TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeper	Total hours
Equipment and Facilities Records 212.20(c); 212.30(b); 212.50(d); 212.60(f).	129	15	1,935	1	1,935
Equipment and Facilities Records 212.30(b); 212.50(d); 212.60(f).	129	3,758	484,782	.08 (5 minutes).	40,237
Records of Components, Containers, and Closures 212.20(c); 212.40(a) and (b).	129	2	258	1	258
Records of Components, Containers, and Closures 212.40(e)	129	36	4,644	.5 (30 minutes).	2,322
Laboratory Testing Records 212.20(c); 212.60(a) and (b); 212.61(a); 212.70(a), (b), and (d).	129	25	3,225	1	3,225
Laboratory Testing Records 212.60(g); 212.61(b); 212.70(d)(2) and (d)(3).	129	501	64,629	.16 (10 min.).	10,728
Conditional Final Releases 212.70(f)	129	1	129	1	129
Out-of-Specification Investigations 212.20(c); 212.71(a)	129	36	4,644	1	4,644
Out-of-Specification Investigations 212.71(b)	129	1	129	1	129
Reprocessing Procedures 212.20(c); 212.71(d)	129	1	129	1	129
Distribution Records 212.20(c); 212.90(a)	129	1	129	1	129
Distribution Records 212.90(b)	129	501	64,629	.25 (15 min.).	16,157
Complaints 212.20(c); 212.100(a)	129	1	129	1	129
Complaints 212.100(b) and (c)	129	1	129	.5 (30 min.)	65
Total					149,266

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Sterility Test Failure Notices 212.70(e)	129	.25	32	1	32

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

Dated: July 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17213 Filed 7–17–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0747]

Assessment of the Risk of Human Salmonellosis Associated With the Consumption of Tree Nuts; Request for Comments, Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting comments and scientific data and information that may help us in performing a quantitative assessment of the risk of human salmonellosis (an infection with bacteria called *Salmonella*) associated with the consumption of tree nuts. The purpose of the risk assessment will be to quantify the public health risk associated with the consumption of potentially *Salmonella* contaminated tree nuts and to evaluate the impact of risk-based preventive controls on the risk of human salmonellosis arising from consumption of tree nuts.

DATES: Submit either electronic or written comments and scientific data and information by October 16, 2013.

ADDRESSES: Submit electronic comments and scientific data and information to *http://www.regulations.gov.* Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS–06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1914.

SUPPLEMENTARY INFORMATION:

I. Background

The consumption of whole raw almonds has been associated with outbreaks of human salmonellosis (an infection with bacteria called *Salmonella*), during the years 2000–2001 (Ref. 1) and the years 2003–2004 (Ref. 2). Salmonellosis has also been associated with other tree nuts such as desiccated coconut (i.e., coconut meat which has been shredded or flaked and then dried to remove as much moisture as possible) (Ref. 3) and pine nuts (Ref. 4). In addition, *Salmonella* has been found in a variety of tree nuts destined for human consumption including almonds (Ref. 5), cashew nuts and Brazil nuts (Ref. 6), macadamia nuts (Ref. 7), walnuts (Ref. 8) and pistachio nuts (Ref. 9). In the United States, tree nuts have repeatedly been recalled due to *Salmonella* contamination; between 2009 and 2012 pine nuts, pistachios, shelled hazelnuts, walnuts, cashew nuts

and macademia nuts have been recalled because of potential *Salmonella* contamination (Refs. 10 and 11). These outbreaks, published reports of *Salmonella* in tree nuts destined for human consumption, and recalls emphasize the need to assess the risk of salmonellosis associated with tree nuts intended for human consumption, and to evaluate the appropriate risk-based preventive controls needed to reduce the risk of human salmonellosis.

