

Pet Food Institute (PFI) Meeting

January 24, 2014

Attendees: Daniel McChesney, CVM; Sharon Benz, CVM; Terry Proescholdt, CVM; Michael Taylor, OFVM; Kari Barrett, OFVM; Laura Pillsbury, OFVM; Megan Bensette, OFVM; Duane Ekedahl, Pet Food Institute; Peter Tabor, Pet Food Institute; Jill Franks, MARS; Randy King, P&G; Chris Cowell, Nestle Purina

Purpose

PFI wanted to relay concerns shared at the December 12, 2013 meeting with Mike Taylor with the overarching goal of maintain information-sharing meetings with FDA and to continue to demonstrate industry progress in ensure product safety.

Area of Concern: FDA's "zero tolerance" policy for *Salmonella* in pet food

***Salmonella* in Animal Food Compliance Guidance CPG 690.800**

- **FDA characterization of "significant risk" of pet food to human health.** PFI believes the risk of *Salmonella* to human health via transmission from pet food should be stated with less emphasis. FDA data documents a significant decrease in the rate of *Salmonella* found in pet food (including raw food) from 15+% to 2.5%. (Used for reference: USDA allows 7.5% in raw poultry.)
- **Pet food associated with higher *Salmonella* risk to human health in guidance.** PFI would like to see data on human health risk posed by *Salmonella* in animal feed.
- **FSIS *Salmonella* Action Plan frames meat and poultry as a very large source of contamination.** FSIS goal is to prevent 5,000 *Salmonella*-related illnesses/year. Illness incidence as a result of pet food is much lower (~ 200 cases over the past 40 years).

PFI Data on rates of *Salmonella* found in pet food

Multiple tests, some with non-distributed plan production lots (dry food) that tested positive for *Salmonella* and some with non-distributed pet food and recalled pet food. Found very low levels of *Salmonella*, ranging from <.003 MPN/gram (in the majority of the samples) to .639 MPN/gram.

Lack of definition on infectious dose

Additionally, infectious dose is not clearly defined. Definition of infectious dose varies greatly, even within FDA publications. A reasonable middle ground would be 15 organisms. Pet food with *Salmonella* frequently tests lower than this. There are complicating factors, such as individual susceptibility and the variation of bacteria species, strain or subtype.

McChesney noted that FDA's zero policy tolerance is really a 95% tolerance level with a 5% confidence interval.

Other arguments

- Human exposure to pet food is minimal
- Outbreaks attributed to dry pet food have been minimal compared to other food commodities

PFI proposed next steps:

- Promote consumer action-oriented public health campaigns (i.e., hand washing). Many companies already including this on their labels and websites.

- Continued data and information sharing with FDA.

When asked by Taylor for specific asks:

- **Change in FDA communications to put actual risk of contamination in perspective. Would also like to see more communications on what industry is doing to minimize risk. FDA's communications on its annual salmonella survey focus on the message that the rate of *Salmonella* is too high. PFI would like to see the communications on this study tempered/focusing on actual risk.**
- **Currently any detection of *Salmonella* mandates a recall. PFI would like to see a level of contamination or a list of particular *Salmonella* serotypes that warrant a recall.**

Taylor noted this wasn't a decision-focused meeting but FDA would keep these asks in mind moving forward.

FDAAA

1. Pet food labeling research –MARS research has found that current labeling is very confusing to consumers, esp. for terms like “crude,” “nutritional content,” and “guaranteed analysis.” Consumers like labels with the term “complete and balanced” and that specify appropriate life stage (i.e., adult, senior). Research also demonstrates that consumers want to know where their pet food is made. **ASK: PFI would like to work with FDA on this draft regulation, will submit comments, request consideration of timing so PFI has time to prepare research when submitting comments.**

Pet Food Institute Review with FDA



January 24, 2014



PFI Participants

- Randy King, DVM, PhD – Procter & Gamble Pet Care; Member, PFI Board; Member, PFI Regulatory Affairs Committee
- Jill Franks – Mars Pet Care; Chairperson, PFI Regulatory Affairs Committee
- Chris Cowell – Nestle Purina Pet Care; Member, PFI Regulatory Affairs Committee; Chairperson, PFI Product Safety Subcommittee
- Duane Ekedahl – President, PFI
- Peter Tabor – Vice President, Regulatory & International Affairs, PFI



FDA Review Agenda

- Introductions
- *Salmonella* and Pet Food – Review and Potential Next Steps
- FDAAA – Opportunities for Input from PFI
- Closing



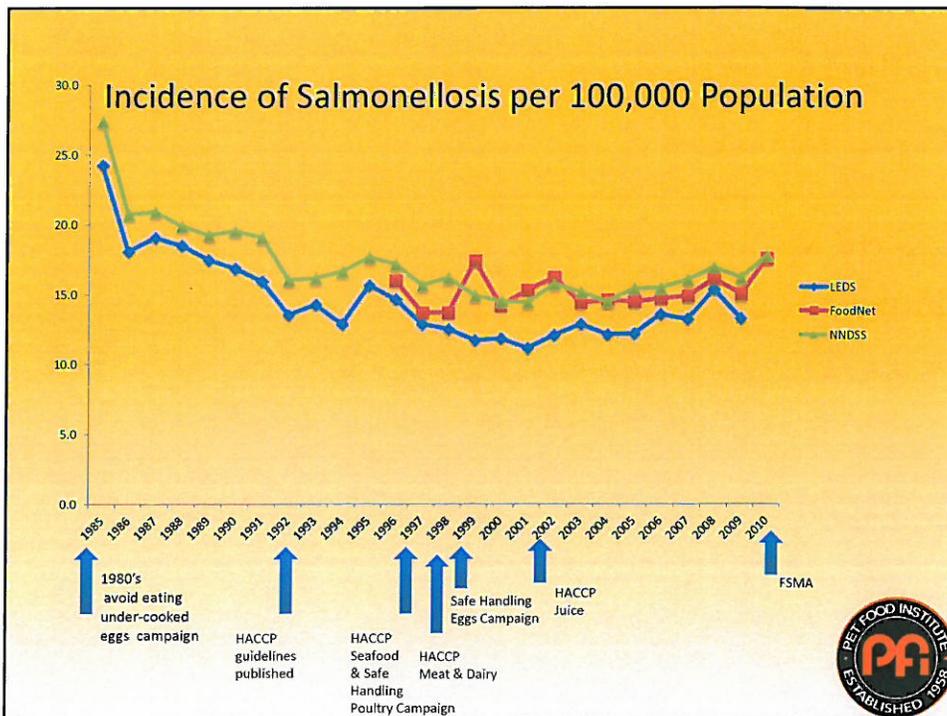
Salmonella and Pet Food – Overview and Potential Next Steps

