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10 **UNITED STATES DISTRICT COURT**
11 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

13 CENTER FOR FOOD SAFETY and CENTER)
14 FOR ENVIRONMENTAL HEALTH,)

15 *Plaintiffs,*)

16 v.)

17 ALEX M. AZAR II, SECRETARY OF U.S.)
DEPARTMENT OF HEALTH AND HUMAN)
18 SERVICES; SCOTT GOTTLIEB, M.D.,)
COMMISSIONER OF U.S. FOOD AND DRUG)
19 ADMINISTRATION and U.S. DEPARTMENT)
OF HEALTH AND HUMAN SERVICES,)

20 *Defendants.*)
21 _____)

Case No.: 3:18-cv-06299

**COMPLAINT FOR DECLARATORY AND
EQUITABLE RELIEF**

Administrative Procedure Act Case

INTRODUCTION

1
2 1. This is an action for declaratory and equitable relief regarding the failure by the
3 Defendant Food and Drug Administration (FDA or the agency) to promulgate final regulations
4 and complete actions by mandatory deadlines set by Congress in the Food Safety Modernization
5 Act of 2011 (FSMA).¹

6 2. FSMA is the first major overhaul of our country’s food safety laws since 1938,
7 and was intended to be a needed sea-change in how we regulate our food system and protect the
8 public health.² It was passed by Congress in bipartisan fashion, because foodborne illness is an
9 epidemic in the United States. The Centers for Disease Control and Prevention (CDC) estimates
10 that every year, as a result of foodborne diseases, 48 million people (1 in 6 Americans) get sick,
11 128,000 are hospitalized, and 3,000 die.³ Serious long-term health effects associated with several
12 common types of food poisoning include kidney failure, chronic arthritis, and brain and nerve
13 damage.⁴ During the years leading up to FSMA’s passage, continuous high profile outbreaks
14 related to various foods, ranging from spinach to peanut products to eggs, underscored the dire
15 and urgent need for oversight improvements.⁵

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20 ¹ Food Safety Modernization Act of 2011, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified
as amended in scattered sections of 21 U.S.C. § 301 *et seq.*)

21 ² Congress passed the Federal Food, Drug and Cosmetic Act on June 25, 1938. 21 U.S.C. § 301
22 *et seq.* (1938).

23 ³ Ctrs. for Disease Control & Prevention, *Food Safety: Foodborne Illness and Germs*,
24 <https://www.cdc.gov/foodsafety/foodborne-germs.html> (last updated Feb. 16, 2018).

25 ⁴ FoodSafety.gov, *Food Poisoning*, <http://www.foodsafety.gov/poisoning/index.html> (last
accessed Oct. 11, 2018).

26 ⁵ Gardiner Harris and William Neuman, *Senate Passes Sweeping Law on Food Safety*, N.Y.
27 Times, Nov. 30, 2010, <https://www.nytimes.com/2010/12/01/health/policy/01food.html> (last
28 accessed Oct. 11, 2018).

1 3. FSMA enables FDA to better protect public health by strengthening its ability to
2 regulate and granting the agency enhanced preventative authority.⁶ The law also granted FDA
3 new enforcement capacity, such as mandatory recall authority, and the ability to prescribe
4 additional recordkeeping requirements, such as for facilities handling “high-risk” foods. It was
5 Congress’s intent that the implementation of these measures by FDA would result in lives being
6 saved, illnesses prevented, and spare even more people from being infected in the first place, by
7 shoring up and dramatically improving the way we regulate our food system.

8 4. Unfortunately, the positive public health outcomes that were the original intent
9 behind FSMA can only be realized if the FDA complies with the law, by promulgating
10 regulations, completing required actions, and enforcing provisions mandated by Congress. A
11 statute without its implementing regulations is an empty vessel. FDA’s failure to so implement
12 FSMA leaves all Americans vulnerable to foodborne illness.

13 5. By 2012 FDA missed at least seven statutory Congressional deadlines for
14 promulgating FSMA’s implementing food safety regulations. Because of this failure to comply
15 with Congress’s express mandates, the Plaintiffs brought suit to compel FDA to promulgate the
16 required regulations. *See Ctr. For Food Safety v. Hamburg*, 954 F.Supp.2d 965 (N.D. Cal. 2013)
17 (hereafter *FSMA I*).

18 6. The Court held that the FDA’s failure to promulgate the mandated regulations by
19 their statutory deadlines constituted a failure to act under the Administrative Procedure Act
20 (APA) and unlawful withholding of the regulations in violation of FSMA and the APA. *Id.* The
21 Court then granted injunctive relief, establishing a timeline for FDA to promulgate final
22 regulations. *FSMA I*, 2013 WL 1282144 (June 21, 2013); 2013 WL 4396563 (August 13, 2013).
23 After FDA’s motion for a stay pending appeal was denied, 2013 WL 5718339 (October 21,
24 2013), the parties settled and established deadlines for the completion of the rulemakings in a
25 consent decree approved by the Court, which retained jurisdiction to oversee and enforce it. *See*

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27 ⁶ U.S. Food & Drug Admin., *Background on the FDA Food Safety and Modernization Act*
28 (*FSMA*), <https://www.fda.gov/newsevents/publichealthfocus/ucm239907.htm> (last updated Jan. 30, 2018).

1 *id.* Dkt. No. 87. FDA met each deadline in timely fashion and promulgated the rules, the last of
2 which was issued in May 27, 2016.

3 7. Unfortunately, since *FSMA I*, FDA has failed to meet at least two other important
4 food safety FSMA action deadlines not at issue in that litigation. At issue in this matter are these
5 separate agency actions, by which FDA was mandated to classify and designate which foods that
6 are classified as “high-risk” for foodborne illness purposes, and to create additional record
7 keeping requirements for facilities handling such foods. *See* 21 U.S.C. §§ 2223(d)(1)-(2).

