1 {York Stenographic Services, Inc.}

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- 2 HIF168.000
- 3 MARKUP ON H.R. 2749, THE FOOD SAFETY ENHANCEMENT ACT OF 2009
- 4 WEDNESDAY, JUNE 17, 2009
- 5 House of Representatives,
- 6 Committee on Energy and Commerce
- 7 Washington, D.C.

- 8 The Committee met, pursuant to call, at 10:17 a.m., in
- 9 Room 2123 of the Rayburn House Office Building, Hon. Henry
- 10 Waxman (chairman of the committee) presiding.
- 11 Members present: Representatives Waxman, Dingell,
- 12 Markey, Pallone, Eshoo, Stupak, Engel, Green, DeGette, Doyle,
- 13 Schakowsky, Gonzalez, Inslee, Baldwin, Matheson, Butterfield,
- 14 Melancon, Barrow, Matsui, Christensen, Castor, Space,
- 15 McNerney, Sutton, Braley, Welch, Barton, Upton, Stearns,
- 16 Deal, Whitfield, Shimkus, Buyer, Radanovich, Pitts, Walden,
- 17 Terry, Rogers, Burgess, Blackburn, Scalise and Gingrey.
- 18 Staff present: Kristin Amerling, Chief Counsel; Caren

- 19 Auchman, Communications Associate; Alvin Banks, Special
- 20 Assistant; Phil Barnett, Staff Director; Jen Berenholz,
- 21 Deputy Clerk; Brian Cohen, Senior Investigator and Policy
- 22 Advisor; Allison Corr, Special Assistant; Sharon Davis, Chief
- 23 Legislative Clerk; Earley Green, Chief Clerk; Caitlin
- 24 Haberman, Staff Assistant; Elana Leventhal, Policy Advisor;
- 25 Karen Lightfoot, Communications Director/Senior Policy
- 26 Advisor; Virgil Miller, Professional Staff Member; Karen
- 27 Nelson, Deputy Committee Staff Director for Health; Jennifer
- 28 Owens, Special Assistant; David Rapallo, General Counsel;
- 29 Rachel Sher, Counsel; Mitchell Smiley, Special Assistant;
- 30 Bruce Wolpe, Senior Advisor; Clay Alspach, Counsel; Ryan
- 31 Long, Counsel; Lance Kotschwar, General Counsel; and Chad
- 32 Grant, Legislative Analyst.

- 33 H.R. 2749
- 34 10:17 a.m.
- The {Chairman.} The committee will come to order.
- Today we mark up the Food Safety Enhancement Act of
- 37 2009, bipartisan legislation that will fundamentally change
- 38 the way we protect the safety of the food supply. This is
- 39 the kind of legislative achievement that should give
- 40 Americans confidence that Congress can respond in an
- 41 effective bipartisan way to solve urgent problems. A series
- 42 of foodborne disease outbreaks in spinach, peanuts and
- 43 peppers, to name a few, has not only sickened and killed
- 44 American consumers but has shaken public confidence in the
- 45 industry that produces one of our most basic and important
- 46 commodities, and it has laid bare unacceptable gaps in our
- 47 food safety laws. Today the committee will act to close those
- 48 gaps and give the Food and Drug Administration new
- 49 authorities, new tools and a new source of funding to carry
- 50 out this vital mission.
- 51 Under the legislation, FDA will have clear authority to
- 52 issue and require manufacturers to meet strong, enforceable
- 53 performance standards to ensure the safety of various types
- 54 of food. FDA will establish a food traceback system so that
- 55 public health officials can easily determine the cause of

- 56 foodborne disease outbreaks. FDA will be required to inspect
- 57 all food facilities, the riskiest ones at least once per
- 58 year. FDA will be given new authority to ensure that
- 59 imported foods are safe. FDA will be given new tools,
- 60 recalls, records access and penalties to punish bad actors to
- 61 act quickly when presented with a food safety emergency, and
- 62 FDA will get a new dedicated source of funding from a \$500
- 63 annual registration fee on food facilities to help conduct
- 64 its vital work of keeping America safe.
- But FDA will not be the only cop on the beat. One of
- 66 the most important changes that will occur under this bill is
- 67 a new focus on prevention and a shared responsibility between
- 68 FDA and food manufacturers to keep the food supply safe. The
- 69 bill will require manufacturers to implement preventive
- 70 systems to stop outbreaks before they occur. All food
- 71 facilities will have to conduct hazard analyses, assess
- 72 potential food safety risks and develop plans to keep the
- 73 food supply safe.
- 74 The most remarkable thing about the bill is the
- 75 consensus behind it. Consumer and public interest groups
- 76 support it. The Grocery Manufacturers Association and other
- 77 food industry groups support it, and most importantly, a
- 78 broad bipartisan group of Energy and Commerce Committee
- 79 members support it. I think it is important to acknowledge

- 80 those responsible. I will begin with Chairman Emeritus
- 81 Dingell, the dean of Congress and the dean of food safety, an
- 82 unrelenting public health watchdog. He takes great pride in
- 83 seeing his work come to fruition. Chairman Stupak has left
- 84 an undeniable mark on this bill through his work on the
- 85 Oversight and Investigation Subcommittee and tireless efforts
- 86 to fix the problems he has helped identify. Chairman
- 87 Pallone, who has worked on this issue for over a decade,
- 88 shepherded this bill through his subcommittee and helped get
- 89 us to this point today. I also want to thank the thoughtful
- 90 contributions of Representatives DeGette and Sutton for their
- 91 early stages of this process.
- 92 I also want to thank our Republican colleagues, Ranking
- 93 Member Barton and Ranking Member Deal, Representative
- 94 Shimkus. You and your staffs have worked incredibly hard
- 95 over the last few weeks to bridge gaps, find creative
- 96 solutions to problems and help make sure this bill works
- 97 better for everyone. I appreciate all the efforts and your
- 98 commitment to keep the food supply safe. You have helped to
- 99 provide beyond a shadow of a doubt that there is no partisan
- 100 gap when it comes to keeping the food supply safe.
- The legislation we are marking up represents a huge
- 102 accomplishment for this committee. We stand on the verge of
- 103 passing a comprehensive, broadly supported and bipartisan

104	reform of our Nation's food safety laws. We will see a
105	strong vote out of committee today and that will send a loud
106	message about the need to move this legislation quickly. I
107	know that we still have work to do, but I am more confident
108	than ever that we will be able to take this legislation to
109	the Floor and I am hopeful that before too long we can have a
110	comprehensive food safety bill on President Obama's desk.
111	[The prepared statement of Mr. Waxman follows:]

112 ******** COMMITTEE INSERT **********

113 The {Chairman.} I want to yield to the ranking member 114 of the Subcommittee on Health, Mr. Deal. 115 Mr. {Deal.} Thank you, Chairman Waxman, and thank you 116 for holding the markup on this bill, the Food Safety 117 Enhancement Act of 2009. Certainly having a safe food supply 118 is something that people on both sides of the aisle have as a 119 priority and I think the markup today will indicate that we 120 have come to a very good agreement in being able to ensure 121 that Food and Drug Administration has the resources and the 122 authority to do what they need to be sure that our food 123 supply is safe for the American people, and this committee I 124 think deserves great credit for working in a bipartisan 125 fashion. 126 Last week the Subcommittee on Health did hold a markup 127 on this bill. At that time various members offered 128 amendments, most of which were withdrawn with the 129 understanding that we would work on those issues before the 130 full committee, and I am pleased to report that that has been 131 done and the product that we will have before us today is a 132 result of the cooperative efforts of both sides of the aisle 133 and the staffs that it work to make this bill a reality. I 134 am looking forward to the markup. I hope that it will be a 135 smooth markup and one in which we can all agree that this

- 136 bill embodies the safeguards that all of us want for the food
- 137 supply for our country, and thank you for your efforts and
- 138 your staffs' efforts and your members' efforts and thanks to
- 139 the people on my side of the aisle as well and to their
- 140 staffs for working very diligently on this undertaking. I
- 141 yield back my time.
- [The prepared statement of Mr. Deal follows:]
- 143 ********* COMMITTEE INSERT *********

144 Mr. {Pallone.} [Presiding] Thank you, Mr. Deal, and I 145 will recognize myself next for an opening statement. 146 I am pleased to be here today to mark up H.R. 2749. 147 Today we take a giant step forward on food safety. For more 148 than a decade, many of us have been focused on the need that 149 has been increasing in importance to protect the health, the 150 safety and the well-being of consumers with modern food 151 safety standards. We have done tremendous work introducing 152 legislation, collaborating with interest groups to identify 153 the problems and trying to come up with feasible and 154 effective solutions. 155 We have also done a lot of work in this committee on the 156 issue, and we have had numerous hearings on food safety that 157 highlighted the flaws and shortfalls of our current system. We heard heart-wrenching stories about victims of foodborne 158 159 illness including one of a woman who overcame cancer only to 160 succumb to a foodborne illness. We heard testimony from 161 industry experts and consumer advocates, and we heard from 162 the agency responsible for protecting our Nation's food 163 supply, the FDA. What we learned and what we believe has 164 been inserted in what has before us today, a food safety bill 165 that will modernize our antiquated food safety laws and 166 catapult the FDA into the global marketplace of the 21st

- 167 century.
- 168 This bill will require all food facilities to register
- 169 with the FDA on annual basis, providing the agency with an
- 170 up-to-date list of all the facilities that sell products in
- 171 the United States. It will require facilities to pay a
- 172 registration fee that will be used to help defray the costs
- 173 of food safety activities as put forth by the bill. The bill
- 174 emphasizes prevention and safety plans that will help ensure
- 175 that food is safe when it leaves the factory door and is
- 176 placed on our grocery store shelves. These controls are
- 177 crucial in preventing foodborne illness outbreaks and in
- 178 protecting all Americans.
- The bill also provides the FDA with necessary
- 180 enforcement authorities. It creates new and updated civil
- 181 monetary penalties and criminal penalties. It provides the
- 182 FDA with recall authority so that when a food is
- 183 contaminated, the FDA can quickly get that food off the
- 184 shelves and away from American consumers and it directs the
- 185 agency to collect information, conduct a pilot study and
- 186 issue regulations on traceability for food that will allow us
- 187 to rapidly trace a food outbreak back to the source of the
- 188 contamination.
- 189 I think we have come a long way from where we started so
- 190 many years ago and what we are considering today is very

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     strong. It is a bipartisan piece of legislation that will
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     empower the FDA and improve our food safety system.
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     bill like this doesn't happen overnight, and I have to also
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     mention the hard work that my colleagues on both sides of the
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     aisle have put into this bill. Chairman Waxman has dedicated
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     countless hours to the legislation to seeing it to fruition.
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     Chairman Emeritus Dingell has been working on this issue and
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     this legislation in various renditions for so many years.
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     Mr. Stupak, who has done so much work on the Oversight
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     Subcommittee, held numerous hearings and conducted
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     investigations that were crucial to informing us of the food
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     safety problems. Ms. DeGette has been a champion on
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     traceability and recall and worked closely with us on these
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     key provisions. And I also want to thank my Republican
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     colleagues, Ranking Member Barton, Mr. Deal and Mr. Shimkus,
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     for their hard work. In the last few weeks we have really
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     been able to come together on many of the issues, and I would
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     like to commend the collaborative nature and the constructive
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     tone of those conversations. Thanks to all of us, we have
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     before us today a bipartisan bill that will provide the FDA
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     with the resources and authorities it needs to protect our
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     Nation's food safety, and I just want to thank everybody
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     again.
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[The prepared statement of Mr. Pallone follows:]