- PFI Input on *Salmonella* in Animal Food Compliance Guide (CPG 690.800)
- Review of *Salmonella* in pet food
- Potential next steps



Salmonella in Animal Food Compliance Policy Guide 690.800

- FDA characterization of “significant risk” of pet food to human health
 - FDA data: *Salmonella* rate for all pet foods tested, including raw diets, fell in last 10 years from 15+% to 2.5%
 - 5% lower than the USDA allowable *Salmonella* rate for raw poultry
 - Less than 0.1% of reported cases of human salmonellosis are attributed to pet food
- Different treatment of pet food and animal feed
 - Does FDA have data on human health risks posed by *Salmonella* in animal feed?
- USDA FSIS *Salmonella* Action Plan – December 2013
 - Goal: prevent 5,000 Salmonella-related illnesses/year
 - 2011 goal: 20,000/year reduction in illness



Human Salmonellosis Cases/Outbreaks Attributed to Pet Food/Treats

- 1976
 - 2 cases (mother & daughter) ; S. Havana ?; Report from Eugene Oregon Register; Attributed to dry dog food
- 1995
 - Cases ?; Salmonella Infantis; Report from M. Imanishi presentation at IPPE, 2013; Attributed to pig ear dog treats
- 2004-2005
 - 9 cases; Salmonella Thompson; Report from M. Imanishi presentation at IPPE, 2013; Attributed to beef/salmon dog treats
- 2006-2008
 - 79 cases (out of a total of 127,490 cases [LEDS] or 0.06%)
 - Outbreak strain: S. Schwarzengrund
 - Attributed to dry pet food from a single plant
- 2012
 - 51 cases (out of a total of 40828 cases [LEDS for 2010] or 0.1%)
 - Outbreak strain: S. Infantis
 - All attributed to dry pet food from a single plant



A Typical Year for FDA *Salmonella* Recalls and Illness Attributed to Pet Food - 2011

2011 Dry Pet Food <i>Salmonella</i> Recalls	3
2011 Pet Treats <i>Salmonella</i> Recalls	7
2011 Human Food <i>Salmonella</i> Recalls	60
2011 Human Salmonellosis Attributed to Pet Food	None



Why Are We Seeing So Few Outbreaks?

- Cases not identified – neither case nor outbreak data support pet food (or pet ownership) as a major contributor
- No link to Pet Food – many other sources of *Salmonella* in the home
- Variable *Salmonella* Potency – very complex to address, yet CPG considers it for animal feed
- Insufficient Infective Dose/Exposure – can be risk-assessed and managed through consumer education

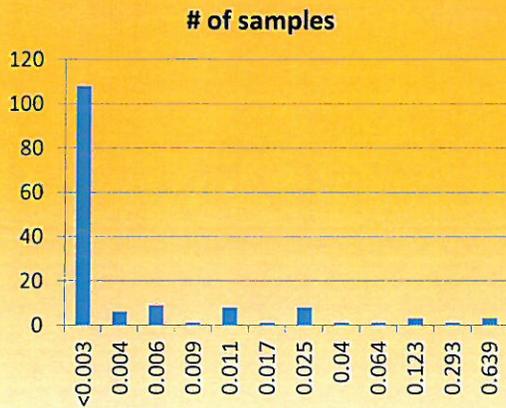


Examples of *Salmonella* Quantitation Efforts

- Objective
 - Determine *Salmonella* concentration in finished extruded pet food product with best microbiological methods available.
- Approach
 - Use non-distributed plant production lots that tested positive for *Salmonella* (post-extrusion) to establish definitive bacterial concentration, for possible use in risk assessment



Most Probable Number – Range of Samples 3 lots (150 samples)

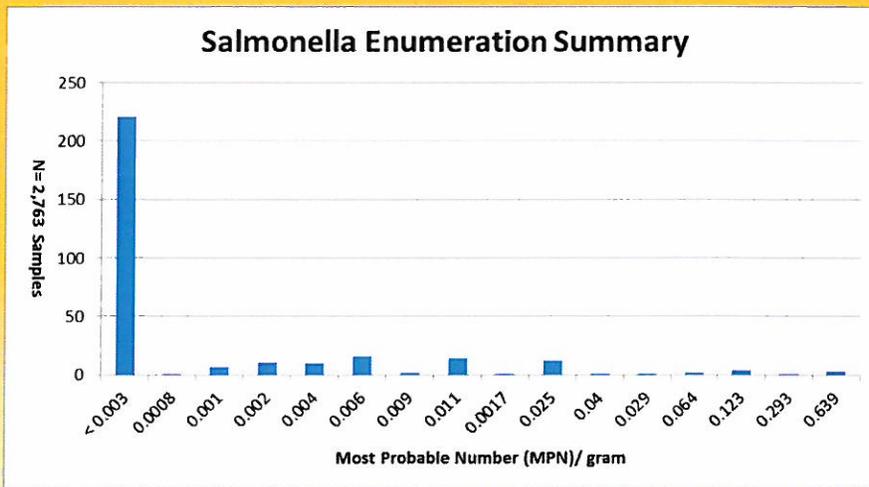


MPN/gram	# of samples
<0.003	108
0.004	6
0.006	9
0.009	1
0.011	8
0.017	1
0.025	8
0.04	1
0.064	1
0.123	3
0.293	1
0.639	3



MPN Results on Finished Product

Salmonella Enumeration Summary



What Do We Know About Infectious Dose, Microbial Risk Assessment, and the Application of these to Zero-Tolerance?