8 8. The overarching purpose of these FSMA “high risk” food provisions is to
9 improve FDA’s food-tracing capabilities and expedite the recall process during an outbreak.⁷ In
10 the years that FDA has failed to complete these requirements, devastating foodborne illness
11 outbreaks have unfortunately continued and spread across the country, killing hundreds and
12 hospitalizing thousands of Americans; as Congress intended, these foodborne illness outbreaks
13 may have been prevented or lessened if these FSMA measures were in place.

14 9. FDA’s failure to implement FSMA’s critical food safety regulations by their
15 statutory deadlines is an abdication of the agency’s fundamental responsibilities. Moreover, the
16 agency’s unlawful withholding is putting millions of lives at continued risk from contracting
17 foodborne illnesses, contrary to Congress’s commands. This lawsuit therefore seeks to require
18 FDA to complete the high-risk food actions FSMA requires by Court-established deadlines.

19 **JURISDICTION**

20 10. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal
21 question) and 28 U.S.C. § 1346 (United States as Defendant).

22 11. Plaintiffs have a right to bring this action pursuant to the Administrative
23 Procedure Act (APA). 5 U.S.C. § 702.

24 12. The relief requested is specifically authorized pursuant to 5 U.S.C. § 706(1) and
25 28 U.S.C. § 1651 (writ).

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⁷ *See* 21 U.S.C. § 2223(d)(1).

1 **VENUE**

2 13. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e) because one or
3 more of the Plaintiffs reside in this District.

4 **PARTIES**

5 14. Plaintiff CENTER FOR FOOD SAFETY (CFS) brings this action on behalf of
6 itself and its members. CFS is a public interest, nonprofit membership organization that has
7 offices in San Francisco, CA; Portland, OR; and Washington, DC. CFS represents over 950,000
8 consumer and farmer members, from every state across the country. FDA's continued failure to
9 adhere to mandatory deadlines established by FSMA has adversely affected CFS and its
10 members.

11 15. Since the organization's founding in 1997, CFS's overarching mission has been to
12 protect our food, farms, and the environment. For twenty years, CFS has been at the forefront of
13 organizing a powerful food movement, fighting the industrial model of food production and
14 instead promoting organic, ecological, and sustainable alternatives. Industrial food production
15 systems have led to an increase in the prevalence of foodborne illness, perhaps first among the
16 many health and environmental problems they have caused. For example, one major cause of
17 food contamination is overcrowded, unsanitary conditions on confined animal feeding
18 operations, or factory farms, where animals get sick and pass diseases on to other animals, or
19 where food is contaminated through contact with animal waste. Another factor is our industrial
20 food distribution system, through which contaminated food is transported across the nation. In
21 addition, our increased reliance on imported foods (e.g., sixty percent of our seafood is imported)
22 with unknown safety standards puts the U.S. food supply at risk. Adding to this perfect storm of
23 risk is government deregulation and inadequate funding for inspections and oversight. CFS seeks
24 to redress and prevent these harms through promoting sustainable, healthful forms of agriculture
25 and food production, as well as proper government oversight and regulation of industrial
26 paradigms.

27 16. CFS combines multiple tools and strategies in pursuing its goals, including public
28 and policymaker education, outreach, campaigning and, when necessary, public interest

1 litigation. With regard to education, CFS disseminates to government agencies, members of
2 Congress, and the general public a wide array of informational materials addressing foodborne
3 illnesses and food supply. These materials include news articles, policy reports, legal briefs,
4 press releases, action alerts, and fact sheets.

5 17. CFS also sends action alerts to its membership. These action alerts generate
6 public involvement, education, and engagement with governmental officials on issues related to
7 fighting the health and environmental impacts of industrial agriculture and promoting a more
8 sustainable, healthier food system. Collectively, the dissemination of this material has made CFS
9 an information clearinghouse for public involvement and governmental oversight of food safety
10 issues.

11 18. As *FSMA I* illustrates, CFS is one of the leading public interest organizations
12 working to protect food safety through FSMA's direly-needed improvements.

13 19. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH (CEH) also brings this
14 action on behalf of itself and its members. CEH is located in Oakland, CA. Founded in 1996,
15 CEH is a nonprofit organization dedicated to protecting the public from environmental and
16 public health hazards. CEH is committed to environmental justice, promoting a safe and
17 sustainable food supply, supporting communities in their quest for a safer environment, and
18 fostering corporate accountability. CEH promotes safer food and farming to provide families the
19 right to know what they are feeding their families. CEH works in support of safer, sustainable
20 food production that serves to regenerate natural resources, support healthier food for consumers,
21 and create healthier environments for farmers, farm workers, and rural communities. CEH's
22 scientific investigations, food safety testing, legal advocacy and litigation, and work with state
23 and national food advocacy coalitions all converge around the goals of ending unsafe,
24 unsustainable food production practices and supporting ecological, organic alternatives that
25 promote healthier farming and a healthier food supply. As part of its work in this area, CEH was
26 also a plaintiff in *FSMA I*. CEH and its members are being, and will be, adversely affected by
27 FDA's failure to adhere to FSMA's mandatory deadlines.
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1 nerve damage.¹³ In financial terms, the annual costs to the U.S. economy due to foodborne
2 illness have been estimated to top \$93 billion a year, and that figure does not include all costs.¹⁴

3 30. On January 4, 2011, President Obama signed FSMA into law. FSMA enables
4 FDA to better protect public health by strengthening the food safety system. FSMA's major
5 elements can be divided into five key areas: preventive controls, inspection and compliance,
6 response, imported food safety, and enhanced partnerships.¹⁵ Preventive controls and response to
7 foodborne illness outbreaks are only effective to the extent they are followed; therefore, FSMA
8 grants FDA inspection and enforcement powers to ensure compliance as well as the power to
9 create additional recordkeeping requirements for certain facilities and mandate recalls.