215 ******** COMMITTEE INSERT *********

- 216 Mr. {Pallone.} Our next opening statement is Mr.
- 217 Stearns, the gentleman from Florida.
- 218 Mr. {Stearns.} Thank you, Mr. Chairman, and I want to
- 219 thank everybody for the bipartisan effort. I am sort of
- 220 encouraged that we can do this, particularly in light of what
- 221 is happening on the House Floor today. Many of us had
- 222 amendments we were ready to offer last night at 8:30, 9:00 at
- 223 night and suddenly they recessed the House and now all these
- 224 amendments after the rule presented is not--the rule
- 225 indicates that out of the 123 amendments, we are down to
- 226 about 20 amendments, so I am so glad we can come here and
- 227 have bipartisanship on this bill.
- 228 I notice Chairman Waxman called Mr. Dingell the dean of
- 229 food safety, so the dean of food safety is a brand-new title,
- 230 Mr. Dingell, that you can carry with you forever now.
- 231 Americans deserve to have a regulatory system in place
- 232 that does it utmost to inspect and ensure that the food they
- 233 purchase to feed their families obviously is safe and
- 234 affordable. I believe that this committee after productive
- 235 bipartisan negotiations has crafted legislation that will
- 236 enhance the FDA's food regimen and not cripple the food
- 237 industry with needless over-regulation which would drive up
- 238 the cost of food by forging a food inspection system that

- 239 strikes a balance between oversight and personal
- 240 accountability, and it is all our hope that this legislation
- 241 will ensure that tainted food never again slips through the
- 242 public-private safety net that this legislation will
- 243 institute.
- I note in the summary of the bill that there is a waiver
- 245 that farms that sell directly to consumers have to have
- 246 records but at the same time open marks that sell vegetables
- 247 will be able to still do so pending that they do keep copious
- 248 records, so I think for those small towns on Saturdays where
- 249 all the farmers come in and sell their produce, they will not
- 250 be affected, and I think that is good, so I appreciate that
- 251 allowance which is in the bill.
- I hope, Mr. Chairman, that the resources that are
- 253 required to implement this bill will be provided too, and
- 254 with that, I yield back.
- 255 [The prepared statement of Mr. Stearns follows:]
- 256 ********* COMMITTEE INSERT **********

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257 Mr. {Pallone.} Thank you. You referenced the dean of 258 food safety. Was that the title he gave you, Mr. Dingell? 259 Chairman Dingell is next. Mr. {Dingell.} Mr. Chairman, I want to thank you for 260 your kind words. I am not sure being the dean of anything is 261 262 particularly good. It seems to me that you are getting old. 263 But I want to thank you, Mr. Chairman, for this markup. 264 I thank Chairman Waxman for his efforts and leadership. We 265 will note that there are a number of members who have been 266 the sponsors of this legislation, Mr. Waxman, Mr. Pallone, Mr. Stupak, Ms. DeGette and Ms. Sutton. But there are a lot 267 268 of others who have participated in this undertaking including 269 our good friends, Mr. Barton, Mr. Deal, Mr. Shimkus and a lot 270 of members on the Republican side, and I want them to know 271 that I am grateful for it. 272 What we are showing today is that this committee can 273 function in the great traditions not only of this committee 274 but of the House and that we can work together in a 275 bipartisan fashion to achieve important advances in the 276 public interest. We did it last year, as you will remember, 277 Mr. Chairman, on the consumer product safety legislation,

279 my colleagues will remember that the Senate meddled around

which turned out to be a great piece of legislation, although

- 280 with it just a little bit and caused some complications.
- I do want to note that we have a considerable measure of
- 282 appreciation for the participation and kindness of the
- 283 Grocery Manufacturers Association. Their negotiations in
- 284 good faith have resulted in us being able to move forward
- 285 together on the important components of this bill, the first
- 286 of which are additional enforcement mechanisms and tools
- 287 available to Food and Drug, and the second are of course
- 288 mechanisms to enable us to fund the operations that have to
- 289 be taken by Food and Drug including a very valuable system of
- 290 registration and other steps which will enable Food and Drug
- 291 to do the things necessary to assure public safety.
- I want to commend the staff of the minority, the staff
- 293 of the majority and my two staff members, Mr. Virgil Miller
- 294 and Ms. Katie Campbell, for their hard work on this matter
- and for what they have done.
- 296 Mr. Stupak has been a great leader in this matter in
- 297 what he has done in the Subcommittee on Investigations and
- 298 Oversight, and you, Mr. Chairman, have been a significant
- 299 value in your efforts to lead us towards this legislation.
- I want to quote one of the witnesses who appeared before
- 301 the Subcommittee on Health earlier this month in a
- 302 legislative hearing. `The Food Safety Enhancement Act is a
- 303 well-vetted, mature bill.'' It is also, I am pleased to

304 note, bipartisan, and we have, as I indicated, worked 305 together in a remarkable, good way to achieve that purpose. 306 It dates back to the first food safety legislation I 307 introduced in 1998, the Imported Food Safety Act. The Food 308 Safety Enhancement Act has been informed by a number of 309 hearings conducted at the Health and Oversight and 310 Investigation Subcommittees and the stories of countless 311 victims of contaminated food products, news articles which 312 appear regularly in the press about unsafe imports and major 313 problems with regard to food safety that are affecting the 314 health and well-being of the American people. We have had 315 valuable technical assistance from FDA, and I would just 316 observe what a remarkable difference a new Administration 317 We have had technical assistance from consumer, 318 public health and victim advocacy organizations and the 319 regulated industry, and again I want to comment on GMA's 320 participation and cooperation. We have also had the valuable 321 and valued input of members of this committee, both 322 Republicans and Democrats. 323 Amongst other things, the legislation we consider today 324 will prevent food safety problems before they occur. The 325 legislation requires foreign and domestic food facilities to 326 have safety plans in place to identify and mitigate hazards.

It will increase the frequency of inspections and it allows

328 FDA to adjust this frequency for low-risk products based on 329 honest and transparent risk assessment. It provides strong 330 and flexible enforcement tools including mandatory recall, 331 stronger penalties for bad actors, administrative detention, 332 quarantine and subpoena authority. It provides FDA tools to 333 ensure imported products into the United States meet our 334 safety standards and it significantly expands FDA traceback 335 capabilities in the event of an outbreak of foodborne 336 illness, something which my colleagues will note we have had 337 real problems with regard to tomatoes, jalapeno peppers, 338 peanuts and other things. And most importantly, it generates 339 the resources to support FDA food safety activities, 340 something that this committee is going to have to protect 341 from the fine Italian hands of our beloved friends over there 342 at Appropriations and in the Budget Committee. 343 I want to thank the members of this committee on both 344 sides of their aisle for their patience and their willingness 345 to work with us to address delicate matters. We have tried 346 to satisfy all of our colleagues and we will continue to work with them to see to it that they are content with the 347 348 consequences of the legislation. The bill before us is a 349 better piece of legislation because of the collaboration of 350 both sides of the aisle, and I want my colleagues to again 351 note that I look forward to continued discussions as we

- 352 prepare the bill for the Floor. The Food Safety Enhancement
- 353 Act is a monumental piece of legislation that will go a long
- 354 way to comforting our consumers and boosting their confidence
- in the safety of our Nation's food supply, particularly the
- 356 stuff coming in from abroad.
- I will note that as soon as we finish this, we must
- 358 start on one more little chore, which will relate to the
- 359 safety of pharmaceuticals, and I look forward to having the
- 360 same kind of good work and cooperation and goodwill of all of
- 361 our colleagues on the development of that legislation upon
- 362 which I intend to start forthwith.
- I would urge my colleagues to vote in favor of the
- 364 substitute which will be coming up, and I would observe that
- 365 it is approaching voting age and that the American people
- 366 deserve nothing else.
- 367 Thank you, Mr. Chairman.
- 368 [The prepared statement of Mr. Dingell follows:]
- 369 ********* COMMITTEE INSERT **********

370 Ms. {DeGette.} [Presiding] Thank you very much, Mr. 371 Dingell. 372 The gentleman from Kentucky. 373 Mr. {Whitfield.} Madam Chairlady, thank you, and I 374 simply want to express my appreciation to the members and 375 staff on both sides of the aisle in addressing some of the 376 concerns of many members on the original bill. I think, as 377 Chairman Dingell said, the bill is a better bill now and one 378 that will help ensure the food supply of our country, the 379 safety of that food supply, and I look forward to working 380 with all of us as we move the bill toward the Floor. I yield 381 back.

[The prepared statement of Mr. Whitfield follows:]

383 ********* COMMITTEE INSERT *********

384 Ms. {DeGette.} The gentleman from Michigan.

385 Mr. {Stupak.} Thank you, Madam Chair, for holding this

important markup today on H.R. 2749, the Food Safety 386

corrected.

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387 Enhancement Act. 388 As chairman of the Oversight and Investigation 389 Subcommittee, I along with Ranking Member Whitfield, Shimkus 390 and Walden have held 10 hearings over the last 2 years to 391 examine the safety and security of our Nation's food supply. 392 From these 10 hearings, we have learned that the FDA does not 393 have the regulatory tools or financial resources needed to 394 ensure food from domestic and foreign food producers is safe. 395 We also know that the industry has done an inadequate job of 396 regulating itself as is evident by the numerous food 397 contamination outbreaks that the American people have 398 witnessed over the past 2 years. All signs suggest our 399 government regulatory system does not ensure the safety of 400 the food industry and it is a broken system which must be

402 H.R. 2749 takes various steps towards addressing the 403 gaping holes in our Nation's food supply by recognizing the 404 food industry and the FDA must share the responsibility for 405 securing our Nation's food supply. Provisions granting the 406 FDA additional authority such as quarantine, recall, subpoena

- 407 power and access to records are all addressed in H.R. 2749.
- 408 These are valuable tools that will aid the FDA when a food
- 409 outbreak occurs.
- 410 H.R. 2749 also calls on industry to do more to monitor
- 411 and prevent contaminated food from entering the food supply.
- 412 For too long we have allowed industry to adhere to voluntary
- 413 guidelines. H.R. 2749 instills accountability by holding
- 414 industry responsible for the costs associated with the
- 415 recalls and re-inspections.
- I want to thank my colleagues and friends, Chairman
- 417 Dingell, Chairman Pallone, Chairman Waxman, for their hard
- 418 work on this issue. I also want to thank their staffs, who
- 419 have worked diligently to see this bill come before us today.
- 420 Their dedication has paid off with a piece of legislation
- 421 that will help protect and ensure all Americans have access
- 422 to safe food. I wish to thank Erika Smith of my personal
- 423 staff for all the work she has put in on this bill to make
- 424 this markup a reality. I also want to thank Ranking Members
- 425 Barton, Deal and Shimkus for their willingness to work with
- 426 us, not only on this legislation but also on the numerous
- 427 food safety hearings and investigations this committee and
- 428 the Oversight and Investigation Subcommittee have held over
- 429 the past 2 years.
- I am proud to be part of such great legislation and I

- 431 urge all my colleagues to support this legislation. I yield
- 432 back.
- [The prepared statement of Mr. Stupak follows:]
- 434 ********* COMMITTEE INSERT *********

435 Ms. {DeGette.} The gentleman from Illinois.

436 Mr. {Shimkus.} Thank you, Madam Chairman. This is what

- 437 we can do when we really work together structurally,
- 438 deliberately, and I do think it is a model for some even more
- 439 contentious issues like health care and global warming, but I
- 440 don't want to shock my colleagues or prejudice them but I do
- 441 support the Manager's Amendment. I know it is shocking.
- It represents agreements on both sides. A particular
- 443 part that I am very pleased that got in was establishing a
- 444 risk-based system. It gives an inspection regime that gives
- 445 the FDA the flexibility to change the frequency and
- 446 inspections for low-risk facilities, allows the FDA to access
- 447 records and information they need to ensure food safety plans
- 448 are being properly implemented, giving companies the
- 449 flexibility of using different preventive control systems
- 450 that work best for their so long as they meet FDA standards,
- 451 and where things are working we let existing authority remain
- 452 with respect to USDA and the oversight of alcohol
- 453 manufacturers and distributors. Those are just a few details
- 454 on what this bill does to give FDA the necessary tools and
- 455 authority to do its job when it comes to the safety of our
- 456 food supply.
- 457 Again, Madam Chairman, I support the Manager's Amendment

458 and I am glad that we were all able to work together. I too 459 want to thank Chairman Emeritus Dingell, Chairman Pallone, 460 Chairman Waxman, Chairman Stupak, Ranking Members Barton and 461 Deal and all our staffs. I particularly want to highlight my 462 staff, Chris Sarley, who spent a lot of time with members of 463 your staff, sometimes in good mood, sometimes in bad mood, 464 but I do think we got to a better product, as a lot of people 465 are saying. I look forward to continuing the process in this 466 bipartisan manner as this bill moves out of this committee 467 and also on equally important legislation should we look to 468 address needs the FDA may have with respect to its authority 469 over drugs, devices and cosmetics, and with that, I yield 470 back my time.