A Quote from Poultry Reviews

- "...quantitative risk assessments can provide some indication of relative risk by linking the level of a pathogen to some measure of human health impact." (Mead et al. 2010)



Definition of Infectious Dose

- “It is well recognized that infectious dose cannot be expressed as a **single numerical input** but is, **instead, a range of concentrations** with somewhat defined probabilities of causing infection and/or disease.” (emphasis added; RTI, 2009 for FDA)
- “For practical purposes [infectious dose] might be defined as ‘a dose at which an organism can reproduce in the host and produce a measurable effect.’” (Johnson, 2003 for OSHA)



Other Infectious Dose Factors

- There can be substantial variability:
 - Individual susceptibility (young/elderly/immuno-compromised)
 - Differences in infectious dose as a function of species, strain, or subtype of the organism in question
- **We found many different references – covering a wide range!**



Salmonella Infectious Dose References

Year	Author	Comments	Type	Non-typhoidal Infectious dose
1976	D'Aoust & Pivnick, 1979	<100 organisms/100 g of chocolate; 1000 salmonella per serving of contaminated ice cream	Editorial – no data	<100
1985	D'Aoust, 1985	Salmonella in Cheese related outbreak- author uses cases (recall of food eaten) to reconstruct MPN	Publication	1
1998	Vought & Tatini	Salmonella in ice cream – suggests protection of high sugar and fat of matrix lead to lower infective dose	Publication	26
2001	Infective dose in volunteers (Kothary & Babu)	>100,000 organisms- made note that it depends on strains used and physical conditions of individuals exposed	publication	>100,000 organisms-
2001	Safe Practices for food processes Chapter IV	10-100,000 (number of cells)	Produce related book chapter	10-100,000
2003	WHO	Ingestion of Innoculum with 10 ⁹ to 10 ⁸ CFU	Authoritative body	10 ⁸ to 10 ⁹
2009	RTI; Fresh produce risk ranking tool prepared for FDA	Infectious dose can't be expressed as a single numerical input, but is a range 15-20 for <i>Salmonella enterica</i> and 100,000 for <i>Salmonella typhi</i>	Produce related risk assessment tool	15-20
2009	FDA Bad Bug Book	15-20 cells depends on health of host and strain differences	Manual	15-20
2010	Public Health Agency of Canada- (Greig)	Some pathogens infect at 1-100 units; although volunteer studies indicate high infectious dose, outbreak data shows 10-10 ⁹ CFU	Presentation at meeting	1-100
2010	FDA CPG 527.300 – Dairy	"as little as 15-20 organisms can cause illness"	Authoritative body	15-20
2011	PHAC	1000 for non-typhoidal; also discusses sensitive population s that may be susceptible to lower levels.	Pathogen safety data sheet	1000
2011	Klochko & Wallace	Although infectious dose varies, a large inoculum is thought to be necessary to overcome stomach acidity.....about 10 ⁶ . Different stomach conditions can decrease infective dose to 10 ³ cells	Infectious disease physicians may be good "experts"	10 ⁶
2012	FDA Bad Bug Book	"Infective dose as low as one cell depending on age and health of host and strain..."	Contact Mr. Thomas Hammack?	1

Expert Input on Zero Tolerance Approach – Mead et al. 2010

- In November 2008, an international group of experts was convened to consider the principal scientific and technical factors that affect the setting of a microbiological criterion for *Salmonella* contamination of raw chicken
- Of particular concern: use of criteria implying a zero tolerance for *Salmonella* and suggesting complete absence of the pathogen
 - "[This] notion can be interpreted differently by various stakeholders and was considered inappropriate because there is neither an effective means of eliminating *Salmonella* from raw poultry nor any practical method for verifying its absence.
 - "Therefore, it may be more useful at present to set food safety metrics that involve reductions in hazard levels. Such terms as 'zero tolerance' or 'absence of a microbe' should be avoided unless defined and explained..."
 - "Risk assessment provides a more meaningful approach than a zero tolerance philosophy..."



Zero tolerance – Mead et al. (2010)

- “The adoption of quantitative risk assessment practices in microbiological food safety makes evident the reality that zero risk is unattainable...”
- “The choice of zero tolerance, implying the complete absence of exposure understanding, may be regarded as the expression of a regulatory preference for the precautionary principle, and has little to do with food safety and human health.”