10 31. Due to ongoing current public health epidemic, Congress established specific
11 implementation deadlines for FDA in FSMA. These deadlines require FDA to complete various
12 FSMA implementation tasks by dates certain including *inter alia*: the promulgation of
13 regulations; completion of industry guidance documents and reports; enhanced tracking
14 mechanisms for food products to help identify possible contamination incidents; and a consumer-
15 friendly website for recall information and foodborne illness outbreaks. Unfortunately, FDA has
16 failed to meet many of these deadlines.

17 ***Center for Food Safety v. Hamburg (FSMA I)***

18 32. On August 29, 2012, CFS sued FDA because of its failure to promulgate seven
19 major FSMA food safety rules, including (i) preventive controls for human food; (ii) preventive
20 controls for animal food; (iii) a foreign supplier verification program; (iv) produce safety
21 standards; (v) accreditation of third-party auditors; (vi) sanitary transport of food and feed; and
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23 ¹³ FoodSafety.gov, *Food Poisoning*, <http://www.foodsafety.gov/poisoning/index.html> (last
24 accessed Oct. 11, 2018).

25 ¹⁴ Robert Scharff, *State Estimates for the Annual Cost of Foodborne Illness*, 78 J. Food Prot.
26 1064 (2015).

27 ¹⁵ U.S. Food & Drug Admin., *Background on the FDA Food Safety Modernization Act (FSMA)*,
28 <https://www.fda.gov/food/guidanceregulation/fsma/ucm239907.htm> (last updated Jan. 30, 2018).

1 (vii) protection against intentional contamination.¹⁶ In April 2013, this Court granted Plaintiffs’
2 motion for summary judgment, holding that FDA violated FSMA and the APA by failing to
3 promulgate these regulations by their statutory deadlines.¹⁷ The Court then granted injunctive
4 relief and established a timeline for the FDA to promulgate final regulations. *FSMA I*, 2013 WL
5 1282144 (June 21, 2013); 2013 WL 4396563 (August 13, 2013). After FDA’s motion for a stay
6 pending appeal was denied, 2013 WL 5718339 (October 21, 2013), the parties settled and
7 established deadlines for the completion of the rulemakings in a consent decree approved by the
8 Court, which retained jurisdiction to oversee and enforce it. *See id.* Dkt. No. 87.¹⁸ FDA met each
9 deadline in timely fashion and promulgated the rules, the last of which was issued in May 27,
10 2016.¹⁹

11 *The Continuing Epidemic of Foodborne Illness*

12 33. During and after the time it took FDA to finalize the regulations at issue in *FSMA*
13 *I*, there have unfortunately been dozens of major foodborne illness outbreaks, underscoring the
14 continued need for all FSMA regulations to be implemented to effectuate the statute.

15 34. For example, in March 2013, a *Salmonella* Heidelberg outbreak from chicken
16 reached twenty-nine states and Puerto Rico.²⁰ The outbreak hospitalized approximately 240
17 people and sickened 634 people.²¹ Also in March 2013, a Hepatitis-A outbreak linked to

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19 ¹⁶ *See Ctr. for Food Safety v. Hamburg*, 954 F.Supp.2d 965, 966-67 (N.D. Cal. 2013).

20 ¹⁷ *Id.* at 970-71.

21 ¹⁸ Consent Decree, *Ctr. for Food Safety v. Hamburg*, No. 12-cv-04529-PJH (N.D. Cal. Feb. 24,
22 2014), ECF No. 85-1.

23 ¹⁹ *See* U.S. Food & Drug Admin., *FSMA Final Rule of Produce Safety*,
24 <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm> (last updated Oct. 12,
2018).

25 ²⁰ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Multidrug-Resistant*
26 *Salmonella Heidelberg Infections Linked to Foster Farms Brand Chicken (Final Update)*,
<https://www.cdc.gov/salmonella/heidelberg-10-13/index.html> (last updated July 31, 2014).

27 ²¹ *Id.*

1 pomegranates spread to 10 states, sickened 165 people, and hospitalized 71 people.²² There were
 2 nine other outbreaks reported by the CDC in 2013.²³

3 35. In May 2014, a *Salmonella* Newport outbreak from cucumbers reached twenty-
 4 nine states and the District of Columbia.²⁴ The outbreak resulted in 275 reports of illness, with at
 5 least 48 people hospitalized and one death.²⁵ The same month there was a *Cyclospora* outbreak
 6 from cilantro that sickened 304 people in nineteen states, with seven individuals hospitalized.²⁶
 7 There were eleven other outbreaks reported by the CDC in 2014.²⁷

8 36. In early 2015, the CDC investigated an outbreak of *Listeriosis* from prepackaged
 9 caramel apples that spanned twelve states from North Carolina to Washington State in
 10 February.²⁸ The outbreak killed seven people, hospitalized thirty-four people, and infected thirty-

12 ²² Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Hepatitis A Virus Infections*
 13 *Linked to Pomegranate Seeds from Turkey (Final Update)*,
 14 <https://www.cdc.gov/hepatitis/Outbreaks/2013/A1b-03-31/index.html> (last updated Dec. 27,
 2017).

15 ²³ Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak*
 16 *Investigations*, [https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-](https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html)
 17 [list.html](https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html) (under “List of Selected Outbreak Investigations, by Year,” select “2013”) (last updated
 Oct. 4, 2018).

18 ²⁴ Ctrs. for Disease Control & Prevention, *Outbreak of Salmonella Newport Infections Linked to*
 19 *Cucumbers — United States, 2014*,
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a3.htm> (last updated Feb. 20, 2015).

20 ²⁵ *Id.*

21 ²⁶ Ctrs. for Disease Control & Prevention, *Cyclosporiasis Outbreak Investigations — United*
 22 *States, 2014*, <https://www.cdc.gov/parasites/cyclosporiasis/outbreaks/2014/index.html> (last
 updated June 15, 2018).

