule so
11 far. There was discussion about holding and testing for
12 large plants. 'Hold and test' also affects small plants as
13 well in a different way. It causes great problems for
14 plants in that for most of the product produced is going to
15 customers. The product is already spoken for. They don't
16 have the ability to hold large amounts of product.

17 We think that whatever is eventually decided or
18 made as a rule, USDA really needs to take a leadership role
19 in working with AAMP and with the other trade associations
20 to provide help to the small and very small plants in
21 complying with this rule or the other rules formulated.
22 These things should include process validation, as well as
23 ways for the small and small plants to comply with

Heritage Reporting Corporation

(202) 628-4888

1 performance based standards.

2 There would need to be very clearly laid out
3 guidelines for processors we think, maybe technical
4 assistance to small and very small plants similar to what
5 was done during preparation for HACCP. If you remember back
6 then, the small and the very small plant HACCP technical
7 training program began as part of discussions with USDA
8 about how things could be done to help these plants. In
9 fact, the very first technical sessions were held in AAMP's
10 offices by USDA. Possibly small and very small plants will
11 then cooperate with larger plants to formulate means of
12 complying with the listeria rule.

13 The other possibility which happened during HACCP
14 was to get the land grant universities involved. We worked
15 with a lot of those folks to begin with. Get a lot of the
16 animal science and microbiological departments at those
17 universities involved.

18 To answer a couple of questions that were raised
19 yesterday, though, we've already started moving ourselves in
20 some areas. AAMP is right now in the process of producing a
21 video with the help of our plant members and science
22 consulting members and universities on how to do a testing
23 program in a small plant and even the possibility of small

Heritage Reporting Corporation

(202) 628-4888

1 plants doing it with their own equipment. Those such things
2 are possible, and that's something we want to do as part of
3 a video.

4 The other part of this would deal with how to --
5 plants in a way to prevent listeria, how to do a good job --
6 plants. AAMP has offered several seminars on dealing with
7 listeria and process validation, and we're setting up more
8 seminars as well.

9 There have already been discussions at our
10 association about acting as a facilitator to negotiate with
11 laboratories that are supplying and consult members of our
12 association to negotiate for costs that small and very small
13 plants would be able to afford, so this is something that's
14 already been started.

15 The other thing I wanted to mention was the
16 question about the guidelines. The guidelines that the
17 Agency published came out late last week. I haven't had a
18 chance to look through them very well yet, so I'm not going
19 to say anything about them other than to say that it would
20 be helpful in the future when the guidelines are published
21 that we can get a hold of them as soon as possible so that
22 we can run them by, so we can get them to the members of our
23 meat inspection committee and our science committee and

Heritage Reporting Corporation

(202) 628-4888

1 people at the universities so they can give us some feedback
2 on them. That would be very helpful.

3 I'm just going to mention one thing in passing
4 that may create a few chuckles around the table. There is
5 nobody from field operations here. I don't see anybody
6 anyway. Oh, there she is. Okay. I didn't see you there.
7 It might be of interest to you to know that on one USDA
8 survey, and I won't say where it is, the inspectors were
9 going to plants and telling everybody they were going to be
10 enforcing this new rule within a week or so, the rule being
11 the USDA listeria rule. Don't worry. This was taken care
12 of at the district office level. I just want to emphasize
13 that it never should be said that program employees at USDA
14 don't want to do their jobs.

15 In closing, I guess I'd like to say that industry
16 and USDA share a mutual goal concerning listeria. I guess I
17 think our mutual goal is to make sure that it isn't in the
18 food that the industry produces. And that consumers don't
19 eat food and then get sick with listeriosis.

20 At this point, we're going to provide as much
21 information as we can, and I hope to have more discussions
22 with people in the Agency about what exactly they would need
23 to be helpful from our neck of the woods, so to speak. At

Heritage Reporting Corporation

(202) 628-4888

1 this point, I guess the way the rule is laid out today we
2 don't see that the rule as proposed by USDA is the way to
3 accomplish those goals, and hopefully we can go over the
4 next one, however long it takes. We'll be able to achieve
5 those goals through changes and other modifications.

6 Thank you.

7 MS. GLAVIN: Thank you. That was very helpful.
8 It would be particularly helpful to the extent that you can
9 be specific about what are the provisions that, for example,
10 might cause a plant to stop producing a product or to stop
11 making ready-to-eat product and even more useful if you
12 could go beyond that and suggest alternatives that would
13 achieve the goal without that negative impact. I know
14 that's easier said than done, but the more specific you can
15 be the more useful it is.