Moving the Conversation Forward

- Pet food is not human food
 - Human exposure is minimal (no allergen requirements FSMA Animal Food proposed rule)
- Infectious dose of *Salmonella* is likely >15 organisms
- Positive tests often indicate very low level contamination (<1 organism/375 g sample) in pet food
 - Does this constitute a credible public health risk?
- Outbreaks attributed to dry pet food compared to other food commodities have been minimal
- “Zero” becomes more elusive as controls improve



Next Steps for FDA Consideration

- Increased collaboration with FDA on potential “fixes”
- Promote industry-wide public health campaigns (e.g., hand washing statements on labels and/or websites, etc.)
 - Companies are doing this on their labels, websites
 - PFI has supported balanced and factual “safe handling of pet food” statements, such as the one adopted by AVMA this year.
- Take a more risk-based approach to what “zero” means for *Salmonella* in pet food, as has been done for microbial concerns in animal feed and human food



Food & Drug Administration Amendments Act (FDAAA) of 2007

Opportunities for PFI Input



FDAAA Questions and Opportunities

- Where in the process is the Pet Food Labeling draft regulation?
 - Opportunity to work with FDA on the draft?
 - Research has identified ways to improve pet food labels for our consumers
- How will FDAAA address nutritional, ingredient standards?
 - Relationship with AAFCO standards?
- Will the draft regulation be issued in the CFR?
 - Relationship with AAFCO, state laws? FSMA?





PET FOOD LABELING SUMMARY

NO ONE

reads the back of pet food labels

...they are confusing and overwhelming

If they do, they are only looking at...

2-3 first ingredients
% of protein & possibly fat
 serving sizes (with new brands)

Issues with Current Label...

Ideal Future State...

 <p style="font-size: 0.8em;">Long, run-on sentences are intimidating. Ingredients "require a Ph.D. to understand"</p>	<div style="border: 1px solid #0070C0; padding: 2px; text-align: center; font-weight: bold; font-size: 0.8em;">INGREDIENTS</div> 	 <p style="font-size: 0.8em;">Breakouts with headers and simplified names are key. Consider using larger fonts and showing what purpose each ingredient serves</p>
 <p style="font-size: 0.8em;">There is a total misunderstanding of how to read this section. "Crude" is seen as negative, and "min/max" is confusing</p>	<div style="border: 1px solid #0070C0; padding: 2px; text-align: center; font-weight: bold; font-size: 0.8em;">GUARANTEED ANALYSIS</div> 	<p style="font-size: 0.8em;">"Nutritional Facts" and white & black chart are more familiar; also consider: Showing how much of each nutrient is needed daily</p> <p style="font-size: 0.8em;"> Tying this to the ingredients list and feeding guide</p>
 <p style="font-size: 0.8em;">While an endorsement is a plus, many are unsure if the FDA monitors pet food</p>	<div style="border: 1px solid #0070C0; padding: 2px; text-align: center; font-weight: bold; font-size: 0.8em;">NUTRITIONAL STATEMENT</div> 	<p style="font-size: 0.8em;">Badges are easier to read. Complete & balanced not understood. FDA is a more well known entity (AAFCO is completely unknown)</p>
 <p style="font-size: 0.8em;">"Distributed by" is misunderstood and suggests no responsibility for food quality</p>	<div style="border: 1px solid #0070C0; padding: 2px; text-align: center; font-weight: bold; font-size: 0.8em;">MANUFACTURER STATEMENT</div> 	<p style="font-size: 0.8em;">Identification of the manufacturer is important. Also the location and where the food is made, if possible</p>



Conclusions

- Collaborate with FDA to ensure that policy/guidance on *Salmonella* in pet food is based on updated, science- and risk-based assessments
- Identify opportunities for early input into FDAAA ingredient, nutrient and labeling rulemaking



Backgrounder for Pet Food Institute Meeting

Date: January 24, 2014
Time: 11:30am – 12:30pm
Location: CVM – Conference Room 152

Subject: FDA meeting with Pet Food Institute (PFI)

Attendees:

FDA

Michael Taylor, Deputy Commissioner, OFVM
Laura Pillsbury, Special Assistant, OFVM
Kari Barrett, Advisor for Public Engagement, OFVM
Daniel McChesney, Director, Office of Surveillance and Compliance, CVM
Sharon Benz, Director, Division of Animal Feeds
Terry Proescholdt

Pet Food Institute

Duane Ekedahl, President, PFI
Peter Tabor, Vice President, PFI

Members

Randy King, DVM, PhD, Proctor & Gamble - Board Member
Jill Franks, Mars Pet Care – Chair, Regulatory Affairs Committee
Chris Cowell, Nestle Purina Pet Care – Chair, Product Safety Subcommittee

Purpose: PFI requested this meeting to discuss new industry data on assessing the public health risk of salmonella in pet food. They would also like to provide input on FDAAA.

Agenda:

- 1) Introductions
- 2) Salmonella in Pet Food – an Examination of the Record
- 3) FDAAA – Possible input from PFI

Background:

- FDA last met with PFI in December 2013. During that meeting, PFI expressed its concerns about the Preventive Controls Rule and FDAAA, see Tab A.

Salmonella (see Tab B)

- Salmonella does occur in pet food at a rate significantly higher than in human food.

- Prevalence of salmonella in pet food is significantly lower than other animal foods and has been going down for the last 5+ years. While salmonella is going down, it is still a problem and people still become ill from contact with pet food.
- Pet food is a small contributor to the overall level of human disease related to salmonella

Attachment(s):

Tab A: Minutes from the December 2013 meeting

Tab B: Salmonella and Pet Food slides

Executive Secretariat Contact: Felecia Hogue, ESS, 240-402-2913

Tab A: Minutes from December 12, 2013 Meeting

Attendees:

Bernadette Dunham, CVM
Tracey Forfa, CVM
Daniel McChesney, CVM
Sharon Benz, CVM
Terry Proescholdt, CVM
Michael Taylor, OFVM
Sharon Mayl, OFVM
Megan Bensette, OFVM
Duane Ekedahl, Pet Food Institute
Peter Tabor, Pet Food Institute
Jill Franks, MARS
Randy King, P&G
Chris Cowell, Nestle Purina