23 ²⁷ Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak*
 24 *Investigations*, [https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-](https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html)
 25 [list.html](https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html) (under “List of Selected Outbreak Investigations, by Year,” select “2014”) (last updated
 Oct. 4, 2018).

26 ²⁸ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to*
 27 *Commercially Produced, Prepackaged Caramel Apples Made from Bidart Bros. Apples (Final*
 28 *Update)*, <https://www.cdc.gov/listeria/outbreaks/caramel-apples-12-14/index.html> (last updated
 Sept. 11, 2015).

1 five people.²⁹ *Listeriosis* also contaminated Blue Bell ice cream in 2015.³⁰ This outbreak killed
2 three people and hospitalized all ten people it affected.³¹ Between June-October 2015, *Listeriosis*
3 also contaminated soft cheeses and the outbreak spread across Washington, California, Colorado,
4 Illinois, Michigan, Ohio, Tennessee, Virginia, New York, and Massachusetts, killing three
5 people, and infecting thirty people.³² These are just three of the eleven outbreaks the CDC
6 recorded for 2015.³³

7 37. In January 2016, CDC announced an outbreak of *Listeriosis* that contaminated
8 packaged salads in nine states.³⁴ The outbreak killed one person and hospitalized all nineteen
9 people affected.³⁵ A few months later, CDC announced an outbreak of *Listeriosis* that
10 contaminated frozen vegetables in Washington, California, Maryland, and Connecticut, killing
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14 ²⁹ *Id.*

15 ³⁰ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Blue Bell*
16 *Creameries Products (Final Update)* [https://www.cdc.gov/listeria/outbreaks/ice-cream-03-](https://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/index.html)
17 [15/index.html](https://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/index.html) (last updated Page last updated: July 13, 2015).

18 ³¹ *Id.*

19 ³² Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Soft*
20 *Cheeses Distributed by Karoun Dairies, Inc. (Final Update)*
21 <https://www.cdc.gov/listeria/outbreaks/soft-cheeses-09-15/index.html> (last updated Oct. 23,
2015).

22 ³³ Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak*
23 *Investigations*, [https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-](https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html)
24 [list.html](https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html) (under “List of Selected Outbreak Investigations, by Year,” select “2015”) (last updated
Oct. 4, 2018).

25 ³⁴ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Packaged*
26 *Salads Produced at Springfield, Ohio Dole Processing Facility (Final Update)*
<https://www.cdc.gov/listeria/outbreaks/bagged-salads-01-16/index.html> (last updated Mar. 31,
2016).

27 ³⁵ *Id.*

1 three people, and hospitalizing all nine people affected.³⁶ In March 2016, another *Listeriosis*
2 outbreak occurred in California and Florida, sickening two and killing one.³⁷ The CDC reported
3 eleven other outbreaks during 2016.³⁸

4 38. In March 2017, CDC announced an outbreak of *Listeriosis* linked to soft raw milk
5 cheese, which killed two people and infected eight people in Connecticut, Florida, Vermont, and
6 New York.³⁹ In May 2017, a *Cyclospora* outbreak caused 597 people in thirty-six states to get
7 sick.⁴⁰ Also in 2017, four different outbreaks of *Salmonella*, all from papaya, caused 2 deaths, 79
8 hospitalizations, and 251 sicknesses.⁴¹

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10 ³⁶ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Frozen*
11 *Vegetables (Final Update)*, [https://www.cdc.gov/listeria/outbreaks/frozen-vegetables-05-](https://www.cdc.gov/listeria/outbreaks/frozen-vegetables-05-16/index.html)
12 [16/index.html](https://www.cdc.gov/listeria/outbreaks/frozen-vegetables-05-16/index.html) (last updated July 15, 2016).

13 ³⁷ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Raw Milk*
14 *Produced by Miller's Organic Farm in Pennsylvania (Final Update)*,
<https://www.cdc.gov/listeria/outbreaks/raw-milk-03-16/index.html> (last updated Dec. 14, 2016).

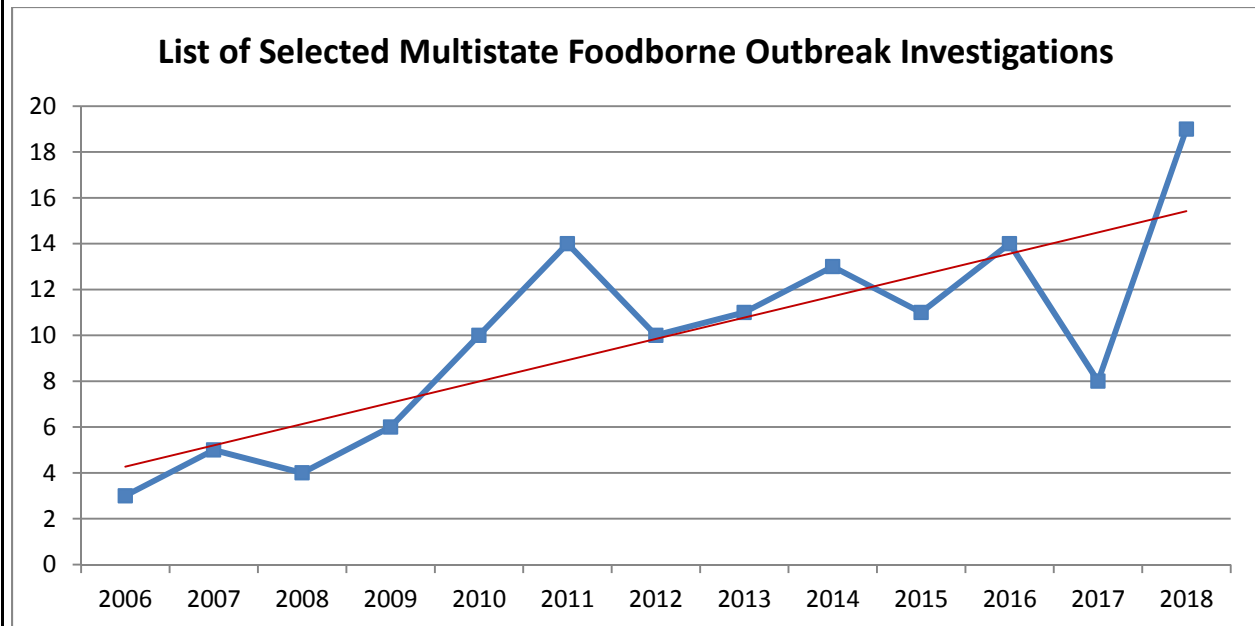
15 ³⁸ Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak*
16 *Investigations*, [https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-](https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html)
17 [list.html](https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html) (under "List of Selected Outbreak Investigations, by Year," select "2016") (last updated
18 Oct. 4, 2018).