The exact sequence of events leading to human salmonellosis outbreaks from consumption of tree nuts is not fully understood. For example, during the 2000–2001 outbreak, investigations supported previous findings (Ref. 12) that contamination and cross-contamination risks exist within tree nut facilities and at preceding points of production (Ref. 1). Notably, the specific 2000–2001 *Salmonella* outbreak strain was shown to persist in one of the affected orchards for a period of at least 5 years, emphasizing the potential risk of cross-contamination even years after *Salmonella* is introduced into an orchard (Ref. 13).

Risk assessments can be used to evaluate potential risk reduction strategies; determine the adequacy and expected efficacy of preventive controls; and guide risk management policies, outreach efforts, data collection initiatives, and research priorities. The purpose of this risk assessment will be to quantify the public health risk associated with the consumption of tree nuts potentially contaminated with *Salmonella,* and to evaluate the impact of risk-based preventive controls on the risk of human salmonellosis arising from consumption of tree nuts. The risk assessment model will be used to evaluate practices used in the United States, as well as policies related to risk-based preventive controls. Specifically, the risk assessment will assist us in determining the levels of contamination reduction appropriate for reducing the risk of human salmonellosis from tree nuts.

II. Request for Comments and Scientific Data and Information

We are requesting comments and the submission of scientific data and information relevant to this risk assessment. We specifically request scientific data and information concerning, but not limited to, the following factors that may affect the risk of human salmonellosis associated with the consumption of tree nuts:

1. *Salmonella* contamination in different tree nuts sampled at harvest, distribution (including transportation), manufacturing/processing plant (including at times before, during, and after application of treatments designed to reduce bacterial contamination), retail, or anywhere else in the supply chain, including:

- The frequency of detecting the presence of *Salmonella* in different types of domestically produced or imported tree nuts, sampled at different stages of the farm-to-fork continuum as described previously. If available, for each data point, we also invite information regarding the following: (1) How the nuts were handled prior to analysis (e.g., pre-processing storage conditions, processing treatments and conditions, post-processing storage, etc.); (2) the size of the analytical unit; (3) number of positives; (4) total number tested and the time period in which the testing was conducted; (5) test method; and (6) sampling protocol (e.g., simple random, stratified random, targeted);
- The number of *Salmonella* present per amount (i.e., unit volume or weight) of contaminated domestically produced or imported tree nuts, sampled at different stages of the farm-to-fork continuum as described previously. If available, for each data point, we also invite information regarding the following: (1) How the nuts were handled prior to analysis (e.g., pre-processing storage conditions, processing treatments and conditions, post-processing storage, etc.); (2) the analytical method used; and (3) sampling protocol (e.g., simple random, stratified random, targeted). We ask that the testing data be provided in unaggregated form and that Most-Probable Number (MPN) patterns as well as raw data (e.g., number of positive and negative tubes per dilution step in the MPN analysis) be provided if available;
- The frequency of detecting the presence of *Salmonella* in tree nut lots associated with outbreaks of human salmonellosis. If available, for each data point, we also invite information regarding the following: (1) How the nuts were handled prior to analysis (e.g., pre-processing storage conditions, processing treatments and conditions, post-processing storage, etc.); (2) size of the analytical unit; (3) number of positives; (4) total number tested; (5) analytical test method; and (6) sampling protocol (e.g*.,* simple random, stratified random, targeted); and
- The number of *Salmonella* present per amount (i.e*.,* unit volume or weight) of contaminated tree nuts associated with outbreaks of human salmonellosis. If available, for each data point, we also invite information regarding the following: (1) How the nuts were handled prior to analysis (e.g., pre-processing storage conditions, processing treatments and conditions, post-processing storage, etc.); (2) analytical method used; and (3) sampling protocols (e.g., simple random, stratified random, targeted). We ask that the testing data be provided in unaggregated form and that MPN patterns as well as raw data (e.g., number of positive and negative tubes per dilution step in the MPN analysis) be provided if available; in addition, we would ask that data regarding the variability in the number of *Salmonella* cells present in different samples from the same lot of contaminated nuts associated with an outbreak also be provided if available.