PFI Areas of Concern about Preventive Controls Rule

1. Requesting extension of comment period – essentially see the rule as requiring twice as much as human preventive controls but comment period being half the amount of time.
2. Concerned that available data and science do not warrant the increased scrutiny of pet food, especially surrounding reports (or lack thereof of human illness).
3. PRIA in preventive controls rule is largely underestimating costs. Mike noted this is a draft PRIA, the final is yet to be released but if PFI is interested in meeting with our economists, we'd be happy to set up a meeting.
4. Records management requirement needs to consider context. Challenges include sharing electronic documents with FDA without explanation.
5. Third party audits concerns around high-risk facilities/countries and timing of certification and accreditation. Sharon explained the regulation is not as restrictive as it appears; there are a variety of ways to certify.
6. Communications
 - a) Timing of jerky and FSMA mixed messages in media and suggested FSMA rule was a result of jerky, argued FDA should have spread out these announcements. Result was a concerned and uninformed consumer (MARS reported getting thousands of calls from consumers despite not having a jerky product on the market). FDA explained it was purely a result of the government shutdown.
 - b) Communications on preventive controls rule artificially inflates incidence of human illness attributed to pet food. U.S. pet food industry is one of the most regulated in the world, so PFI has concerns with our statement that FDA is issuing the PCAF rule in part because pet food is not regulated.

Dan noted that lack of illness in this area is largely due to good business practices and the statement about lack of animal food regulation is factually accurate.

- c) PFI wants to know FDA's policy on correcting inaccurate statements in the press. Concerns over headlines in the press. Mike offered to look at any opportunities to clarify the messaging, explained that we correct news articles when they are factually inaccurate.

FDAAA

1. Pet food labeling – PFI would like to provide input but we explained the proposed rule is in the end stages of clearance, recommended they submit comments to the docket. Explained our regulation will be very similar to AAFCO's guidelines.
2. PFI would also like a timeline for ingredient definitions, especially around the term “natural.” Sharon explained CVM is reviewing the AAFCO guidelines to make GRAS determinations.
3. PFI expressed concerns over conflicting federal and state regulations re labeling.
4. PFI has some research on consumer preference for ingredient and nutrition labels. They will share with FDA (not sure if they meant during comment period)?
5. Salmonella CPG – voiced concern that the guidance suggests Salmonella from animal food is a significant health risk for humans, their data suggests Salmonella in pet food has dropped over the past few years. PFI would like FDA to better frame communications on the risk. For example, in comparison with Salmonella on raw poultry, risk of human illness from Salmonella in pet food is much lower.

Next Steps

1. PFI would like to see more consumer messaging from FDA on safe pet food handling in the home.
2. PFI would like FDA to take a more risk-based approach to what “zero tolerance” means for Salmonella in pet food.

From: [Mayl, Sharon L](#)
To: [Natanblut, Sharon](#); [Sepe, Daniel](#); [Barrett, Kari](#); [DeLancey, Siobhan](#)
Cc: [Pillsbury, Laura](#)
Subject: FW: Slides for PFI Meeting with FDA (10Dec13).pptx
Date: Wednesday, December 11, 2013 7:40:51 PM
Attachments: [Slides for PFI Meeting with FDA \(10Dec13\).pptx](#)

They also wanted a webinar on the import provisions. I think they will follow up with Dan.

From: Taylor, Michael R
Sent: Wednesday, December 11, 2013 7:16 PM
To: Natanblut, Sharon; DeLancey, Siobhan
Cc: Pillsbury, Laura; Mayl, Sharon L; Barrett, Kari
Subject: FW: Slides for PFI Meeting with FDA (10Dec13).pptx

Sharon and Siobhan,

The pet food folks made some points this morning about our pet food safety messages that I said we'd follow up on (see slides). I heard this by the phone, but Sharon Mayl was there in person. We should download to you so you can figure out next steps.

Thanks.

Mike

From: Tabor, Peter [<mailto:peter@petfoodinstitute.org>]
Sent: Wednesday, December 11, 2013 8:35 AM
To: Taylor, Michael R
Subject: Slides for PFI Meeting with FDA (10Dec13).pptx

For the meeting. Thanks.

Peter

From: [Clapp, Nicole](#)
To: [Mayl, Sharon L](#); [Pillsbury, Laura](#); [Barrett, Kari](#); [Tollefson, Linda](#); [Schor, Danielle](#); [Weller, Kelly](#)
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute
Date: Wednesday, December 04, 2013 4:01:51 PM

Yes, he'll be there. I'd sent an email to Peter requesting that the meeting be moved up to 8:30am so that Mike would be able to attend. I confirmed this time change was OK with CVM but didn't hear back from Peter. Nonetheless, I will forward the invite to you now

From: Mayl, Sharon L
Sent: Wednesday, December 04, 2013 3:59 PM
To: Pillsbury, Laura; Clapp, Nicole; Barrett, Kari; Tollefson, Linda; Schor, Danielle; Weller, Kelly
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

I just received a thank you for my help in getting Mike to the 12/11 meeting at CVM. Does that mean that he will be there? I did not hear back from anyone here.

From: Pillsbury, Laura
Sent: Monday, December 02, 2013 4:34 PM
To: Mayl, Sharon L; Clapp, Nicole; Barrett, Kari; Tollefson, Linda; Schor, Danielle; Weller, Kelly
Subject: Re: Greetings from Peter Tabor at the Pet Food Institute

I'm sure of it. Nicole - pls be sure to include Sharon on the invite.

From: Mayl, Sharon L
Sent: Monday, December 02, 2013 04:00 PM Eastern Standard Time
To: Clapp, Nicole; Pillsbury, Laura; Barrett, Kari; Tollefson, Linda; Schor, Danielle; Weller, Kelly
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

I am available if Mike would like me to attend for FSVP purposes.