19 ³⁹ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Soft Raw*
20 *Milk Cheese Made by Vulto Creamery (Final Update)*,
<https://www.cdc.gov/listeria/outbreaks/soft-cheese-03-17/index.html> (last updated May 3, 2017).

21 ⁴⁰ Ctrs. for Disease Control & Prevention, *Cyclosporiasis Outbreak Investigations – United*
22 *States, 2017*, <https://www.cdc.gov/parasites/cyclosporiasis/outbreaks/2017/index.html> (last
23 updated June 15, 2018).

24 ⁴¹ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Salmonella Urbana Linked to*
25 *Imported Maradol Papayas (Final Update)* [https://www.cdc.gov/salmonella/urbana-09-](https://www.cdc.gov/salmonella/urbana-09-17/index.html)
26 [17/index.html](https://www.cdc.gov/salmonella/urbana-09-17/index.html) (last updated Nov. 3, 2017); *Multistate Outbreak of Salmonella Newport and*
27 *Salmonella Infantis Infections Linked to Imported Maradol Papayas (Final Update)*
<https://www.cdc.gov/salmonella/newport-09-17/index.html> (last updated Nov. 3, 2017);
28 *Multistate Outbreak of Salmonella Anatum Infections Linked to Imported Maradol Papayas*
(Final Update), <https://www.cdc.gov/salmonella/anatum-9-17/index.html> (last updated Nov. 3,
2017); *Multistate Outbreak of Salmonella Infections Linked to Imported Maradol Papayas*
(Final Update), <https://www.cdc.gov/salmonella/kiambu-07-17/index.html> (last updated Nov. 3,
2017).

39. Finally, earlier this year, in January of 2018, chicken salad contaminated with *Salmonella* Typhimurium killed one person, hospitalized 94, and sickened 265 people in Minnesota, Wisconsin, South Dakota, Nebraska, Iowa, Illinois, Indiana, and Mississippi.⁴² In April 2018, an outbreak of *E. coli* in romaine lettuce sickened at least 210 people, with 96 hospitalized and 5 deaths.⁴³ At the time this complaint was written, there have already been nineteen multistate foodborne illness outbreaks *just in 2018*, the highest number of outbreaks since 2006.⁴⁴



Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak Investigations*, <https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html> (last updated Oct. 4, 2018).

⁴² Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Salmonella Typhimurium Linked to Chicken Salad (Final Update)*, <https://www.cdc.gov/salmonella/typhimurium-02-18/index.html> (last updated Apr. 6, 2018).

⁴³ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of E. coli O157:H7 Infections Linked to Romaine Lettuce (Final Update)*, <https://www.cdc.gov/ecoli/2018/o157h7-04-18/index.html> (last updated June 28, 2018).

⁴⁴ Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak Investigations*, <https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html> (under “List of Selected Outbreak Investigations, by Year,” select “2018”) (last updated Oct. 4, 2018).

1 40. The above examples are merely illustrative and not in any way comprehensive.
 2 Between 2013 and the present, there have been foodborne illness outbreaks that reached all fifty
 3 states, Washington D.C., and Puerto Rico. These are almost certainly conservative figures as
 4 they indicate only those investigations involving “multistate” foodborne illness investigations in
 5 which “CDC was the lead public health agency.”⁴⁵ Moreover, “CDC data suggests there is
 6 under-reporting of foodborne illness by consumers.”⁴⁶

7 ***FDA’s Failure to Act With Regards to “High-Risk” Foods***

8 41. As explained above, the critical purpose of FSMA is to “rapidly and effectively”
 9 identify recipients of a food to prevent or mitigate a foodborne illness outbreak and to “address
 10 credible threats of serious adverse health consequences or death to humans or animals as a result
 11 of such food being adulterated . . . or misbranded” under sections 402 and 403(w) of the Federal
 12 Food, Drug, and Cosmetic Act.⁴⁷ Congress repeatedly invoked the imperative nature of FSMA.⁴⁸

13 42. As such, Congress included numerous provisions focused specifically on the goal
 14 of “rapidly and effectively” preventing or mitigating foodborne illness outbreaks. One such
 15 crucial provision was FSMA Section 204, “Enhancing tracking and tracing of food and
 16

17
 18 ⁴⁵ *Id.*

19 ⁴⁶ Susan Arendt et al., *Reporting of Foodborne Illness by U.S. Consumers and Healthcare*
 20 *Professionals*, 10 Int. J. Environ. Res. Pub. Health 3684, 3686 (2013),
 21 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3774464/pdf/ijerph-10-03684.pdf> (last accessed
 22 Oct. 15, 2018).

23 ⁴⁷ 21 U.S.C. § 2223(d)(1).

24 ⁴⁸ *See, e.g.*, 156 Cong. Rec. H8861, H8885 (daily ed. Dec. 21, 2010) (statement of Rep.
 25 Waxman) (“There is no time for any further delay.”); *id.* (statement of Rep. Pallone) (“The
 26 modernization of our food safety system is desperately needed.”); *id.* at H8889 (statement of
 27 Rep. Dingell) (“We will bring to a halt a shameful situation where 48 million Americans are
 28 sickened by bad food, 128,000—yes 128,000 Americans—hospitalized and 3,000 people killed
 by bad food.”); *id.* (statement of Rep. Jackson Lee) (“The safety and sanitation of food produced
 and distributed throughout the United States is of utmost importance. The health and well being
 of every person in this country hinges on the quality and effectiveness of the food inspection
 process.”).