16 MR. DERFLER: Phil Derfler from Animal Science.
17 The guidance material is drafted. We tried to get it
18 available so we'd have it for this meeting, but you can take
19 a look at and give us comments on it.

20 MR. SHIRES: Oh, I understand that. We're going
21 to do that. We talked about it a while back. It just
22 seemed as if it would have been helpful if we could have it
23 at that time, too, but we're certainly going to do that now.

1 We're going to give this to our people.

2 MR. DERFLER: Mimi and Paul and a lot of other
3 people worked very hard on that.

4 MR. SHIRES: Oh, I know. I'm not throwing any
5 stones. I know that everybody worked hard to get it done
6 and to get it out. It's just unfortunate with the timing
7 the way it was that we weren't able to do that, and that it
8 wasn't able to be done.

9 MS. GLAVIN: Okay. Other comments or questions?
10 Stan?

11 MR. EMERLING: Stan Emerling representing the
12 North American Meat Processors Association. I was listening
13 to the conversation and I just have some thoughts which --

14 MS. GLAVIN: Can you stay closer to the
15 microphone?

16 MR. EMERLING: Sure. I'm sorry. I just jotted
17 down some thoughts, which -- conversations here, but I would
18 assume -- . Regardless of the -- , I don't think any of us
19 want to produce product that can cause illness or death.

20 I think the moral question here is whether the law
21 can accomplish what -- types and correlations of listeria
22 and bacteria, the illness causing illness and side effects.

23 I really think the question is whether the information

Heritage Reporting Corporation

(202) 628-4888

1 should be approached through testing of the performance
2 standard without the regulatory implications would be a
3 first step that should be taken, after which we have that
4 information that could be conveyed and put all together and
5 then see what we should do.

6 It just seems that if we know what's causing the
7 illness, it's Lm. But we're not sure of its correlation to
8 where it comes from -- the environment -- if we could come
9 up with some of those answers before trying a new regulation
10 -- six months or whatever it may be. It's just a
11 philosophical question --

12 MS. GLAVIN: Thank you, Stan. Anything more?
13 Charlotte?

14 MS. CHRISTIN: Charlotte Christin, CSPI. I
15 understand the point that Stan is making. I think that the
16 problem is the deaths and illnesses continue.

17 It's been more than two years since the Sara Lee
18 Bilmar outbreak. We have continued to have recalls. We
19 have continued to have more deaths and illnesses. At some
20 point you've got to stop banging your head against the wall
21 and figure well, maybe I should change my approach.

22 I think one of the reasons why we were so pleased
23 that the Agency was able to move this proposal forward is to

1 see that there has been progress on this. This is one of
2 the reasons we submitted a petition. We were anxious to get
3 some sort of change. We don't want to keep banging our
4 heads on the wall, and we don't want to keep seeing deaths
5 and illnesses.

6 MS. GLAVIN: Thank you. I sense that we are about
7 wound down. I don't want to cut anyone off who has
8 additional questions or comments. Thank you, especially for
9 you who stayed until the very last.

10 I have found this to be a very useful several
11 days. I think the level of discussion has been extremely
12 high, and there's an enormous amount of good information
13 shared and an enormous amount of real effort to address what
14 we all agree is a problem. Thank you.

15 (Whereupon, at 2:28 p.m. the meeting in the above-
16 entitled matter was concluded.)

CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

Public Meeting to Receive Comments

Name of Hearing or Event

N/A

Docket No.

Washington, D.C.

Place of Hearing

May 10, 2001

Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 188 through 322, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by Marcia Logan, who was in attendance at the above identified hearing, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript (1) by preparing the typewritten transcript from the reporting or recording accomplished at the hearing and (2) by comparing the final proofed typewritten transcript against the recording tapes and/or notes accomplished at the hearing.

5-10-01

Date

Karen StrykerName and Signature of Transcriber
Heritage Reporting Corporation5-10-01

Date

Lorenzo JonesName and Signature of Proofreader
Heritage Reporting Corporation5-10-01

Date

Marcia LoganName and Signature of Reporter
Heritage Reporting CorporationHeritage Reporting Corporation
(202) 628-4888