From: Clapp, Nicole
Sent: Monday, December 02, 2013 3:52 PM
To: Pillsbury, Laura; Barrett, Kari; Tollefson, Linda; Mayl, Sharon L; Schor, Danielle; Weller, Kelly
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

Sure

From: Pillsbury, Laura
Sent: Monday, December 02, 2013 3:51 PM
To: Barrett, Kari; Clapp, Nicole; Tollefson, Linda; Mayl, Sharon L; Schor, Danielle; Weller, Kelly
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

This conflicts with one of his quarterly CORE meetings at University Station, but he would like to do both if possible. Nicole, can you work to see if CVM and PFI are willing to entertain moving their meeting earlier by 30 minutes to 8:30-9:30 AM and Kathy moving CORE back by 1 hr to 10:30-noon?

From: Barrett, Kari
Sent: Monday, December 02, 2013 3:48 PM
To: Clapp, Nicole; Tollefson, Linda; Mayl, Sharon L; Schor, Danielle; Weller, Kelly; Pillsbury, Laura
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

Laura/Nicole - Do you want to confirm with Mike if this is something he'd like to/is available to do? Kari

From: Clapp, Nicole
Sent: Monday, December 02, 2013 3:43 PM
To: Tollefson, Linda; Barrett, Kari; Mayl, Sharon L; Schor, Danielle; Weller, Kelly; Pillsbury, Laura
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

It's 9-10am

From: Tollefson, Linda
Sent: Monday, December 02, 2013 3:42 PM
To: Barrett, Kari; Mayl, Sharon L; Schor, Danielle; Weller, Kelly; Clapp, Nicole; Pillsbury, Laura
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

I believe it's in the morning at CVM but not sure.

From: Barrett, Kari
Sent: Monday, December 02, 2013 3:35 PM
To: Tollefson, Linda; Mayl, Sharon L; Schor, Danielle; Weller, Kelly; Clapp, Nicole; Pillsbury, Laura
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

Thanks Linda! Any chance you know what time the meeting is on December 11? I assume it's at CVM? Kari

From: Tollefson, Linda
Sent: Monday, December 02, 2013 3:14 PM
To: Barrett, Kari; Mayl, Sharon L; Schor, Danielle; Weller, Kelly; Clapp, Nicole; Pillsbury, Laura
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

PFI will be meeting with CVM on December 11 and they meet frequently. Mike has been invited to their meetings several times and I suggest he try to get to this one in order to hear their thoughts on FSVP (their agenda item #1) and pet food labeling (agenda item #3). Agenda item #2 has to do with PFI's continued unhappiness over our publicizing salmonella contamination of pet food incidents (on our website). While it's true that pelleted, heat treated pet food has low Salmonella contamination rates, there's a great deal of opportunity for cross contamination and re-contamination of pet food products so on that issue Mike should defer to CVM as the experts.

I'll be in China next week (replacing Mike) so can't join this time.

Linda

From: Barrett, Kari
Sent: Monday, December 02, 2013 3:06 PM
To: Mayl, Sharon L; Schor, Danielle; Weller, Kelly; Clapp, Nicole; Pillsbury, Laura; Tollefson, Linda
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

Bringing Linda into the conversation. Linda, would you recommend this be a meeting with Mike/you/handled by CVM? Kari

From: Mayl, Sharon L
Sent: Monday, December 02, 2013 12:45 PM
To: Mayl, Sharon L; Schor, Danielle; Barrett, Kari; Weller, Kelly; Clapp, Nicole; Pillsbury, Laura
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

Any thoughts on this?

From: Mayl, Sharon L
Sent: Monday, November 25, 2013 9:08 AM
To: Schor, Danielle; Barrett, Kari; Weller, Kelly; Clapp, Nicole; Pillsbury, Laura
Subject: FW: Greetings from Peter Tabor at the Pet Food Institute

FYI re topics for discussion.

From: Tabor, Peter [<mailto:peter@petfoodinstitute.org>]
Sent: Friday, November 22, 2013 2:50 PM
To: Mayl, Sharon L
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

Thanks for the quick reply, Sharon. Re the topics for discussion during this meeting, they are:

1. FSMA – PFI’s effort to develop comments and areas of concern such as economic impact of the regulations once implemented; some perhaps unintended consequences of provisions of the proposed rules on foreign supplier verification and third-party accreditation; and FDA access to records;
2. Salmonella Compliance Policy Guide (690.800) – PFI has gathered data regarding the low prevalence of Salmonella in pet food that we’d like to share as the basis for a conversation on FDA’s messaging to its field personnel as well as to consumers regarding the Salmonella risks from pet food, including the data to support FDA’s messaging; and
3. FDAAA – We’re interested in learning more about the status of the FDAAA implementing regulations and in providing input as to how these regulations could look/work to provide consumers with relevant, appropriate information regarding dog and cat food nutrition.

Please contact me with further questions – we really hope Mike can join the meeting. Thanks.

Regards,

Peter Tabor
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M: +1.202.210.4055
F: +1.202.367.2120
peter@petfoodinstitute.org

From: Mayl, Sharon L [<mailto:Sharon.Mayl@fda.hhs.gov>]
Sent: Friday, 22 November, 2013 14:27
To: Tabor, Peter
Subject: RE: Greetings from Peter Tabor at the Pet Food Institute

Hi Peter. Thanks for your message. I will check with his scheduler on this. Can you give me a better idea of the specific issues that you would like to discuss?

Thanks.
Sharon

From: Tabor, Peter [<mailto:peter@petfoodinstitute.org>]
Sent: Friday, November 22, 2013 2:20 PM
To: Mayl, Sharon L
Subject: Greetings from Peter Tabor at the Pet Food Institute

Sharon:

We met briefly in September at the coffee shop across from the Omni Shoreham Hotel in NW DC, right before the FDA public meeting to discuss the FSMA FSVP and Third-Party proposed rules. Julie Callahan – my former colleague when we worked at USDA – introduced us.