1 recordkeeping,” which is in subchapter II, “Improving Capacity to Detect and Respond to Food
2 Safety Problems.”

3 43. In an effort to expedite the process for tracing food, and therefore prevent the
4 spread of foodborne illnesses, Section 204 of FSMA mandates FDA to complete several
5 actions.⁴⁹ First, Congress required FDA to conduct pilot projects on potential food-tracing
6 systems, and report the findings from these projects to Congress, which had a deadline of
7 October 1, 2011.⁵⁰

8 44. Second, no later than January 4, 2012, Congress required FDA to designate a
9 classification of “high-risk” foods—meaning foods that were at the highest risk of being carriers
10 of foodborne illness—for which additional recordkeeping requirements were therefore
11 “appropriate and necessary to protect the public health.”⁵¹ This mandate contained criterion on
12 which to base a high-risk designation, including the history and severity of foodborne illness,
13 outbreaks attributed to such foods, and the steps taken during the manufacturing process to
14 reduce the possibility of contamination.⁵²

15 45. Third, Congress required that FDA promulgate a proposed rulemaking, no later
16 than January 4, 2013, to establish these additional “high-risk” food recordkeeping requirements
17 for “facilities that manufacture, process, pack, or hold foods that are designated high-risk
18 foods.”⁵³ FSMA specifies what can be included in the recordkeeping requirements, as well as
19 limitations on when and to which facilities the requirements will apply.⁵⁴

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22 ⁴⁹ See 21 U.S.C. § 2223.

23 ⁵⁰ 21 U.S.C. § 2223(a).

24 ⁵¹ 21 U.S.C. § 2223(d)(2)(A).

25 ⁵² *Id.* § 2223(d)(2)(A)(i)-(vi).

26 ⁵³ *Id.* § 2223(d)(1).

27 ⁵⁴ *Id.* § 2223(d)(1)(A)-(M).
28

1 46. Fourth and finally, Congress required that FDA publish the list of the FDA-
2 designated “high-risk” foods on its website at the same time the agency promulgated the final
3 rule for additional recordkeeping requirements.⁵⁵

4 47. FDA has failed to meet any of these deadlines and/or take most of the
5 Congressionally-required actions. First, FDA did conduct the pilot programs and submit its
6 report to Congress, but it did not do so until November 2016, five years after the statutory
7 deadline. In its report, FDA outlined the need for a more high-tech tracking system for food,
8 reviewed the pilot project results and comments, and made recommendations to Congress.⁵⁶
9 Importantly, in this FDA report, there are multiple references to the further rulemaking on this
10 mandated by § 2223(d)(1) and the “high-risk” designations required by § 2223(d)(2)(A),
11 demonstrating FDA’s understanding of these statutory requirements.⁵⁷

12 48. However, despite (belatedly) conducting the pilot program and report, FDA has
13 yet to undertake any of the remaining FSMA high-risk food requirements. In February 2014, two
14 years after the statutory deadline for the designation of high-risk foods, FDA announced that it
15 was taking the first “tentative” step in complying with the statute, and invited comments on its
16 “draft approach for the review and evaluation of data to designate high-risk foods.”⁵⁸ However
17 this initial scoping request for comment was not required by the statute, nor did it designate any
18 foods as high risk. Rather, it simply explained proposed methods that FDA considered using to
19 classify foods as high-risk, and asked for comments on those methods. Subsequently, now nearly
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22 ⁵⁵ *Id.* § 2223(d)(2)(B).

23 ⁵⁶ U.S. Food & Drug Admin., *Report to Congress on Enhancing Tracking and Tracing of Food*
24 *and Recordkeeping* (Nov. 16, 2016),
25 <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM540940.pdf> (last
26 accessed Oct. 15, 2018).

27 ⁵⁷ *Id.* at 3-4, 6, 10-12, 14, 17, 21-24.

28 ⁵⁸ Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data
and Information, 79 Fed. Reg. 6596 (Feb. 4, 2014).

1 five years later, FDA still has not designated any “high-risk” foods as required by 21 U.S.C. §
2 2223(d)(2)(A).

3 49. Documents obtained through the Freedom of Information Act (FOIA) reveal that
4 FDA is unfortunately no closer today to designating high-risk foods than it was in 2014. On June
5 5, 2018, CFS filed a FOIA request seeking all documents since January 4, 2011 regarding,
6 among other things, the designation of high-risk foods. In response, FDA’s Center for Food
7 Safety and Applied Nutrition produced various slideshow presentations that FDA officials made
8 between 2014 and 2017. The 2017 presentations contain much of the same information as the
9 2014 presentations, and there is no indication that FDA has made any substantive progress
10 toward designating high-risk foods.

11 50. Nor has FDA issued a rulemaking for additional recordkeeping requirements for
12 “high-risk” foods, as required by 21 U.S.C. § 2223(d)(1). Because FDA has failed to promulgate
13 the proposed rule required by § 2223(d)(1), it has necessarily failed to finalize that same rule.
14 References to and contingencies on the final version of the required proposed rule clearly imply
15 the final rule was intended to be completed along the same timeline as other “high-risk”
16 actions.⁵⁹ The specific references to the final rule that was to come of (d)(1) further indicates
17 Congress intended for the FDA to not only propose the rule, but finalize it within the one to two-
18 year timeline.

19 51. In May 2018, a coalition of nonprofit organizations submitted a letter to FDA
20 urging the agency to “act swiftly to carry out the Congressional requirements in FSMA to
21 identify a list of high-risk foods and issue a proposed rule to enhance recordkeeping for those
22 foods.”⁶⁰ As these groups noted, retailers now have the available technology (*e.g.*, blockchain) to
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25 ⁵⁹ See § 2223(d)(2)(B), (e)(1), (i)(1)-(2).