[The prepared statement of Mr. Shimkus follows:]

******** COMMITTEE INSERT *********

471

- 473 Ms. {DeGette.} The gentleman yields back. The 474 gentleman from New York.
- 475 Mr. {Engel.} Thank you, Madam Chairwoman, for holding
- 476 this important markup today. As a cosponsor of the Food and
- 477 Drug Globalization Act of 2009, I am pleased to see this
- 478 important food safety measure moving forward. I look forward
- 479 to addressing drugs and devices later this year as well.
- I want to commend the work that you have done, Mr.
- 481 Dingell, Mr. Pallone and Mr. Stupak, along with our
- 482 Republican colleagues on the bipartisan bill before we have
- 483 before us. I am hopeful that the Senate will work swiftly to
- 484 complement our efforts so that we may enact this bill into
- 485 law. If there is any good that came out of the Peanut
- 486 Corporation of America's salmonella crisis and the series of
- 487 outbreaks linked to spinach, lettuce, tomatoes and peppers,
- 488 it is now clearer than ever that our food safety system is
- 489 broken and in need of critical reforms. Today with this
- 490 legislation, we begin to right those wrongs.
- 491 An AP poll last year found that 46 percent of people
- 492 were scared that they would get sick from tainted food, and
- 493 there is a reason for this fear. U.S. foodborne illnesses
- 494 result in 76 million illnesses, hundreds of thousands of
- 495 hospitalizations and up to 5,000 deaths each year. As one of

- 496 the witnesses astutely pointed out in a prior hearing the 497 Health Subcommittee held on food safety, our Nation is 498 sustaining deaths equivalent to those that perished in the 499 World Trade Center attack in New York every six months. you think about it in those terms, it just takes your breath 500 501 away. And yet historically we have set up the FDA to fail. 502 We expect the FDA to ensure the safety of our Nation's food 503 supply but we haven't given it the resources or authority to 504 get the job done, and while there are many food companies and 505 facilities that are employing best practices to preserve 506 their own food products, unfortunately it is those that don't 507 that cause crippling problems for our public health and 508 That is why it is so important that we pass this economy. 509 bill.
- 510 By granting FDA the ability to mandate clear 511 preventative controls, stronger traceability and mandatory 512 recalls within their food safety authority, we may finally 513 target the spots along the farm-to-store chain where 514 contamination can occur. This along with continued and 515 necessary appropriated funds, and I want to emphasize that, 516 continued and necessary appropriated funds, will enable the 517 FDA to finally shore up our food safety system.
- 519 I am pleased to support the Food Safety Enhancement Act today

Madam Chairwoman, the costs of inaction are too great.

- 520 and urge all my colleagues to do the same, and I yield back
- 521 the balance of my time.
- [The prepared statement of Mr. Engel follows:]
- 523 ******** COMMITTEE INSERT *********

524 Ms. {DeGette.} The gentleman from California is 525 recognized. 526 Mr. {Radanovich.} Thank you, Madam Chair. I want to 527 thank you and Chairman Waxman and Ranking Member Barton for 528 all the work that has been done to bring this important issue 529 of food safety before the committee for consideration today. 530 As a representative of the San Joaquin Valley, one of 531 the most productive agricultural regions in the world, I 532 understand the need to provide safe and nutritious food. The 533 growers and producers I represent are dedicated to supplying 534 only the safest fresh fruits and vegetables possible for 535 consumption worldwide. 536 As we have seen with different food safety outbreaks and 537 the salmonella outbreak last year, a single scare can shut 538 down an entire industry. The salmonella outbreak in 2008 539 sickened over 1,400 people and initially focused on tomatoes 540 as the source. However, federal investigators later traced 541 the salmonella back to peppers from Mexico and not tomatoes, 542 leaving consumers confused and costing the tomato industry 543 hundreds of millions of dollars and calling our food safety 544 standards into question. Given this, I believe that just as 545 each of the various commodities grown in the Central Valley 546 are unique, so should any food safety requirements be

- 547 commodity specific and tailored to the different levels of
- 548 risk presented by each commodity.
- I am pleased to see the compromises made in this
- 550 legislation though there are still areas that need
- 551 improvement. The geographic quarantine section provides the
- 552 FDA with large authority to restrict the movement of foods if
- 553 it prevents a threat. With the traceability requirements
- 554 mandated, quarantine language that would shut down an entire
- 555 region should be unnecessary. The unsafe food could be
- 556 traced back to the producer without punishing other innocent
- 557 producers, packers and distributors in the region with the
- 558 stigma of a quarantine. Additionally, the FDA already has
- 559 the tools needed such as public health advisories that would
- 560 stop the movement of unsafe food without disrupting the
- 561 industries, devaluing production or eroding public confidence
- 562 to the extent that a quarantine would. Adjusting the
- 563 provision to require an imminent threat before the quarantine
- 564 authority can be exercised raises the threshold and protects
- 565 geographical regions from the negative impacts of unnecessary
- 566 quarantines. I thank the committee for this addition into
- 567 the geographic quarantine section.
- As this bill proceeds, I encourage my colleagues to
- 569 reach out to the farmers and ranchers whose very livelihoods
- 570 depend on producing the safest food in the world. Keeping

- 571 them engaged in an open and outgoing dialog as Congress moves
- 572 forward is critical to ensure that the law that we create is
- 573 effective and that compliance is obtainable. We must
- 574 remember that they want safe food just as much as consumers
- 575 do.
- As a committee, we have a responsibility to develop the
- 577 policy that provides Americans with the confidence that they
- 578 have the safest possible food on their table. I look forward
- 579 to this markup and again want to thank members for their
- 580 contribution to this bill.
- Thank you, and I yield back.
- [The prepared statement of Mr. Radanovich follows:]
- 583 ********* COMMITTEE INSERT *********

Ms. {DeGette.} The gentleman yields back. 584 585 gentleman from Texas is recognized. 586 Mr. {Green.} Thank you, Madam Chairman, and I want to 587 thank you for holding this markup on H.R. 2749, the Food 588 Safety Enhancement Act of 2009. 589 As a member of both the Health Subcommittee and the 590 Oversight and Investigation Committee, I have been involved 591 in the numerous hearings we have had on food safety issues. 592 We have investigated food contamination incidents in the 593 United States involving spinach, cantaloupes, peanut butter 594 and tomatoes. Each time Energy and Commerce held a hearing, 595 we found the FDA did not have the resources, funding, 596 manpower or technology it needs to protect the American food 597 supply and fulfill its mission. In fact, the FDA does not 598 even have the ability to require mandatory recalls, and we 599 have been relying on the voluntary efforts of food 600 manufacturers to ensure safety of their products. 601 been several examples of how our food safety system has 602 failed us and for years we have simply said the FDA is 603 underfunded and we should allocate them more resources. The 604 FDA clearly does need increased funding and this bill 605 provides some of those funds, and we will have to appropriate

more but I am happy the Food Safety Enhancement Act finally

- 607 gives the FDA the authority to improve the systems to protect
- 608 our food supply.
- I am pleased today we will finally be moving a
- 610 comprehensive food safety bill out of the committee to full
- 611 House consideration, and thank you again. I yield back my
- 612 time.
- [The prepared statement of Mr. Green follows:]
- 614 ******** COMMITTEE INSERT *********

620 Ms. {DeGette.} The gentleman from Oregon is recognized. 621 Mr. {Walden.} Thank you, Madam Chairman, and I 622 congratulate you and others who have worked so hard and 623 diligently on this issue. As you know, our Oversight and 624 Investigation Subcommittee heard testimony on February 11 of 625 this year, probably the eleven thousandth hearing we have had 626 on this subject, so I am glad to see legislation moving. 627 Our hearing on the PCA salmonella outbreak included 628 testimony from Peter Hurley of Wilsonville, Oregon. 629 son, 3-year-old Jacob, became sick in early January as did a 630 lot of Americans. For about 2 weeks Peter and his wife 631 watched as their son suffered stomach pain resulting in 632 vomiting and diarrhea. They took him to the doctor. 633 doctors couldn't figure out what was wrong with him, so they 634 suggested that he needed to keep some food down, give him the 635 food types that he enjoyed the most. Well, Jacob's favorite 636 food was Austin brand peanut butter crackers, which turned 637 out tragically to be the very thing that was poisoning him. Oregon State officials tested six packages of the crackers 638 639 that the Hurleys still had in their home and three of the six 640 packages contained salmonella, peanut butter that was 641 contaminated and shipped by PCA.

Madam Chair, I think our hearings over the years have

- 643 shown us that we needed a new and modern and updated FDA. I
- 644 think this legislation accomplishes that. I know that with
- 645 any sweeping legislation that adds new inspection regimes and
- 646 record requirements, we should be diligent in our duty of
- 647 following it through the process and after it is implemented
- 648 and make corrections and adjustments where necessary.
- I want to thank the majority for their work in making
- 650 this a sound and bipartisan product, and if you are looking
- 651 for a sexier title for the bill, I suggest we call it Jacob's
- 652 Law after Jake, who survived this horrible ordeal, and
- 653 hopefully no child and no parents will have to suffer this
- 654 again. Thank you, Madam Chair.
- 655 [The prepared statement of Mr. Walden follows:]
- 656 ********* COMMITTEE INSERT *********

657 Ms. {DeGette.} The Chair thanks the gentleman. The 658 Chair now recognizes herself for 3 minutes.

659 I am glad to hear that my colleague from Oregon 660 mentioned the Hurley family because as he will recall, at the 661 end of the last Oversight and Investigations hearing we had this spring, the last of a series that lasted over a number 662 of years, I told Peter Hurley, Jacob's dad, that we would 663 664 make a commitment to him and his family that we would pass 665 comprehensive food safety legislation this year, and we are, 666 and you know, today this is the way legislation should go 667 because we are doing it on a bipartisan basis. 668 worked together. We have explored the issues. Everybody has 669 pulled together to make this happen.