In a few weeks, some members of the PFI Board of Directors will be in town for meetings, including a meeting with FDA's CVM to discuss topics/issues of concern. For this year's meeting, scheduled for 9:00-10:00 on Wed, 11 Dec, we have also extended an invitation to Mike Taylor. The thinking here is that we'd very much like his input on a few topics related to pet food regulation and FDA's messaging on pet food. It's truly our intention to work with FDA to improve the safety of pet food and we think we have a good story to tell from a safety standpoint, so we'd like to have Mike participate in this conversation with CVM.

I just wanted to alert you to this invitation that was sent to Mike yesterday (Thu) afternoon and ask you to see if he can make himself available. PFI has invited Mike to a several meetings and conferences in the past but we've been unsuccessful in securing his participation. Any assistance or guidance you can provide in this respect would be appreciated. Thanks and have a great weekend.

Regards,

Peter Tabor
Vice President, Regulatory & International Affairs
Pet Food Institute
T: +1.202.367.1236
M: +1.202.210.4055
F: +1.202.367.2120
peter@petfoodinstitute.org

From: [Clapp, Nicole](#)
To: [Barrett, Kari](#); [Pillsbury, Laura](#); [Weller, Kelly](#); [Schor, Danielle](#)
Cc: [Clapp, Nicole](#)
Subject: RE: Meeting with Pet Food Institute
Date: Friday, December 13, 2013 10:21:17 AM

Hello – yes, I will. Given Mike’s suggestions to hold it at CVM and his schedule next week, I’ll look at scheduling the week of Jan. 13th per Duane’s request.

thanks

From: Barrett, Kari
Sent: Friday, December 13, 2013 10:16 AM
To: Barrett, Kari; Clapp, Nicole; Pillsbury, Laura; Weller, Kelly; Schor, Danielle
Subject: RE: Meeting with Pet Food Institute

Including Kelly too for OFVM SMI tracker. Kari

From: Barrett, Kari
Sent: Friday, December 13, 2013 10:15 AM
To: Clapp, Nicole; Pillsbury, Laura
Subject: FW: Meeting with Pet Food Institute

Nicole - Will you be following up on scheduling? Will Exec Sec be participating re: notes? Kari

From: Taylor, Michael R
Sent: Friday, December 13, 2013 10:00 AM
To: Dunham, Bernadette M; McChesney, Daniel G
Cc: Flynn, William T; Forfa, Tracey; Barrett, Kari; Pillsbury, Laura
Subject: RE: Meeting with Pet Food Institute

Absolutely. Wouldn’t do it any other way. If it works scheduling wise, we can do it at CVM.

Mike

From: Dunham, Bernadette M
Sent: Friday, December 13, 2013 8:15 AM
To: Taylor, Michael R; McChesney, Daniel G
Cc: Flynn, William T; Forfa, Tracey; Barrett, Kari; Pillsbury, Laura
Subject: Re: Meeting with Pet Food Institute

Hi Mike,

I would respectfully ask that when you meet with Randy and Duane please include Dan, Terry Proescholdt and Sharon Benz. Thanks. :)

Cheers,
Bernadette

Dr. Bernadette Dunham, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration
MPN-IV, Rm. 181
7519 Standish Place
Rockville, MD 20855
Phone: 240-276-9000
Fax: 240-276-9001
Bernadette.Dunham@fda.hhs.gov
Excellence. Leadership. Innovation.

From: Taylor, Michael R
Sent: Friday, December 13, 2013 05:07 AM Eastern Standard Time
To: Dunham, Bernadette M
Cc: Flynn, William T; Forfa, Tracey; Barrett, Kari; Pillsbury, Laura
Subject: Fw: Meeting with Pet Food Institute

Bernadette et al,

See below from Duane. I'm happy (and inclined) to do this. Any thoughts?

Mike

From: Ekedahl, Duane [<mailto:dekedahl@smithbucklin.com>]
Sent: Thursday, December 12, 2013 03:10 PM Eastern Standard Time
To: Taylor, Michael R
Subject: Meeting with Pet Food Institute

Dear Mike,

Listening to the news last evening, with the lead story being FDA action on antibiotics in livestock and your interview, we now fully understand why we missed you yesterday and are grateful to have had you for half an hour.

The part of our presentation you missed was, we feel, important new industry data on assessing the public health risk of salmonella in pet food. This was given by Randy King of P & G, a PFI board member.

Randy and I would appreciate the opportunity to visit your office for a brief 30 minute discussion which would expand on the overheads you have. We could be available anytime next week, the week of December 16, or the week of January 13.

Please let us know if this will work.

With best wishes,

Duane

Duane Ekedahl
President
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2025 M Street, NW, Suite 800
Washington, DC 20036
(202) 367-1120
duane@petfoodinstitute.org
www.petfoodinstitute.org

From: [Clapp, Nicole](#)
To: [Benz, Sharon A](#); [Proescholdt, Terry](#); [McChesney, Daniel G](#); [Barrett, Kari](#)
Cc: [Pillsbury, Laura](#)
Subject: RE: Meeting with the Pet Food Institute
Date: Wednesday, January 08, 2014 11:58:09 AM

All - based on travel schedules, PFI has confirmed they are available on 1/24 to meet at CVM from 11:30am-12:30pm.

Sharon - are you able to make this time work?

Nicole

-----Original Message-----

From: Clapp, Nicole
Sent: Tuesday, January 07, 2014 4:56 PM
To: Benz, Sharon A; Proescholdt, Terry; McChesney, Daniel G; Barrett, Kari
Cc: Pillsbury, Laura; Clapp, Nicole
Subject: RE: Meeting with the Pet Food Institute
Importance: High

Good afternoon - kindly confirm your availability to meet with PFI at CVM on January 24th after 11:30am. If 1/24 doesn't work for you all, I'll work to identify some additional dates for the week of the 20th.