26 ⁶⁰ Letter from Center for Foodborne Illness Research & Prevention et al. to Scott Gottlieb, FDA
27 Commissioner, 2 (May 24, 2018),
28 <https://cspinet.org/sites/default/files/attachment/Consumers%20letter%20to%20Comm.%20Gottlieb%20re%20traceability-5-24-18.pdf> (last accessed Oct. 15, 2018).

1 “identify the origin of certain produce shipments in as little as 2.2 seconds.”⁶¹ This technology
 2 “enables food providers and other members of the [food production and distribution] ecosystem .
 3 . . . to trace contaminated product to its source in a short amount of time and stem the spread of
 4 illnesses.”⁶² In light of these advances in technology, FDA can no longer shirk the mandatory
 5 actions required of it by Congress to designate high-risk foods and issue a rule for enhanced
 6 recordkeeping for those foods.

7 52. In sum, FDA has failed to comply with the Congressional mandates of the FSMA
 8 “high-risk” food provisions. FDA has failed to establish the list of “high-risk” foods as required
 9 by Section 204(d)(2)(A).⁶³ FDA has also failed to issue a rulemaking setting forth additional
 10 recordkeeping requirements for those “high-risk” foods as required by Section 204(d)(1).⁶⁴
 11 Despite clear statutory deadlines to designate “high-risk” foods and create additional
 12 recordkeeping requirements for those foods, FDA has failed to comply with these deadlines.
 13 Because FDA has not even proposed rules for additional recordkeeping requirements for “high-
 14 risk” foods, it also has not completed that rulemaking and published the list of “high-risk” foods
 15 on its website as required by Section 204(d)(2)(B).⁶⁵

16 ***Harm to Plaintiffs***

17 53. The interests of Plaintiffs, organizationally and through their hundreds of
 18 thousands of members, are being and will be adversely affected by Defendants’ continued failure
 19 to (1) designate “high-risk” foods; (2) promulgate additional recordkeeping requirements for
 20

21 _____
 22 ⁶¹ *Id.* at 1.

23 ⁶² Aitken, R., *IBM forges blockchain collaboration with Nestle & Walmart in global food safety*,
 24 *Forbes*, Aug. 22, 2017, [https://www.forbes.com/sites/rogeraitken/2017/08/22/ibm-forges-
 25 blockchain-collaboration-with-nestle-walmart-for-global-food-safety/#36c113993d36](https://www.forbes.com/sites/rogeraitken/2017/08/22/ibm-forges-blockchain-collaboration-with-nestle-walmart-for-global-food-safety/#36c113993d36) (last
 26 accessed Oct. 15, 2018).

26 ⁶³ 21 U.S.C. § 2223(d)(2)(A).

27 ⁶⁴ *Id.* § 2223(d)(1).

28 ⁶⁵ *Id.* § 2223(d)(2)(B).

1 “facilities that manufacture, process, pack, or hold” those “high-risk” foods; and (3) publish the
2 list of “high-risk” foods on the FDA’s website.

3 54. In particular, Defendant’s unlawful withholding and unreasonable delay of FSMA
4 implementing actions pursuant to 21 U.S.C. § 2223, regarding “high-risk” foods, injures Plaintiff
5 organizations by putting their members’ health and safety in increased jeopardy, through the risk
6 of contracting foodborne illnesses. Without a list of designated high-risk foods that is accessible
7 to the public through FDA’s website and the additional reporting requirements to “rapidly and
8 effectively” track and trace these foods to prevent or mitigate foodborne illness outbreaks,
9 Congress’s will is thwarted and Plaintiffs’ members are deprived of information that they
10 otherwise would have, and are put at a greater risk of contracting a foodborne illness. Foodborne
11 illness affects their health, well-being, and finances.

12 55. For example, Plaintiffs’ members and their families have fallen ill as a result of
13 foodborne illness outbreaks in, among other foods, mangoes, imported melons, and raw foods.
14 The effects of these illnesses included severe vomiting and diarrhea, weight loss, and
15 hospitalization. Plaintiffs’ members also pay a price premium to make food from scratch and to
16 buy organic produce and products to reduce the risk of contracting a foodborne illness.

17 56. In addition, Defendants’ unlawful withholding and unreasonable delay injures
18 Plaintiff organizations by frustrating their food safety missions, and forcing the organizations to
19 divert organizational resources to address FDA’s delay and food safety risks, resources that
20 would otherwise be used in other organizational program areas. Plaintiff organizations are forced
21 to fill the gap for their members and consumers generally, taking policy, outreach, and campaign
22 actions to identify foodborne illness outbreaks and high risk foods.

23 57. CDC estimates that each year 48 million people (or 1 in 6 Americans) gets sick,
24 128,000 are hospitalized, and 3,000 die of foodborne diseases, including Plaintiffs’ members.⁶⁶
25 While some will recover, many will die or have serious long-term health effects that can be

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27 ⁶⁶ Ctrs. for Disease Control & Prevention, *Food Safety: Foodborne Illness and Germs*,
28 <https://www.cdc.gov/foodsafety/foodborne-germs.html> (last updated Feb. 16, 2018).

1 devastating to both the victims and their families. Serious long-term health effects associated
2 with several common types of food poisoning include kidney failure, chronic arthritis, and brain
3 and nerve damage.⁶⁷ The preventative measures contained in FSMA that Congress required to be
4 carried out by FDA with regards to high-risk foods are critical, as they would dramatically
5 reduce the number of illnesses caused by foodborne pathogens in the U.S., as well as reduce the
6 economic healthcare burden of treating these problems. The “high-risk” foods recordkeeping
7 requirements would enhance FDA’s oversight of those facilities that “manufacture, process,
8 pack, or hold . . . high-risk foods” so the agency could more “rapidly and effectively identify
9 recipients of a food to prevent or mitigate a foodborne illness outbreak.”⁶⁸ In an era of seeking
10 ways to lower healthcare costs, prevention of foodborne illnesses and outbreaks should be
11 paramount.