670 It almost looks easy but everybody, particularly on the 671 Oversight and Investigation Subcommittee, Mr. Stupak and 672 everybody else, we will attest that it was difficult because 673 when we started this effort 7 years ago, we had a food safety 674 system in disarray and it had been in disarray for many years 675 and it continued in disarray, story after story, recall after 676 recall, and in those days it was difficult for us to even 677 convince people that we needed mandatory recall authority for 678 the Food and Drug Administration, much less traceability and 679 some of the other components that are here in this

- 680 comprehensive bill today and so it really has been an
- 681 extraordinary team effort and that team effort has been
- 682 directed at one goal: protecting the safety and health of
- 683 our constituents.
- We hope that this bill today will give the resources and
- 685 the power to the Food and Drug Administration to be able to
- 686 protect that health and safety, and if there are problems
- 687 with our food system to make sure that we can address those
- 688 problems quickly. That is why I am particularly pleased that
- 689 the chairman had worked with me and others to include
- 690 mandatory recall authority by the FDA in the bill. We hope
- 691 that we will be able to catch contamination and avoid
- 692 contamination before it happens, but if there is contaminated
- 693 food found, we will be able to have recall authority.
- And secondly, I am so delighted that the FDA will be
- 695 implementing traceability systems for the entire food agency.
- 696 We saw this last year with the tomato and then jalapeno
- 697 recall where we never really could figure out what was wrong
- 698 with the salsa, but what we did know was people across the
- 699 country were being sickened and what we also knew was that
- 700 the entire tomato industry was devastated for that year. So
- 701 traceability is going to help us identify quickly and remove
- 702 the foods in a targeted way that are causing sickness.
- I just want to say one last thing, and that is, I have a

- 704 staff member to thank who is here today, Steve Plevniak.
- 705 Steve is my food safety maven on my staff. He has been with
- 706 me for 7 years, just about as long as we have been studying
- 707 these issues, and he is leaving us to go elsewhere, so this
- 708 is a fine end for his Congressional career and I just really
- 709 want to thank Steve and all the staff of the whole committee
- 710 who have worked so hard on this legislation.
- 711 [The prepared statement of Ms. DeGette follows:]
- 712 ********* COMMITTEE INSERT **********

- 713 Ms. {DeGette.} With that, I will now recognize the
- 714 gentleman from Nebraska.
- 715 Mr. {Terry.} Thank you. Very quickly, I want to thank
- 716 everybody involved in this. Like Mr. Pallone, I have a
- 717 constituent who died of the E. coli in spinach, California
- 718 spinach, and we have had several other E. coli outbreaks.
- 719 Amazingly, even though people think of E. coli in meat, it
- 720 has been salads and sprouts in our district, and it is a
- 721 delicate balance for Nebraska because we do have agribusiness
- 722 with lots of facilities and they will bear some of the cost
- 723 burdens for modernizing the FDA. But I think this does
- 724 strike a balance. We need a couple of improvements here and
- 725 I will offer an amendment later on that I hope the leadership
- 726 will work with me on.
- 727 So I just want to congratulate everybody who has been
- 728 working on this bill and particularly the majority for
- 729 actually accepting some of our recommendations and really
- 730 working in earnest. Thank you, and I yield back.
- 731 [The prepared statement of Mr. Terry follows:]
- 732 ********* COMMITTEE INSERT ***********

- 733 Ms. {DeGette.} The gentleman yields back. The Chair
- 734 now recognizes the gentlelady from Illinois.
- 735 Ms. {Schakowsky.} Thank you, Madam Chairman, for this
- 736 markup, and I want to thank Mr. Waxman, Mr. Dingell, Mr.
- 737 Pallone, Mr. Stupak, you, Madam Chairman, Ms. Sutton and
- 738 those on the minority side who worked with us to craft a
- 739 really good bill. This is the way that Congress should work.
- 740 As I mentioned before, this issue is very personal to
- 741 me. I began my public career working to ensure that food on
- 742 our store shelves had clear expiration dates at a time when
- 743 every single thing was secretly coded, and I also have a very
- 744 dear friend, Nancy Donnelly, who lost her only child, her
- 745 son, Alex, in 1993 after he ate ground beef contaminated with
- 746 E. coli. My thoughts and my gratitude today go out to her
- 747 because she turned her tragedy in to tireless advocacy for
- 748 food safety.
- 749 So we have as a result of all this work a strong bill
- 750 that will strengthen the Food and Drug Administration's
- 751 ability to keep our food system safe and help prevent some
- 752 tragedies in the future. It establishes mandatory recall for
- 753 the FDA but the real strengths of the bill, I think, are in
- 754 its prevention components, stopping an outbreak before
- 755 tainted food can reach our kitchen tables, requiring all food

- 756 facilities to implement hazard control plans, to analyze,
- 757 anticipate and preempt any point at which a potentially
- 758 dangerous contaminant could affect a food product. It also
- 759 increases inspections. Studies have shown that Americans
- 760 support thorough and frequent inspections of the places where
- 761 their food comes from.
- We must maintain if not strengthen the timetables for
- 763 inspections contained in the Manager's Amendment. The
- 764 Manager's Amendment also will implement a requirement that
- 765 positive test results are reported to the FDA. I think this
- 766 is a great addition. The agency has to have enough
- 767 information to know where the problems are. I am also
- 768 pleased that at my urging the Manager's Amendment includes
- 769 stronger language on data gathering, sharing and research
- 770 into the public health effects of foodborne illness.
- 771 There is also new language from Mr. Markey calling for
- 772 reevaluation of the presence of BPA in food and beverage
- 773 containers. Research indicates that BPA is not safe and I
- 774 think Chicago's effort to limit its presence in children's
- 775 food and beverage containers should be replicated and
- 776 strengthened at the national level. I think we have made
- 777 improvement since the health committee last week. I think we
- 778 should continue to examine whether the bill's language is
- 779 strong enough. I am going to introduce and offer an

- 780 amendment that I will later withdraw that deals with the
- 781 relationship between non-therapeutic antibiotic use in
- 782 livestock and resistant bacterial infections. I hope that I
- 783 can work with the committee to deal with this issue in the
- 784 near future.
- 785 So I thank you and yield back.
- 786 [The prepared statement of Ms. Schakowsky follows:]
- 787 ********* COMMITTEE INSERT **********

788 Ms. {DeGette.} The gentleman from Michigan, Mr. Rogers. 789 Mr. {Rogers.} Thank you, Madam Chair. I am pleased 790 that we have been able to work together today to address most 791 of the concerns that we had on this side of the aisle during 792 the hearing and subcommittee markup. As I have said many 793 times, I believe food safety should be a bipartisan issue and 794 I am glad to see we have made considerable bipartisan 795 progress on this bill. While the bill is not perfect, I 796 believe it will improve FDA's ability to protect our Nation's 797 food supply and it is something I can support. 798 The Manager's Amendment includes many important changes 799 in the bill including a more practical inspection schedule. 800 Exemptions for farms regulated by USDA, an exemption for 801 alcohol manufacturers already regulated by Treasury and a 802 more reasonable approach to recall authority and civil 803 monetary penalties, and I hope this experience will be a 804 great guide for this committee on health care reform. 805 Through regular order and bipartisan collaboration, we have 806 reached a very sensible compromise that incorporates good ideas from both sides of the aisle. 807 808 If we can do this for food legislation, we certainly

must be able to do on a massive overhaul of our health care system. Unfortunately, Republicans haven't even been able to

811	see one word of the health care bill being written by a very
812	few members. Supposedly we will see the bill just a few days
813	before we begin a series of hearings, and CBO won't even be
814	given a chance to score the bill before those hearings. We
815	have also been told that the Health Subcommittee won't even
816	be given a chance to mark up health care reform legislation
817	due to its artificially rushed timeline. I think certainly
818	the American people and members of this committee deserve
819	better, Madam Chair, and on this issue that will affect every
820	constituent and every family and every business across the
821	United States, I hope that we can find some time to work in a
822	bipartisan manner to get to the same kind of place we did on
823	FDA food legislation, and I would again hope and encourage
824	that we could use this as our template how we move forward
825	and how this body is supposed to operate.
826	With that, Madam Chair, I congratulate all those
827	involved in today's bill's efforts and would yield back the
828	remainder of my time.

[The prepared statement of Mr. Rogers follows:]

830 ******** COMMITTEE INSERT *********

831	Ms. {DeGette.} The gentleman yields back. The
832	gentleman from Pennsylvania.
833	Mr. {Doyle.} I will waive.
834	[The prepared statement of Mr. Doyle follows:]
835	*********

836	Ms. {DeGette.} The gentleman from Texas, Mr. Gonzalez.
837	Mr. {Gonzalez.} Waive opening.
838	[The prepared statement of Mr. Gonzalez follows:]
839	*********

840 Ms. {DeGette.} The gentlelady from Wisconsin. 841 Ms. {Baldwin.} Thank you, Madam Chairwoman, for 842 bringing this bill before our committee for markup this 843 morning. I also want to commend Chairman Waxman, Chairman 844 Pallone, Chairman Stupak and Chairman Emeritus Dingell for 845 their work in putting this legislation together and to our 846 friends across the aisle for working with us on key issues of 847 concern. I appreciate the fact that this has been a 848 bipartisan process. 849 In the past few weeks I have mentioned that I would 850 really like to see increased coordination between the federal 851 government and the States in the area of food safety, and I 852 am pleased to say that I think that Congress and the FDA 853 agree that in order to meet this rigorous new set of food 854 safety requirements, which I strongly support, we need to 855 work together as much as possible. Once again, I urge the 856 FDA to rely on our extensive network of State-based 857 inspectors and regulators to avoid duplication wherever 858 possible. 859 Another way the FDA can maximize its resources is to

Another way the FDA can maximize its resources is to

860 utilize experienced third parties, and I am happy to say that

861 with this new draft I am confident that laboratories that

862 currently provide the FDA with much-needed support and

- testing and analysis will be able to continue their very productive partnership moving forward.
- Like many of my colleagues, I have been inspired by the
- 866 families that have turned tragedy into action around this
- 867 issue. When I first entered Congress, I had the opportunity
- 868 to meet with a remarkable young family. When she was living
- 869 in Wisconsin, Barbara Kowalchek lost her young son, Kevin, to
- 870 food poisoning from meat contaminated with E. coli. She has
- 871 since founded the Center for Foodborne Illness and has been a
- 872 tireless advocate for a stronger food safety system. Her
- 873 mission in life has been to ensure that the same tragedy
- 874 experienced by her family never happens again. I am so proud
- 875 of her work and I hope that this legislation can be a
- 876 testament to her son's legacy and her tremendous advocacy.
- 877 Again, thank you to all of my colleagues here who worked
- 878 so hard on this legislation. I look forward to seeing it
- 879 pass into law soon, and Mr. Chairman, I yield back.
- 880 [The prepared statement of Ms. Baldwin follows:]

881 ******** COMMITTEE INSERT *********

882 The {Chairman.} The gentlelady yields back her time. 883 Mr. Barton. 884 Mr. {Barton.} Thank you, Mr. Chairman. I am going to 885 submit my formal statement for the record, but just to summarize it, we appreciate the bipartisan effort that has 886 887 been made on this bill. We appreciate the compromises that 888 have been made. We had concerns at subcommittee about 889 flexibility. The Manager's Amendment is going to provide 890 some flexibility. We had concerns about the open-endedness 891 of the civil monetary penalty, which we are giving the FDA for the first time. We have reached a compromise on those 892 893 penalties that I think is fair and reasonable, and while 894 there are some issues that we want to continue to discuss 895 between now and the Floor action, this is a good product. I 896 want to commend you, Chairman Pallone and Chairman Dingell 897 for your efforts, and I want to thank Nathan Deal and the 898 Republicans on my side that have worked to make this day 899 possible. This does show the committee can work together, 900 and we are very supportive of the final product and look 901 forward to taking this spirit of cooperation a step further

904 [The prepared statement of Mr. Barton follows:]

as we go to the larger issue of health care reform in the

902

903

next several weeks.

905 ******** COMMITTEE INSERT *********

906 The {Chairman.} Thank you very much, Mr. Barton. 907 Mr. Matheson. Mr. {Matheson.} Well, thank you, Mr. Chairman, and 908 909 while a lot of people have commended the process and where we 910 are right now, I think it is important for all of us to do 911 that because this is a complicated set of issues and I think 912 that the fact that this committee has worked hard and worked 913 collectively to come up with some consensus, I think that is 914 noteworthy and I commend the chairman for doing that and all 915 the other folks. There are so many to thank, I won't name 916 everyone, but I commend the chairman for his leadership on 917 this issue and I am pleased that this bipartisan agreement 918 has been worked out. 919 I know there are a few issues still to be talked about 920 as it goes to the Floor. I have one, and while I am 921 disappointed we weren't able to work out language to deal 922 with providing a label requirement for lead content on 923 ceramicware, I am hopeful that we will be able to find some 924 solution to this issue as we go to the Floor. It is an issue 925 I have been talking about since 2006, and I am hoping we can 926 resolve it in this bill but we seem to have exhausted good

options prior to this markup. But I do believe there is an

opportunity that we can figure this out. I think the science

927

929	already tells us what constitutes trace amounts of lead in
930	products and I think we can work as a committee to direct the
931	FDA to address this issue and issue appropriate guidance
932	because at the end of the day my motivation is consumers
933	should know if they have products that have a lead glaze put
934	on their ceramicware.