2. *Salmonella* survival, growth or inactivation dynamics in different tree nuts during transportation and storage, including:

- Data or models on survival, growth or inactivation of *Salmonella* in specific tree nuts, including the potential effects of nut composition, water activity, and storage temperature;
- Data or models on survival, growth, or inactivation of *Salmonella* at different stages along the tree nut farm-to-fork continuum, potentially as a function of relative humidity during storage, geographic region, or season; and
- Data or models on survival, growth or inactivation of *Salmonella* in different foods made with *Salmonella*-contaminated tree nuts as ingredients.

3. Current food consumption practices in the United States, including:

- The frequency with which different tree nuts or foods containing tree nuts are consumed by population subgroups (e.g., general adult population, immunocompromised persons, and the elderly);
- The frequency with which different tree nuts are consumed raw (i.e., without undergoing any treatment designed to reduce bacterial contamination on tree nuts between the time of harvest and the time of consumption) by different population subgroups;
- The frequency with which tree nuts that have undergone treatments designed to reduce bacterial contamination are consumed by different population subgroups; and
- Serving sizes for different tree nuts, including serving sizes for consumption of raw tree nuts and/or tree nuts that have undergone treatments designed to reduce bacterial contamination between the time of harvest and the time of consumption.

4. Storage, handling and processing conditions that may affect *Salmonella* survival, growth, or inactivation along

the farm-to-fork continuum and the impact of these conditions on *Salmonella* concentrations on tree nuts, including:

- Typical storage conditions (e.g., time, temperature, relative humidity) for different tree nuts, from the time of harvest until the application of treatments designed to reduce bacterial contamination, and whether those storage conditions change *Salmonella* contamination levels;
- The types of treatments designed to reduce bacterial contamination that are typically applied to different tree nuts before retail, the frequency with which these treatments are applied to different types of tree nuts, the exact processing conditions (e.g., time, temperature, relative humidity), and the efficacy of these treatments in reducing *Salmonella* contamination on different tree nuts;
- Typical storage conditions (e.g., time, temperature, relative humidity) for different tree nuts, from the time treatments designed to reduce bacterial contamination are applied to the time the tree nuts are consumed, including typical storage conditions at retail and in the consumer home.
- The types of handling practices that are typically applied to different tree nuts by the consumer before consumption that may change Salmonella contamination levels, and the typical conditions (e.g., time, temperature) that are applied during these practices.

5. Other comments, including the types of tree nuts that should be evaluated in this risk assessment and information about which types of tree nuts may enter the U.S. market without the application of treatments designed to reduce bacterial contamination.

III. Comments

Interested persons may submit either electronic comments and scientific data and information to *http://www.regulations.gov* or written comments and scientific data and information to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified the Web site addresses in the References section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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10. FDA (Food and Drug Administration). Recalls, Market Withdrawals, & Safety Alerts. Available at *http://www.fda.gov/Safety/Recalls/default.htm.* (Accessed 04/2013).

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13. Uesugi, A.R., M.D. Danyluk, R.E. Mandrell, L.J. Harris. ''Isolation of *Salmonella* Enteritidis phage type 30 from a single almond orchard over a 5-year period.'' *Journal of Food Protection,* 70(8): pp. 1784–1789, 2007.

Dated: July 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17211 Filed 7–17–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0811]

Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation To Treat Clostridium difficile Infection Not Responsive to Standard Therapies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Enforcement Policy Regarding IND Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies,'' dated July 2013. This guidance informs members of the medical and scientific community and other interested persons that we intend to exercise enforcement discretion regarding the investigational new drug (IND) requirements for the use of fecal microbiota for transplantation (FMT) to treat *C. difficile* infection not responding to standard therapies. FDA intends to exercise this discretion provided that the treating physician obtains adequate informed consent from the patient or his or her legally authorized representative for the use of FMT products. Informed consent should include, at a minimum, a statement that the use of FMT products to treat *C. difficile* is investigational and a discussion of its potential risks. This policy does not extend to other uses of FMT. FDA intends to exercise this discretion on an interim basis while we further consider the matter. This guidance has an immediate implementation date because FDA has