Please advise - Thank you

-----Original Message-----

From: Clapp, Nicole
Sent: Friday, January 03, 2014 2:33 PM
To: Benz, Sharon A; Proescholdt, Terry; McChesney, Daniel G; Barrett, Kari
Cc: Pillsbury, Laura; Clapp, Nicole
Subject: Re: Meeting with the Pet Food Institute

All - thanks for your responses.

Unfortunately, Randy King will now be traveling to Europe the week of Jan 13th so he's unavailable 1/17.

Once I'm back in front of my computer on Monday, I'll send dates for consideration the week of 1/20

Thank you, Nicole

-----Original Message-----

From: Clapp, Nicole
To: Benz, Sharon A
To: Proescholdt, Terry
To: McChesney, Daniel G
To: Barrett, Kari
Cc: Pillsbury, Laura
Cc: Clapp, Nicole
Subject: Meeting with the Pet Food Institute
Sent: Dec 26, 2013 4:28 PM

Good afternoon – I trust you all are having a nice holiday.

I'm working on scheduling a meeting with Duane Ekedahl, President of Pet Food Institute and PFI Board Member, Randy King. Randy and Duane will be meeting with the group at CVM as follow up to the December 11th call with

PFI and Bernadette that Mike was unable to attend. PFI wishes to further discuss important new industry data on assessing the public health risk of salmonella in pet food.

Please confirm your availability for an in person meeting on 1/17 for 30-45 minutes between 10:00am – 11:30am and between 4-5pm. I'm hoping I can find additional times the week of 1/13 to offer PFI. In the interim, please let me know as soon as possible if the times above work.

Thank you, Nicole

Nicole M. Clapp ? Executive Assistant to the Deputy Commissioner for Foods and Veterinary Medicine ?
FDA/Office of Foods and Veterinary Medicine (OFVM) ? White Oak Bldg 1-Room 3241(301.796.4665 (phone))*
nicole.clapp@fda.hhs.gov

From: [Bensette, Megan](#)
To: [Pillsbury, Laura](#); [Barrett, Kari](#); [McChesney, Daniel G](#); [Benz, Sharon A](#); [Proescholdt, Terry](#)
Cc: [Clapp, Nicole](#); [Weller, Kelly](#); [Berndt, Susan](#); [Forfa, Tracey](#); [McDermott, Catherine](#)
Subject: RE: Notes from Pet Food Institute Meeting - January 24, 2014
Date: Tuesday, January 28, 2014 12:44:51 PM
Attachments: [012414 PFI Meeting Notes with slides.pdf](#)

Now attached.

Megan Bensette
Communications and Public Engagement
Office of Foods and Veterinary Medicine
U.S. Food and Drug Administration
(240) 506-6818

Stay in touch! Follow us on Twitter [@FDAfood](#) and [@FDAanimalhealth](#).

From: Bensette, Megan
Sent: Tuesday, January 28, 2014 12:43 PM
To: Pillsbury, Laura; Barrett, Kari; McChesney, Daniel G; Benz, Sharon A; Proescholdt, Terry
Cc: Clapp, Nicole; Weller, Kelly; Berndt, Susan; Forfa, Tracey; McDermott, Catherine
Subject: Notes from Pet Food Institute Meeting - January 24, 2014

Hope this is helpful. Asks are in blue text, slides also attached for records. Thanks.

Megan Bensette
Communications and Public Engagement
Office of Foods and Veterinary Medicine
U.S. Food and Drug Administration
(240) 506-6818

Stay in touch! Follow us on Twitter [@FDAfood](#) and [@FDAanimalhealth](#).



Comparison of *Salmonella* Prevalence in Different Animal Feed

Type of Feed	2002-2006	2007-2009
Poultry Feed	12.9 (12/93)*	9.1 (2/22)
Cattle Feed	3.3 (4/121)	6.1 (4/66)
Swine Feed	13.3 (8/60)	0 (0/15)
Horse Feed	0 (0/17)	0 (0/9)
Medicated Feed	11.9 (7/59)	13.3 (2/15)
Feed for Minor Species	0 (0/13)	3.6 (2/55)
Ingredient	30.9 ^a (104/337)	19.4 ^b (40/206)
Supplement for Pets	18.8 (3/16)	7.1 (6/84)
Pet Food/Treat	12.4 ^a (19/153)	6.1 ^b (44/719)
Total	18.1 ^a (157/869)	8.5 ^b (100/1189)

Pet Food Recalls

Pet food statistics October 2010-August 2011

- Recalling firms 26
- Total products recalled 131
- Firm recall initiated by FDA sampling 10
 - 4 separate recalls from one firm
- Firm recall initiated by State sampling 8
- Firm recall initiated by Firm 8
- Salmonella the major contributor

Pet Food recalls	FY 2011	FY 2012	FY 2013
Recalling Firms	26	11	22*
Total Products recalled	131	26	204
Firm initiated recall by FDA Sampling	10	5	8
Firm initiated recall by State sampling	8	2	7
Firm initiated recall by Firm	8	4	7

* Large number of recalls due to peanut butter incident and salmonella in parsley flakes



Summary of *Salmonella* prevalence in pet food samples collected and analyzed in FY2012

	# Collected and analyzed	# of Positive	Prevalence %
Dog Food	66	0	0
Cat Food:	46	0	0
Dog Treats	279	8	2.87
Cat Treats	5	0	0
Pet Nutritional Supplements	36	0	0
Other Pet Food (bird, fish, guinea pig, rabbit, rodent)	16	2	12.50
Total	448	10	2.23