So again, I look forward to continuing to work with the committee, and again, Mr. Chairman, congratulations on moving this bill forward and I encourage all members of the committee to support the bill. I will yield back my time.

[The prepared statement of Mr. Matheson follows:]

940 ******** COMMITTEE INSERT *********

941 The {Chairman.} Thank you, Mr. Matheson. 942 Mr. Buyer. 943 Mr. {Buyer.} Thank you, Mr. Chairman. Specifically, I 944 would like to thank you for accepting an amendment, several 945 amendments, in particular to clarify the bill to ensure that 946 fisheries are included in the definition of farms which are 947 exempt under the tracking and trace requirements under 948 section 107. I had offered the fisheries amendment on behalf 949 of Congress Gresham Barrett of South Carolina, who is very 950 concerned with regard to those of whom seek clams, oysters, 951 the shrimpers and the fishermen in the low country of South 952 Carolina. As he thought about that, he also then thought 953 about the coastal plains all around the boundaries of our 954 country, and I want to thank Mr. Pallone, who also has a 955 Congressional district and so he understands the sea and the 956 importance of this amendment to the fishing industry and 957 agreeing that they should be treated in the same regard as 958 the farmers when it comes to direct sales from farms. I 959 think this amendment will help ensure that they are not 960 subject to unnecessary regulatory burdens and will save many 961 of the small businesses in our Nation's coastal communities.

Additionally, I want to thank you and also Mr. Dingell for working with us on an amendment to ensure that the

- 964 primary responsibility of regulating the alcohol industry 965 remains in the hands of the Tax and Trade Bureau. I hope we 966 have arrived at an agreement that is acceptable to the 967 alcohol and beverage industry and ensures that the stringent 968 oversight of TTB remains in place. I believe that TTB has 969 done a good job ensuring the safety of alcoholic beverages in 970 our country and I do not think it is in the best interest of 971 this committee to interfere with a memorandum of 972 understanding struck between FDA and TTB which has operated 973 very well for many years. 974 I am also pleased that the user fees have dropped to
- 974 I am also pleased that the user fees have dropped to 975 \$500 per facility. These users fees can significantly impact 976 small businesses and so I want to extend my appreciation for 977 that.

978 I am also encouraged by the movement to address the 979 concerns about FDA regulations on our farms and specifically 980 for their impact on livestock and poultry producers. The 981 livestock and poultry operations already carry many of the 982 requirements of this food safety bill such as recordkeeping 983 and inspection activities. While the language is not 984 perfect, I would agree that we have worked hard to reach a 985 consensus and we should also as we work with our friends in 986 the Senate make sure that we are not duplicative, especially 987 with regard to regulations, and we should also remember, let

- us not make the exception the rule. A vast majority of food
 processing companies in America are operating above and
 beyond many of the food safety requirements and their hazard
 risk assessment plans go further and we should recognize that
 and be careful, as I said, about making the exception the
 rule.
- 994 The last comment I would make, Mr. Chairman, is, when we 995 finish this it is off to the drug safety bill, and I am 996 pleased to work with Chairman Dingell and I think that the 997 Buyer-Matheson bill on electronic pedigree for drugs, if you 998 like what has happened here on the tracing requirements for 999 food, you are going to love what Mr. Matheson and I have been 1000 able to come up with with drug pedigree, and Chairman Dingell 1001 and Chairman Waxman, I want to thank you and I look forward 1002 to working with you on the drug safety bill.
- 1003 [The prepared statement of Mr. Buyer follows:]

1004 ********* COMMITTEE INSERT **********

1005 The {Chairman.} Thank you very much, Mr. Buyer. 1006 Mr. Markey. Mr. {Markey.} Thank you, Mr. Chairman, very much. 1007 rise in support of this bill and I want to commend you and 1008 1009 Mr. Pallone along with Mr. Barton and Mr. Deal for the 1010 bipartisan way and the extensive work which has been done on 1011 this important legislation. 1012 I also want to thank each of you and others for working 1013 with me to include language related to the safety of BPA in food and beverage containers. The language that is included 1014 1015 in the bill calls on FDA to evaluate the approved uses of BPA 1016 in food and beverage containers and to tell the committee 1017 whether each use is safe by the end of the year. If FDA 1018 finds that BPA isn't safe, it is additionally directed to 1019 tell us how it plans to protect public health, which could include banning the chemical as well as efforts such as 1020 1021 placing warning labels on products that contain it. As you 1022 know, BPA is a ubiquitous chemical found in most food and 1023 beverage cans and many reusable plastic containers. 1024 also found in most baby bottles until recently when major 1025 baby bottle manufacturers agreed to voluntarily stop using it

1026 because of concerns about its effect on health, which are
1027 many. BPA can be linked to increases in breast and prostate

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1028 cancer risk, heart disease, liver abnormalities and diabetes.
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- 1029 BPA can result in adverse impacts to reproductive health.
- 1030 BPA can be linked to increase in obesity, attention deficit
- 1031 and hyperactivity disorder, brain damage, altered immune
- 1032 function and other problems. BPA can be found at
- 1033 dramatically higher levels in infants than in the rest of the
- 1034 population and is also found in placental tissue and
- 1035 umbilical cord blood and BPA has been found at higher levels
- 1036 in women with a history of repeated spontaneous miscarriages.
- 1037 Not all industries are as receptive to addressing health
- 1038 concerns as the baby bottle manufacturers were. In fact,
- 1039 just recently the food and packaging industry convened a
- 1040 meeting in Washington at which they devised an extensive
- 1041 public relations campaign to claim that there is not really a
- 1042 problem.
- 1043 So I am glad that we have been able to work together in
- 1044 order to construct something which I think is a very good way
- 1045 to approach the issue. I once again thank all concerned and
- 1046 I yield back the balance of my time.
- [The prepared statement of Mr. Markey follows:]
- 1048 ********** COMMITTEE INSERT **********

1054 The {Chairman.} Mr. Pitts waives. Mr. Burgess. 1055 Mr. {Burgess.} Thank you, Mr. Chairman, and this is an 1056 important subject that is before us this morning. 1057 appear that the cake has already been baked irrespective of 1058 substance, style or practicality, and I understand and 1059 appreciate the political calculations which have been made in 1060 order to produce in less than 2 weeks a discussion draft, a 1061 bill, convene a subcommittee mark and now a full committee 1062 mark, all in the interest of food safety. But much like the idea of health care reform where the concept of health care 1063 1064 is universally agreed upon, giving our constituents safe food 1065 is also non-controversial. Food should be safe. But the 1066 devil still is in the details and not all the details here 1067 are completely agreeable. 1068 While there has been considerable conversation about the substance of the bill, there are aspects that are of concern. 1069 1070 In the past I have spoken about the need to have a way to 1071 halt imports so that when a foodborne illness issue arises on 1072 the border on Friday afternoon at 4 p.m., we don't have to 1073 wait until Monday morning for someone to make the decision to 1074 stop the importation of said food. To deal with this 1075 problem, I have introduced legislation dealing with the

Imported Food Safety Improvement Act and I hope to see that

1077 language added to this bill as an amendment.

1078

Also, while I note improvements have been made to the 1079 civil monetary penalties for violations of this Act and we 1080 heard Ranking Member Barton speak to this, right now there is 1081 no differentiation made for those are neither considered an 1082 individual or a company. Most food manufacturers are either 1083 a small business or a very small business and yet whether the intent was intentional or unintentional, because they are not 1084 1085 a single-man operation, these very small businesses could 1086 potentially be hit with a fine as large as \$1 million, even though their annual earnings may only be a fraction of that. 1087 1088 Just as this committee has recognized the need for scale in 1089 the amount of penalties for the individual versus the 1090 company, we need to recognize the need for scale in the 1091 amount of penalties for these very small businesses and the 1092 companies. 1093 Furthermore, the timeline for inspection is problematic. 1094 The Food and Drug Administration has repeatedly stated that 1095 they do not have the inspectors and in fact they have just 1096 recently delivered to us data that underscores that fact, nor 1097 do they even have all the contracts with third-party 1098 inspectors to meet the expectations of this bill. Now, that 1099 is not an excuse for non-performance. We all know that they 1100 have been underfunded and underresourced. I think this is a

- 1101 very real and calculated analysis of their assets and the 1102 Food and Drug Administration simply does not have the human 1103 capital to do what we are going to ask them to do. We must 1104 give them a reasonable amount of time to ramp up inspections 1105 and it strikes me that 18 months does not meet the standard 1106 of reasonableness in this situation. I do not want the Food 1107 and Drug Administration to be back at yet another Oversight 1108 and Investigation hearing to discuss how they did not meet 1109 the expectation demands of the bill. I want us to fix the 1110 inspection problems this time and not continue to deal with 1111 it as an ongoing problem.
- I support the inspection requirements of Senator

 Kennedy's Food Safety Modernization Act as well as those put

 forward by Mr. Costa. Reasonable schedule and rationale for

 inspections is needed.
- And then just finally, as probably been mentioned several times this morning, we got an amendment in the nature of a substitute of 133 pages just before this markup started. It is not identical to the language of the bill and is the result of negotiations going on between the two sides.
- However appreciative I may be of the consideration of the conversation, I am troubled members are not given enough time to read these 133 pages and ensure that all of the
- 1124 contingencies have been met. I am sure the substance of this

- 1125 food safety conversation should allow ample opportunity for
- 1126 members to make their review and we should expect nothing
- 1127 less.
- 1128 Thank you, Mr. Chairman, for the consideration. I will
- 1129 yield back the balance of my time.
- 1130 [The prepared statement of Mr. Burgess follows:]
- 1131 ******** COMMITTEE INSERT **********

The {Chairman.} Thank you, Mr. Burgess.

1133 Ms. Matsui, do you wish to make an opening statement?

1134 Ms. {Matsui.} Thank you, Mr. Chairman. I want to

1135 commend you for your hard work on this essential legislation.

1136 I would also like to compliment my colleagues, Mr. Dingell,

1137 Mr. Pallone and Mr. Stupak, on their contributions to this

1138 critical bill and also the hard work by Ms. DeGette and Ms.

1139 Sutton.

1140 Mr. Chairman, my hometown of Sacramento has had a rich

1141 heritage of agriculture. Although Sacramento is now an urban

1142 area, there are rural areas surrounding it that produce rice,

1143 walnuts, almonds, tomatoes and grapes, and as Mr. Radanovich,

 $1144\,$ my colleague on the other side of the aisle, knows, I was

1145 raised on a farm in central California, which he now

1146 represents. My family raised grapes, plums, peaches and

1147 nectarines. I am now mostly a consumer but I really do have

1148 a fine appreciation about the challenges facing agriculture,

1149 and I also have two toddler grandchildren who just love to

1150 eat. So I am well aware of how critical it is for our food

1151 supply to be safe. If people get sick from food on their

1152 table, they lose confidence in entire aspects of our economy.