12 58. Since Congress passed FSMA, numerous outbreaks have unfortunately continued
13 to occur. Just this year, there have been devastating outbreaks, putting peoples’ health and lives
14 at risk. For example, in May of this year an *E. coli* O157 outbreak from romaine lettuce killed 5
15 people, hospitalized 96 people, and caused 210 to get sick. The outbreak reached thirty-six
16 states.⁶⁹

17 59. FSMA is a substantial overhaul and modernization of federal food safety
18 oversight and evinces Congress’s express and clear intent that FDA act without delay in
19 implementing regulations and enforcing this crucial new law and its preventive food safety
20 measures. Congress required FDA to establish a list of “high-risk” foods by January 4, 2012.

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22 ⁶⁷ FoodSafety.gov, *Food Poisoning*, <http://www.foodsafety.gov/poisoning/index.html> (last
accessed Oct. 11, 2018).

23 ⁶⁸ 21 U.S.C. § 2223(d)(1); *see also* 156 Cong. Rec. H8861, H8887 (daily ed. Dec. 21, 2010)
24 (statement of Rep. DeLauro) (“[a]ll of these tools will help improve the FDA’s ability to respond
25 to food-borne illness outbreaks and to hold industrial food production facilities to higher
standards.”).

26 ⁶⁹ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of E. coli O157:H7 Infections*
27 *Linked to Romaine Lettuce (Final Update)*, [https://www.cdc.gov/ecoli/2018/o157h7-04-](https://www.cdc.gov/ecoli/2018/o157h7-04-18/index.html)
28 [18/index.html](https://www.cdc.gov/ecoli/2018/o157h7-04-18/index.html) (June 28, 2018).

1 Congress further required FDA to propose additional recordkeeping requirements for “high-risk”
 2 foods by January 4, 2013. Years later, however, FDA has still failed to meet these deadlines.
 3 Moreover, because FDA has not issued a proposed rule for recordkeeping requirements, the
 4 agency has also failed to finalize that rule and publish the list of “high-risk” foods on its website.

5 60. These statutory mandates are critical for FDA to improve food-tracing capabilities
 6 and expedite the recall process during an outbreak. Indeed, following the completion of the pilot
 7 projects required by FSMA, FDA acknowledged that “[m]ajor gaps in communication and lack
 8 of common vocabulary made it more difficult to perform tracebacks and link information along
 9 the supply chain.”⁷⁰ FDA’s failures to meet the statutory deadlines for designating high-risk
 10 foods and proposing recordkeeping requirements as well as its failures to finalize the
 11 recordkeeping rule and publish the list of high-risk foods injures Plaintiff organizations by
 12 putting their members’ health and safety in jeopardy, through the risk of contracting foodborne
 13 illnesses.

14 61. The requested relief will redress this harm by compelling FDA to promulgate
 15 regulations and enforce self-executing provisions as required by law for the safety of all
 16 Americans, and Plaintiffs’ members in particular.

CAUSE OF ACTION

[Violation of the FDA Food Safety Modernization Act and
 the Administrative Procedure Act – Against FDA]
 [By Plaintiffs]

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 19
 20 62. Plaintiffs incorporate by reference all allegations contained in paragraphs 1
 21 through 61 *supra*.

22 63. FSMA requires FDA to designate “high-risk” foods and to propose reporting
 23 requirements for those foods by mandatory statutory deadlines described in detail in paragraphs
 24 34 through 38. FSMA also requires FDA to publish a list of “high-risk” foods on its website at
 25 the time it publishes the final rule on reporting requirements for “high-risk” foods. FDA’s failure

26 ⁷⁰ U.S. Food & Drug Admin., *Report to Congress On Enhancing Tracking and Tracing of Food*
 27 *and Recordkeeping* (Nov. 16, 2016),
 28 <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM540940.pdf> (last
 accessed Oct. 15, 2018).

1 to take any of these actions constitutes unlawfully withheld and unreasonably delayed agency
2 action within the meaning of the APA, 5 U.S.C. § 555(b), and FSMA.

3 64. The APA grants a right of judicial review to “a person suffering legal wrong
4 because of agency action, or adversely affected or aggrieved by agency action.” 5 U.S.C. § 702.

5 65. The definition of “agency action” includes a “failure to act.” 5 U.S.C. § 551(13).

6 66. Plaintiffs and their members are adversely affected by FDA’s past and continued
7 failure to complete the actions required by Congress in FSMA. *See id.*

8 67. The APA states that a reviewing court “shall” interpret statutes and “compel
9 agency action unlawfully withheld or unreasonably delayed.” 5 U.S.C. § 706(1),

10 68. FDA’s failure to promulgate said regulations or complete other required actions
11 constitutes unlawfully withheld and unreasonably delayed agency action that this Court shall
12 compel. *See id.*

13 **RELIEF REQUESTED**

14 WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

15 1. Declaring that FDA has violated FSMA and the APA by failing to complete
16 FSMA actions by statutory deadlines;

17 2. Declaring that FDA continues to be in violation of FSMA and the APA by failing
18 to complete FSMA actions by statutory deadlines;

19 3. Ordering FDA to promulgate all FSMA regulations and complete all actions
20 required under FSMA at issue in this case as soon as reasonably practicable, according to a
21 Court-ordered timeline;

22 4. Retaining jurisdiction of this action to ensure compliance with its decree;

23 5. Awarding Plaintiffs attorney’s fees and all other reasonable expenses incurred in
24 pursuit of this action; and

25 6. Granting other such relief as the Court deems just and proper.
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1 Respectfully submitted this 15th day of October, 2018.

2
3 /s/Kellan Smith

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