1153 When E. coli was found in California spinach 3 years ago, the

1154 spinach industry lost hundreds of millions of dollars. Not

- 1155 the spinach industry, not the restaurant industry, not the
- 1156 American consumer and certainly not this committee want to
- 1157 see this happen again.
- 1158 Agriculture made my home State of California what it is
- 1159 today but it did so because people had confidence that food
- 1160 and produce in California is safe to eat. We must restore
- 1161 confidence in our food safety system, Mr. Chairman, and that
- 1162 is why I support today's legislation so strongly.
- The bill before us today strikes a good balance. It
- 1164 protects the consumers who sit down to dinner with their
- 1165 families tonight and eat a meal that they have a right to
- 1166 know is safe. It also acknowledges that the agriculture and
- 1167 food industries are essential to our economic health. I am
- 1168 pleased that the legislation dramatically increases the
- 1169 resources available for the FDA to carry out its critical
- 1170 mission of protecting our food supply. We have known that
- 1171 the FDA has had a resources problem for a long time, and
- 1172 today's bill resolves that issue.
- 1173 Mr. Chairman, I commend you for all that you have done
- 1174 to ensure that the food my constituents eat is safe and
- 1175 healthy. I urge my colleagues to support the Food Safety
- 1176 Enhancement Act, and I yield back the balance of my time.
- 1177 [The prepared statement of Ms. Matsui follows:]

1178 ********* COMMITTEE INSERT **********

1179 The {Chairman.} Thank you very much, Ms. Matsui. 1180 Mr. Scalise. Mr. {Scalise.} Thank you, Mr. Chairman. I appreciate 1181 1182 the bipartisan approach that has been taken on the food 1183 safety bill. Obviously this is an issue I think we can all 1184 find agreement on. It was unfortunate we weren't able to 1185 achieve that level of bipartisanship during the cap-and-trade 1186 energy tax debate but hopefully as we go forward in the days 1187 ahead and begin debating the important issue of health care, 1188 this same bipartisan approach could be taken as we on this 1189 side present our solutions to reforming our Nation's health 1190 care system. I look forward to those debates and look 1191 forward to completing this markup today. I yield back. 1192 [The prepared statement of Mr. Scalise follows:]

1193 ********* COMMITTEE INSERT *********

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1194
           The {Chairman.} Thank you very much.
1195
          Ms. Christensen.
          Ms. {Christensen.} Thank you, Mr. Chairman.
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                                                         Just
1197
     briefly, I am glad to see that this important bill is before
1198
     us today. It is a good day for public health and for the
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     health promotion and protection of the American people. I
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      just want to take this opportunity to applaud you, Mr.
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     Chairman, Ranking Member Barton and the subcommittee chairs
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     and ranking members, many of our colleagues, especially our
1203
      chair emeritus, Mr. Dingell, for the work that has gone into
1204
     creating this bipartisan bill and I look forward to passing
     it today and soon on the Floor. Thank you, Mr. Chairman. I
1205
1206
     yield back.
1207
           [The prepared statement of Ms. Christensen follows:]
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******** COMMITTEE INSERT *********

- 1209 The {Chairman.} Thank you very much.
- 1210 Mr. Space.
- 1211 Mr. {Space.} Thank you, Mr. Chairman. I want to begin
- 1212 by commending the important work that you and Chairman
- 1213 Dingell, Chairman Pallone, Chairman Stupak, Representatives
- 1214 DeGette and of course my colleague from the State of Ohio,
- 1215 Representative Sutton, have done on this legislation. This
- 1216 bill is the product of extensive hearings and negotiations
- 1217 that predate my time on the committee, and I truly appreciate
- 1218 the work that you have done.
- 1219 I also want to thank the bill's authors for taking into
- 1220 consideration the perspective of affected industries in
- 1221 crafting this legislation. I represent an extensive
- 1222 agricultural sector, and the changes made to the original
- 1223 discussion draft are very much appreciated. In particular, I
- 1224 want to thank the chairman for working with the livestock
- 1225 industry to ensure that this legislation works in a logical
- 1226 fashion with their interests. I commend your work as well as
- 1227 the work of that industry to reach consensus on a challenging
- 1228 issue.
- 1229 What is at stake in today's discussion is the safety of
- 1230 the food available to consumers. Earlier this year, a bad
- 1231 actor in the market knowingly distributed a flawed product to

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1232 American consumers leading to well-publicized health
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- 1233 consequences. While this particular actor is not
- 1234 representative of an industry that is generally both safe and
- 1235 responsible, the incident highlighted areas of our Nation's
- 1236 system of food safety that needed improvement. I applaud the
- 1237 authors of the bill for making these improvements and making
- 1238 the food available to our consumers safe.
- 1239 In particular, I applaud the chairman for working to
- 1240 establish systems that encourage individual actors to be both
- 1241 accountable and responsible. By requiring individual
- 1242 facilities to develop their own more thorough safety plans, I
- 1243 believe we have moved toward a system that will effectively
- 1244 protect American consumers. And I also would like to commend
- 1245 the leadership of both the chairman and the ranking member in
- 1246 working toward a bipartisan compromise. I believe that the
- 1247 work done on this issue can be a model for this committee in
- 1248 working towards a bipartisan consensus on challenging issues.
- 1249 I am hopeful we can continue to work in a similar fashion on
- 1250 other issues in this committee.
- 1251 Thank you, Mr. Chairman, and I yield back the balance of
- 1252 my time.
- 1253 [The prepared statement of Mr. Space follows:]
- 1254 ********* COMMITTEE INSERT **********

1255 The {Chairman.} Thank you very much, Mr. Space. 1256 Mr. Barrow. 1257 Mr. {Barrow.} I thank the Chair. I want to commend all 1258 the good work of Chairmen Waxman, Pallone, Dingell and Stupak 1259 and all of the staff members that have contributed to this. 1260 As we all know, some bad actors in my State are a big 1261 part of the reason why we are sitting here today working on 1262 this legislation. The worst of it is that these folks hurt 1263 and killed a lot of Americans as a result of their willful 1264 misconduct, but that wasn't the extent of it. A lot of 1265 perfectly innocent bystanders got hurt too. The economic 1266 impact wasn't confined. It affected a lot of people, 1267 processors and farmers, who are doing the right thing by the 1268 American consumer. 1269 I am pleased to call attention to the fact that the 1270 Manager's Amendment essentially amends the underlying Act in 1271 a way that I think makes a big step towards addressing the 1272 problems we found out about in that instance. One of the 1273 things we found out is that these folks had positive results 1274 of tainted food that they were putting into the marketplace.

the marketplace. They kept on sampling until they found a clean batch and kept on testing until they got a negative

They knew that they had tainted goods they were putting in

1278 test result. What they were doing was, they were shopping 1279 around and continuing to look for a negative test result, 1280 false negatives that would cover up the evidence they had of 1281 the true positives of tainted food they were putting in the 1282 food supply. That really gets my goat, and there is 1283 something we can and ought to do about it. One of the things 1284 I put on the table from the beginning about this process is 1285 to explore ways and means of putting a mandate to report 1286 positive test results in real time so that folks don't have 1287 the option of shopping around for false positives and the 1288 option of sitting on the true positives that they have but 1289 they have to divulge the information so that we know what 1290 they know when they know it. 1291 I am pleased that the bill has been amended essentially 1292 in ways that can address this problem. What it does 1293 essentially is, it requires that the food safety plan that is 1294 a new mandate describe the testing regime that all the 1295 registrants are going to have and also it mandates the FDA to 1296 conduct a pilot program to see how a mandatory reporting regime might actually work because one of the things we 1297 1298 brought out in the hearing is that it is a whole lot easier 1299 said than done. You can have a whole lot of unintended 1300 consequences and cause folks who basically want to dumb down 1301 their testing not to know the things that they need to know,

- 1302 and that is something we don't want to have happen. So I am
- 1303 very pleased that these two approaches are going to reflect
- 1304 what I think is the first step in the direction of mandatory
- 1305 positive test results. I want to see how it works.
- I want to commend again all the staff and the folks who
- 1307 had a hand in it. What I think this will allow us to do is
- 1308 to pick the bad actors out of the pack before they can do
- 1309 harm and help us spot problems real early on before they get
- 1310 out of control.
- 1311 With that, Mr. Chairman, I thank you again for your
- 1312 leadership on this. I want to thank the stakeholders for
- 1313 working with us on this to understand all aspects of this
- 1314 approach, and with that, I yield back.
- [The prepared statement of Mr. Barrow follows:]
- 1316 ******** COMMITTEE INSERT **********

- 1317 The {Chairman.} Thank you, Mr. Barrow.
- 1318 Mr. Gingrey.
- 1319 Mr. {Gingrey.} Mr. Chairman, thank you, and I want to
- 1320 thank you for holding this markup today on H.R. 2749, the
- 1321 Food Safety Enhancement Act of 2009.
- I also want to take the time to commend you, Ranking
- 1323 Member Barton, Health Subcommittee Chairman and Ranking
- 1324 Member Deal for moving this legislation through regular order
- 1325 and for working in a bipartisan way to bring critically
- 1326 important food safety legislation before the committee.
- 1327 Unfortunately, there have been a number of failures in
- 1328 our food safety system over the past several years that range
- 1329 from the E. coli contamination of the California spinach to
- 1330 that incidence of salmonella-tainted peanuts from the Peanut
- 1331 Corporation of America, unfortunately, some of that in my
- 1332 home State of Georgia. Clearly, we need to take proactive
- 1333 steps to better protect the health and welfare of all of our
- 1334 citizens when it comes to the food that they eat on a daily
- 1335 basis.
- 1336 Mr. Chairman, during the subcommittee markup on this
- 1337 legislation last week, we discussed and debated a number of
- 1338 concerns that were raised by members, not for the sake of
- 1339 political gain but for the sake of creating sound policy that

- 1340 will help improve the legislation. To that end, I commend my
- 1341 colleagues in the majority for working with me and accepting
- 1342 an amendment that I think will greatly improve this
- 1343 legislation by recognizing the balance that the Food and Drug
- 1344 Administration has with U.S. Department of Agriculture, when
- 1345 it comes to food safety.
- Mr. Chairman, the language that has been accepted, and I
- 1347 thank you, provides a clear distinction through statutory
- 1348 language that allows both the USDA to continue using its
- 1349 expertise in inspecting facilities, especially when it comes
- 1350 to livestock, and the FDA to focus on the areas of food
- 1351 safety where that agency can excel. This language mirrors
- 1352 the companion legislation that is being considered in the
- 1353 Senate and it codifies the collaboration between FDA and USDA
- 1354 that should exist for our farmers and our livestock
- 1355 producers. So I am pleased that this provision was able to
- 1356 be included in the bill and I am encouraged that this was one
- 1357 of the many items where partisan politics were able to be put
- 1358 aside for the benefit of the American people.
- In the coming weeks, we will be debating comprehensive
- 1360 health care reform and it is my ultimate hope that we can
- 1361 come together much like we have done on food safety today and
- 1362 work in the best interests of the American people on that
- 1363 issue like we are doing this morning.

1364	Again, Mr. Chairman, I commend you for working
1365	diligently with me and with my Republican colleagues to
1366	improve this important legislation. I look forward to our
1367	continued spirit of comity on H.R. 2749 as it moves to the
1368	House Floor, and I yield back the balance of my 16 seconds
1369	[The prepared statement of Mr. Gingrey follows:]

1370 ********** COMMITTEE INSERT **********

1371 The {Chairman.} Thank you, Mr. Gingrey. 1372 Ms. Eshoo. Ms. {Eshoo.} Thank you, Mr. Chairman. I will just be 1373 1374 brief. 1375 I want to start out I think the way everyone has to 1376 congratulate the members that have worked so hard on this and 1377 made this markup possible, certainly yourself, Mr. Pallone, 1378 the chairman emeritus, Mr. Stupak, members from the other 1379 side of the aisle working to work this out because it is so 1380 critical to people in our country. I also want to salute the 1381 consumer organizations who have been obviously the conscience 1382 in this and you are essential, you have been essential, you 1383 will continue to be, and I want to salute you on this. 1384 As I mentioned in a previous hearing, this issue had to 1385 mature in order to have us all arrive at this point today, to 1386 do a food safety bill. Unfortunately, there had to be 1387 catastrophic happenings in the country, and as I said, I had 1388 introduced legislation going back to 1997 with the new 1389 Senator who had just left the House, Dick Durbin. 1390 nonetheless, today is an important date and I think this 1391 bipartisan consensus speaks very well about our seriousness

1393 still an advocate for separate food and drug agencies.

to address the huge shortfalls in our food system. I am

1394	think today obviously is a very, very important step that we
1395	are taking, and I think that this committee should monitor
1396	the impact of the legislation and FDA's capacity to carry out
1397	these reforms. If in fact they don't have the resources that
1398	we are counting on, then this legislation will not be able to
1399	be carried out. It is too serious to let it fall among those
1400	rocks, but today is important. I congratulate and I thank
1401	everyone that has been a part of it, and I yield back, Mr.
1402	Chairman.

[The prepared statement of Ms. Eshoo follows:]

1404 ********* COMMITTEE INSERT *********

The {Chairman.} Thank you very much.

Mr. Melancon.

Mr. {Melancon.} Thank you, Mr. Chairman. I will waive

my opening.

[The prepared statement of Mr. Melancon follows:]

1410 ********** COMMITTEE INSERT *********

- 1411 The {Chairman.} Then the Chair would call on Ms.
- 1412 Sutton, or Mr. McNerney, you are ahead in seniority. Excuse
- 1413 me.
- 1414 Mr. {McNerney.} Thank you, Mr. Chairman. I want to
- 1415 thank you for bringing this legislation forward. This is a
- 1416 personal issue to me. I had a daughter that suffered an E.
- 1417 coli infection, and as a parent, it was very difficult to
- 1418 watch my daughter suffer possible kidney failure and even
- 1419 death. It was 5 days before we even knew what caused the
- 1420 infection. So this is incredibly important. I understand
- 1421 the pain that families go through that suffer these kinds of
- 1422 infections.
- I also represent San Joaquin Valley, which has a
- 1424 tremendous number of producers and food processors, and I
- 1425 understand the need to have regulations in place that aren't
- 1426 overburdensome and protect the legitimate producers from the
- 1427 bad actors. It seems that this bill manages to balance those
- 1428 two needs of protecting the consumers and not overburdening
- 1429 the suppliers. It is a good bipartisan effort. I am proud
- 1430 that we have been able to accomplish this and I urge my
- 1431 colleagues to support the bill. With that, I yield back my
- 1432 time.
- [The prepared statement of Mr. McNerney follows:]

1434 ********* COMMITTEE INSERT *********

The {Chairman.} Thank you, Mr. McNerney.

Ms. Blackburn.

Ms. {Blackburn.} Thank you, Mr. Chairman. I will waive

my opening and look forward to continuing to work on the

bill. Thank you.

[The prepared statement of Ms. Blackburn follows:]

********* COMMITTEE INSERT *********

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1442
           The {Chairman.} Thank you.
1443
          Mr. Inslee.
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          Mr. {Inslee.} Thank you. Mr. Chairman, I want to thank
     you for including my amendment to clarify the intent behind
1445
1446
     the authority given to the Secretary to quarantine geographic
1447
     regions of the country. Limiting the authority of the
1448
     Secretary to quarantine any geographic area no greater than
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      is appropriate to protect public health will not only protect
1450
      the American people but will help safeguard the industry that
1451
      the American people rely on for safe food. I think it was an
1452
      appropriate thing to do.
1453
           I also want to just express relief that we are finally
1454
     adopting measures on leafy green vegetables that have been
1455
     successful in the meat industry. I believe they are going to
1456
     have great effect. Thank you.
           [The prepared statement of Mr. Inslee follows:]
1457
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********* COMMITTEE INSERT ********

- 1459 The {Chairman.} Thank you very much.
- Ms. Sutton.
- 1461 Ms. {Sutton.} Thank you, Mr. Chairman, and I want to
- 1462 thank you for holding this markup on this critical
- 1463 legislation and I am proud to be a sponsor.
- I want to thank all on both sides of the aisle who have
- 1465 been working on this bill and specifically, Mr. Chairman, you
- 1466 and Chairman Pallone, Chairman Emeritus Dingell, Chairman
- 1467 Stupak and Congresswoman DeGette for all of their hard work
- 1468 and long dedication along with representative Schakowsky to
- 1469 this issue, and I am delighted that we are one step close to
- 1470 passage of this bill. And I do want to especially thank Mr.
- 1471 Dingell for his leadership on this legislation and for the
- 1472 inclusion of the mandatory recall provision that I introduced
- 1473 as the Protect Consumers Act for having been included in this
- 1474 bill. I am very grateful for that.
- 1475 I join all of you, Chairman Waxman and others who have
- 1476 spoken in our eagerness to see this bill reach the Floor for
- 1477 passage. We have seen the headlines over foodborne illnesses
- 1478 repeated in our national press and we have seen too many
- 1479 outbreaks of these illnesses and they have highlighted the
- 1480 vulnerability of our food supply and the need for safety
- 1481 reform. The issue of food safety and foodborne illness, as I

1482 have repeated here in this committee, has taken a 1483 disproportionate toll on the State of Ohio, and over the past 1484 year there have been 105 cases of salmonella infection reported in Ohio, and sadly, three deaths from the most 1485 1486 recent peanut-based strain. Among the three who sadly lost 1487 their lives was Nellie Napier, who was a constituent of mine, 1488 and she died from salmonella poisoning which she contracted 1489 in a nursing facility, and I had the opportunity to meet with 1490 Nellie's sons and talk to them about the devastating loss of 1491 their mother, and of course it would be devastating in any 1492 way to lose one's mother but the fact that she died from 1493 eating peanut butter was excruciating for them. You know, it 1494 is our obligation to protect our most vulnerable populations, 1495 and as I mentioned in Ohio, just in April of this year in 1496 Cuyahoga County there were three incidences of illness from 1497 E. coli and we had another death, this time a 7-year-old 1498 girl. 1499 So it is critical that we are taking these steps today 1500 to ensure that the FDA is doing all that it can to protect 1501 our families and ensure our food safety. It is why I 1502 introduced the mandatory recall legislation for the FDA in 1503 the first place because Americans need to know that the food 1504 on their family's table and in their children's lunchboxes is 1505 safe to eat and whether it is grown here or it is imported

1506	from abroad, there must be strict regulation of the supply
1507	line that feeds our Nation, and in this bill we have also
1508	taken aim at the safety of imports, and from our hearings we
1509	learned that close to 13 percent of the food that we eat
1510	comes from abroad, and yet the FDA inspects less than 1
1511	percent of the food shipments arriving at our ports, and this
1512	dynamic needs to change. And so the certification provisions
1513	in this bill we are marking up today will help with the
1514	safety of food imports and this is something that we need to
1515	continue to work on.
1516	Mr. Chairman, I look forward to working with you and all
1517	of my colleagues to pass this legislation out of the full
1518	committee and move it to the House Floor, and I yield back.
1519	[The prepared statement of Ms. Sutton follows:]

1520 ********** COMMITTEE INSERT **********

1521 The {Chairman.} Thank you, Ms. Sutton. 1522 Mr. Braley. Mr. {Braley.} Thank you, Mr. Chairman. 1523 Food safety is something that affects every American and 1524 1525 that is why it is so important that today you are 1526 demonstrating leadership by leading us forward on markup of 1527 this bill. I am supportive of the bill because I know it is 1528 going to address many of FDA's shortcomings and I have had 1529 the opportunity to follow this through a number of hearings 1530 both in the Health and the Oversight and Investigation 1531 Subcommittees. I am confident that this bill will take steps 1532 to prevent future illness and death due to unsafe food 1533 products, and I also want to thank the committee for its hard 1534 work to address my concerns relating to the treatment of carbon monoxide in food packaging and I am pleased to see a 1535 positive resolution of that issue. 1536 1537 In addition, the committee has been very responsive to 1538 my concerns over the treatment of farms in this bill. I have 1539 maintained that we need to ensure coordination among all 1540 government agencies involved in food tracing and farm

1543 Representatives Butterfield, Space and others to come up with

inspections and we don't want to create duplicative

requirements on farmers. I worked closely with

1541

1544	compromise language which will ensure that the food and
1545	facilities are exempt from this Act if they have already
1546	similar regulation under USDA. The committee has worked with
1547	us and I am glad to see that the Manager's Amendment today
1548	exempts USDA-related farms and facilities. I support strong
1549	oversight of food products and facilities and I am glad we
1550	are making sure that our government agencies are coordinating
1551	and avoiding duplicative regulations.
1552	So thank you again, Mr. Chairman, and I am confident
1553	this Food Safety Enhancement Act will take significant steps
1554	to ensure the safety of the food we eat.

[The prepared statement of Mr. Braley follows:]

1556 ********* COMMITTEE INSERT *********

- 1557 The {Chairman.} Any other member wish to make an 1558 opening statement? If not, the Chair would like to recognize 1559 Mr. Dingell. Mr. {Dingell.} Mr. Chairman, I thank you for your 1560 1561 courtesy. 1562 Today, Mr. Chairman, this committee is losing a very 1563 valuable servant. Today is the last day and the last day 1564 before retirement of our good friend, Ray Kent, who has 1565 served as deputy clerk of this committee since August of 1566 1979. Almost everybody on the committee and on the staff 1567 knows Ray and knows what a wonderful, valuable, faithful 1568 servant he has been to the public, to the public interest and 1569 to the members of the committee. We are going to miss him. 1570 He is going to be hard to replace, but on behalf of all of my 1571 colleagues here and on behalf of the committee, I would like 1572 to first thank Ray Kent for his extraordinary public service, 1573 both in terms of length and in terms of quality, but also to 1574 wish him well on behalf of the committee, to congratulate him 1575 and to hope that his retirement is long, successful and 1576 happy, and I thank you for that, Mr. Chairman. 1577 The {Chairman.} Thank you, Mr. Dingell. I want to join
- The {Chairman.} Thank you, Mr. Dingell. I want to join with you in paying tribute and thanking Ray Kent for his service, and I would like to ask the member to join with me

- 1580 in giving him a round of applause.
- We have completed the opening statements on H.R. 2749,
- 1582 the Food Safety Enhancement Act of 2009. I would like to ask
- 1583 unanimous consent that the bill be considered as read and
- 1584 open to amendment at any point, and without objection, that
- 1585 will be the order.
- 1586 [The information follows:]
- 1587 ************** INSERTS 1, 2 ***********

The {Chairman.} I have an amendment at the desk in the nature of a substitute, and without objection, this amendment will be considered as read and open to amendment at any point as well.

[The amendment follows:]

************ INSERT 3 **********

1594 The {Chairman.} This amendment reflects the extensive 1595 bipartisan negotiations we have had on this bill over the 1596 last couple of weeks. It also makes several important 1597 changes to respond to the various concerns stakeholders have 1598 raised about the bill. I will just mention a few of the 1599 major changes. 1600 The language now makes clear that the bill applies to 1601 FDA-regulated farms and facilities. The amendment clarifies 1602 the ways in which the bill applies and does not apply to 1603 facilities, manufacturing alcoholic beverages. 1604 facilities must register but do not have to pay a fee. 1605 also clarifies that the ways in which the Secretary of the 1606 Treasury currently regulates alcoholic beverages will not be 1607 impacted by this bill. 1608 In the area of preventive food safety plans, the 1609 amendment clarifies that FDA must permit the use of 1610 alternative preventive controls that are demonstrated to 1611 effectively address the hazards. The amendment clarifies 1612 that FDA has the authority to require finished-product

that FDA has the authority to require finished-product
testing at high-risk facilities of FDA finds that such
testing or reporting would bring about useful risk
information. Before doing so, FDA must complete two or more
pilot projects and a feasibility study. The amendment makes

- 1617 some important clarifications related to FDA's access to
- 1618 records by describing the situations in which FDA may access
- 1619 such records remotely.
- 1620 Among other changes, the amendment also strengthens the
- 1621 provisions related to the surveillance for foodborne
- 1622 illnesses and includes a bipartisan compromise regarding
- 1623 civil monetary penalties. The amendment clarifies that
- 1624 importers must pay a \$500 annual registration fee just like
- 1625 the other registered facilities are required to do in the
- 1626 bill. The amendment responds to concerns we have heard about
- 1627 duplicative regulation of customs brokers by the U.S. Customs
- 1628 and Border Protection. Under the revised version, customers
- 1629 brokers would only be required to register with FDA but will
- 1630 not have to pay a fee nor will they be subject to any good
- 1631 importer practices.
- In response to the need for new inspectors, the
- 1633 amendment adds a new section that would require the Secretary
- 1634 to support and provide assistance to establish and maintain
- 1635 one more university-affiliated protection training institutes
- 1636 that conduct training related to food protection activities
- 1637 for federal, State, local, territorial and tribal officials.
- 1638 And finally, I want to acknowledge the work by Mr.
- 1639 Markey in addressing public health concerns about BPA in
- 1640 bottles and food packaging. FDA told the committee in

- 1641 legislative hearings that they are working to assess the
- 1642 risks of BPA. The amendment includes language by Mr. Markey
- 1643 that will require FDA to report back to the committee on
- 1644 their findings, and if they find a risk, take appropriate
- 1645 actions to address it.
- 1646 I would like to now call on members who seek recognition
- 1647 for purposes of offering any amendments. The gentleman from
- 1648 Nebraska, Mr. Terry.
- 1649 Mr. {Terry.} Thank you, Mr. Chairman. I have an
- amendment at the desk. It is Terry only, not 1, 2, 3 or 10.
- 1651 Waive the reading.
- [The amendment follows:]

1657

The {Chairman.} The clerk reports the amendment. The gentleman asks unanimous consent to waive the reading, and he is now recognized.

Mr. {Terry.} Thank you, Mr. Chairman.

1658 I first want to apologize for my tardiness. This didn't 1659 come to my attention until just the last few days. But working with agribusiness in Nebraska and food manufacturers 1660 1661 in Nebraska, I have learned that on page 12, line 9, where we 1662 exempt the storage of the grain or commodities on the farm 1663 from the FDA inspection, but what agribusiness typically 1664 does, if you a cereal maker or whatever you are buying the 1665 grain, you will contract for the grain that is on the bin on 1666 the farm for delivery at a certain time in the future. What 1667 happens and needs clarifying then because of that contract, 1668 the ownership technically by contract is changed from the 1669 farmer to whoever contracted for it for a future delivery and 1670 now under this bill when you read it as it is written, then 1671 whoever contracted that grain, even though it is still in the 1672 bin on the farm, they have to go through the licensing or permitting and \$500, and there is a lot of bins with grain 1673 1674 stored on it in Nebraska. That could lead to hundreds of 1675 thousands and millions of dollars, and I think that was kind of an unintended consequence of the language so this fixes 1676

- 1677 that problem.
- 1678 And with that, I would like to yield my time to the
- 1679 chairman to ask if I withdraw, could I count on being able to
- 1680 continue to work with this and see if we can fix what I
- 1681 perceive as more of a technical issue? I yield to the good
- 1682 chairman.
- The {Chairman.} Thank you very much for yielding to me.
- 1684 I appreciate your drawing this issue to our attention. I can
- 1685 see how it may seem unfair that because a farm is acting as a
- 1686 storage facility for raw agricultural commodities other than
- 1687 that from its own farm, it is no longer exempt from the
- 1688 registration requirements of the bill. But we have to look
- 1689 to see whether this is in effect having the farm act as a
- 1690 warehouse or silo. I appreciate your concerns and I
- 1691 certainly want to pledge to you that we will continue to talk
- 1692 to you and see if we can work out these issues.
- 1693 Mr. {Terry.} With that assurance that we can continue
- 1694 to talk and hopefully work this out, I will respectfully
- 1695 withdraw my amendment.
- 1696 The {Chairman.} The gentleman withdraws his amendment.
- 1697 Are there further amendments to the amendment in the nature
- 1698 of a substitute? Mr. Matheson.
- [The amendments follow:]

1700 ************* INSERT 5 **********

- 1701 The {Chairman.} Without objection, the Matheson
- 1702 amendment will be considered as read and the gentleman is
- 1703 recognized.
- 1704 Mr. {Matheson.} Thank you, Mr. Chairman. I will be
- 1705 brief.
- 1706 I mentioned in my opening statement this issue about
- 1707 trying to somehow get more information to consumers so they
- 1708 are aware that there may be lead in the glazing on
- 1709 ceramicware. There is a problem that first manifested, that
- 1710 I learned about in my district of a mother whose baby was
- 1711 ill. They discovered it was lead poisoning. It was because
- 1712 she was eating food off of a plate that she used in her
- 1713 microwave and then through nursing the baby, the baby was
- 1714 exposed to lead. This is a more complicated issue than I
- 1715 originally thought.
- 1716 I will withdraw this amendment in the interest of trying
- 1717 to move towards where we can build consensus on how to
- 1718 perhaps address this issue, and Mr. Chairman, with that I
- 1719 will just yield back my time or yield to you. I hope we can
- 1720 find some way to get around this issue.
- 1721 The {Chairman.} I thank you for bringing up the
- 1722 amendment and for withdrawing it. I want to work with you on
- 1723 it. You have raised a serious matter.

- 1724 Mr. {Matheson.} I yield back.
- 1725 The {Chairman.} The amendment is withdrawn. Further
- 1726 amendments?
- 1727 Mr. {Dingell.} Mr. Chairman.
- 1728 The {Chairman.} Yes, Mr. Dingell.
- 1729 Mr. {Dingell.} I seek recognition to strike the
- 1730 requisite number of words.
- 1731 The {Chairman.} The gentleman is recognized.
- 1732 Mr. {Dingell.} This is just really to engage in, and I
- 1733 thank you, Mr. Chairman, to engage in a colloquy. The
- 1734 gentleman from Utah has been more than gracious on this
- 1735 matter. This is not a new problem and he is absolutely right
- 1736 in catching it. It has been around here since I had hair.
- 1737 It has been a terrible problem, and I am going to suggest to
- 1738 the gentleman that I would like to work with him on it, and I
- 1739 am also going to suggest to him that we probably ought to
- 1740 begin by a letter to both Food and Drug and CPSC asking their
- 1741 technical assistance on how this matter should be addressed.
- 1742 Very frankly, the problem that the gentleman wisely
- 1743 points to is a serious one and it relates to leaching of lead
- 1744 from ceramics into food products. I am not quite sure how
- 1745 Food and Drug addresses this, but if they can't, maybe CPSC
- 1746 can. So I want to thank the gentleman for his kindness in
- 1747 withdrawing and I want him to know I intend to work with him,

- 1748 and I will be in touch with him about necessary
- 1749 communications to the two agencies.
- 1750 Mr. {Matheson.} Thank you.
- 1751 Mr. {Dingell.} And I thank you and yield back the
- 1752 balance of my time.
- 1753 The {Chairman.} Further amendments to the legislation?
- 1754 Ms. Schakowsky.
- 1755 Ms. {Schakowsky.} Yes, Mr. Chairman, I have an
- 1756 amendment at the desk.
- [The amendment follows:]
- 1758 ************** INSERT 6 ***********

1759 The {Chairman.} Without objection, the amendment will 1760 be considered as read and the gentlelady is recognized to 1761 explain her amendment. 1762 Ms. {Schakowsky.} This amendment would require the FDA 1763 to end the non-therapeutic use of antibiotics in livestock 1764 that are contributing to increasing prevalence of antibioticresistant diseases. Foodborne illnesses are now becoming 1765 1766 more difficult to treat due to the increase in antibiotic-1767 resistant strains and the decreased effectiveness of 1768 antibiotics routinely used as a first-line defense. Two 1769 million Americans acquire bacterial infections during their 1770 hospital stay every year and 70 percent of their infections 1771 will be resistant to the drugs commonly used to treat them. 1772 In fact, resistant bacterial infections increase health care 1773 costs by \$4 billion to \$5 billion each year. 1774 A contributing factor to this rise in antibiotic 1775 resistance is the routine feeding of important human 1776 antibiotics like penicillin, tetracycline and ciprofloxacin 1777 to food animals. Seven classes of antibiotics certified by 1778 the Food and Drug Administration as highly or critically 1779 important in human medicine are used in agriculture as animal 1780 feed additives. Many factory farms give these antibiotics in 1781 the daily feeds to cows, chickens and pigs, not to treat

1782 disease but to promote growth, improve feed efficiency and to 1783 compensate for overcrowding and bad sanitation. 1784 classes of antibiotics are among the most critically 1785 important in our arsenal of defense against potentially fatal 1786 human diseases. Approximately 70 percent of antibiotics and 1787 related drugs produced in the United States are given to 1788 cattle, pigs and chickens to promote growth and compensate 1789 for crowded, unsanitary, stressful conditions. This kind of 1790 habitual non-therapeutic use of antibiotics has been 1791 conclusively linked to a growing number of incidents of 1792 antimicrobial-resistant infections in humans and may be 1793 contaminating groundwater with resistant bacteria in rural 1794 areas. 1795 University of Illinois researchers found in 2001 and 1796 2007 that routine tetracycline use at hog farms was 1797 contaminating groundwater with tetracycline-resistant 1798 bacteria which through gene transfer were sharing resistance 1799 with other bacteria. The researchers concluded, 1800 ``Groundwater may be a potential source of antibiotic 1801 resistance in the food chain.'' The Illinois Department of 1802 Health calculates that the incidence of one type of resistant 1803 bacteria, methicillin-resistant Staphylococcus aureus, or MRSA, has risen nearly 57 percent to over 10,000 cases in 1804

1805

just 4 years.

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1806 We should be addressing food safety from farm to fork
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- 1807 including practices in food animal production like routine
- 1808 antibiotic use that can make our food less safe to eat.
- 1809 Reducing antibiotic resistance could save billions of dollars
- 1810 each year in health care costs.
- 1811 Mr. Chairman, I will be withdrawing my amendment but I
- 1812 hope this committee will examine this very important issue in
- 1813 the near future. I yield back.
- 1814 The {Chairman.} If the gentlelady will yield to me, I
- 1815 share your concern and we are not able to work out this issue
- 1816 in this bill because it is contentious and we can't reach a
- 1817 consensus on it before this markup, but I want to emphasize,
- 1818 however, that addressing antibiotic resistance remains a
- 1819 priority for me. Antibiotic resistance poses a real and
- 1820 growing threat to our Nation's ability to fight life-
- 1821 threatening diseases and I want to tell you that we will
- 1822 continue to work toward a solution in this committee.
- 1823 Ms. {Schakowsky.} I thank you, Mr. Chairman. I yield
- 1824 back.
- The {Chairman.} Are there further amendments to the
- 1826 legislation? Yes, Mr. Space.
- 1827 Mr. {Space.} Mr. Chairman, I have an amendment at the
- 1828 desk.
- [The amendment follows:]

1830 ************* INSERT 7 **********

1831 The {Chairman.} Without objection, the amendment will 1832 be considered as read and the gentleman is recognized. Mr. {Space.} Thank you, Mr. Chairman, and I would like 1833 1834 to first state that I do plan to withdraw this amendment. 1835 However, I believe it is important to raise an issue that 1836 concerns many of the farmers that I represent, and that is 1837 the safety of their proprietary information. I would again 1838 reiterate my thanks and commendation for the work of the 1839 authors of this legislation and for working to address the 1840 concerns of the agricultural industry in the draft. I 1841 understand it is not the intent of the authors to make the 1842 proprietary information of America's farmers widely available 1843 to the public under this legislation and I am hopeful that 1844 the authors of the legislation will be willing to work with 1845 me to place safeguards in the legislation to ensure that the 1846 information is not made available widespread to the public. 1847 I yield back. 1848 The {Chairman.} If the gentleman would permit, I will 1849 be certainly be pleased to talk to you further about it. I 1850 think the bill went a long way to deal with this issue but we

1852 Mr. {Space.} Thank you, Mr. Chairman.

should be open to further discussions.

1851

The {Chairman.} The gentleman withdraws his amendment.

- 1854 Are there further amendments to the legislation? If not, the
- 1855 vote now comes on the amendment in the nature of a
- 1856 substitute. All those in favor of the amendment in the
- 1857 nature of a substitute, say aye. Opposed, no. The ayes have
- 1858 it and the amendment is agreed to.
- Now the vote will come on H.R. 2749 as forwarded by the
- 1860 subcommittee as amended by the amendment in the nature of a
- 1861 substitute. All those in favor of reporting out H.R. 2749 as
- 1862 amended, please say aye. Opposed, no. The ayes have it and
- 1863 the motion is agreed. The bill is reported out of committee.
- 1864 That concludes our business. I thank the members for
- 1865 their participation and their willingness to work together.
- 1866 We stand adjourned.
- 1867 [Whereupon, at 11:55 a.m., the subcommittee was
- 1868 adjourned.]