U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

TOPLINE SUMMARY: FDA REPORT ON THE OCCURRENCE OF FOODBORNE ILLNESS RISK FACTORS IN RETAIL FOOD STORE DELI DEPARTMENTS 2019-2022

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Background

This Topline Summary presents the raw data without interpretation from the 2019-2022 Retail Food Store Data Collection on the Occurrence of Foodborne Illness Risk Factors in Retail Food Store Delis.

FDA is conducting another ten-year study that will span 2013-2023 and is designed to provide a means for tracking trends related to the occurrence of contributing factors to foodborne illness outbreaks (foodborne illness risk factors) as well as a means for examining relationships with underlying antecedents (root causes) of poor food safety practices within retail food and food service restaurant facilities.

FDA acknowledges that this data collection occurred during a novel time of the COVID-19 pandemic. While we are interested in the impacts of the pandemic on food safety practices and behaviors, this study is not designed to detect differences in practices within a single data collection period. Once the third and final data collection in this industry segment is complete, FDA will issue a trends report and attempt to analyze the changes in practices over time.

2019-2022 Retail Food Store Data Collection

As part of FDA's current ten-year study, data was collected from 2019-2023 on the occurrence of foodborne illness risk factors and food safety behaviors in retail food store delis. The data contained in this report was collected during the 2019-2023 retail food store data collection. The data will be used as baseline measurements upon which to assess trends in the occurrence of foodborne illness risk factors in retail food store delis over the ten-year period of 2019-2023.

The key objectives of the 2019-2023 data collection period were to identify:

- The occurrence of foodborne illness risk factors
- The prevalence of food safety management systems
- The prevalence of certified food protection managers
- The prevalence of employee health policies

In addition to the aforementioned objectives, the data collection also assessed:

- Handwash behaviors and practices
- Food product holding temperatures

Design and Methodology

A Geographic Information System (GIS) database containing a listing of businesses throughout the U.S. was used as the establishment inventory for the restaurant data collection. The geographic distribution of 27 FDA Retail Food Specialists (Specialists) throughout the U.S. allowed for a broad sampling of facility types in all regions of the U.S. For this study, the target sample size was a total of

438 delis departments. This sample size provided sufficient observations of food safety practices to be 95% confident that compliance percentages derived from the data collections were within 5% of their actual occurrence.

The data collection focused on the occurrence of foodborne illness risk factors. It was not intended to be a comprehensive assessment of compliance with all Food Code requirements. The Specialist's priority was to observe food safety practices and behaviors associated with ten primary data items correlating to risk factors that have been epidemiologically linked to the occurrence of foodborne illness outbreaks.

Each of the data items is comprised of information statements related to specific food safety practices or procedures. If one of these food safety practices was observed to be Out of Compliance the overall data item was Out of Compliance. The Out of Compliance percentage represents the proportion of establishments where a data item was found Out of Compliance at least once when the practice or procedure could be observed.

In addition to observations of food safety practices and behaviors, in each Retail Food Store Deli Specialists completed assessments of:

- Food product temperatures,
- Employee health policies,
- Handwashing frequency,
- Food Protection Manager Certification, and
- Food Safety Management Systems (Procedures, Training, and Monitoring).

Data Limitations

Data collection was done using the FDA Foodborne Illness Risk Factor Study Data Collection Form for Retail Food Store Delis. Data featured in this report is select demographic information on the retail food store, the regulatory authorities with jurisdiction over the retail food store, and the 19 data items on the Data Collection Form. Data collection on some data items was limited and therefore not reflected in this summary. The Protocol for the Data Collection may be accessed at: https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM505468.pdf. The Marking Instructions for the Data Collection Form may be accessed at: https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM505471.pdf.

Acronyms and Defined Terms

CFPM: Certified Food Protection Manager

Data Item: based on FDA Food Code recommendations and are designed to control food safety behaviors/practices. There are 19 Data Items with Data Items 1 – 10 recognized as primary Data Items (See pages 21-28).

EH q: Employee Health question

FDA: U.S. Food and Drug Administration

PIC: Person in Charge

PTM: Procedures, Training, and Monitoring

Risk category: Complexity of food preparation by the food establishment as described in Annex 5 of the 2017 FDA Food Code. This risk categorization was used to determine if an establishment was eligible for data collection.

Activity level: level of activity occurring in the kitchen and other food preparation areas at the time of the data collection.

Multiple unit: food establishments that are part of a multi- unit operation.

Program Standards: Voluntary National Retail Food Regulatory Program Standards. More information may be accessed at: https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm

Grading: determination of whether or not the regulatory jurisdiction incorporates a grading system as part of its retail food inspection program.

IN: mean that all observed occurrences were IN Compliance with the appropriate FDA Food Code provision for that data item or information statement.

Results

The Data Collection form consists of 19 Data Items. Data Results follow the FDA Data Collection Form found on page 17. The Marking Instructions for the Data Collection Form may be accessed at: https://www.fda.gov/media/109676/download.

The presentation of data follows the order of the Retail Food Store Data Collection Form on pages 17-32.

Note: Due to rounding some of the percentages do not add to 100.

Establishment Information

Deli

Risk category	Number	Percentage
2	181	41.3%
3	249	56.8%
4	8	1.8%
Total	438	100.0%

Activity level	Number	Percentage
Light	234	53.42%
Moderate	161	36.76%
Heavy	43	9.82%
Total	438	100.0%

Multiple unit	Number	Percentage
No	21	4.8%
Yes	417	95.2%
Total	438	100.0%

Ownership	Number	Percentage
Company-Owned	377	90.41%
Franchise	25	6.00%
Unsure	15	3.60%
Total	417	100.0%

Enrolled Program Standards	Number	Percentage
No	98	22.37%
Yes	340	77.63%
Total	438	100.0%

Information on the Regulatory Authority

Deli

Meet Standard 1	Number	Percentage
NO – Jurisdiction does not meet Standard 1	231	67.94%
YES – Self Reported	21	6.18%
YES – Verified by Audit	88	25.88%
Total	340	100.0%

Grading	Number	Percentage
NO – Jurisdiction does not have a grading system	253	57.76%
YES – Color Graphic	13	2.97%
YES – Letter Grade	10	2.28%
YES – Letter Grade and Color Graphic	0	0.0%
YES – Numerical Score	63	14.38%
YES – Numerical Score and Color Graphic	2	0.46%
YES – Numerical Score and Letter Grade	27	6.16%
YES – Numerical Score, Letter Grade, and Color Graphic	25	5.71%
YES – Other	45	10.27%
Total	438	100.0%

Deli

Inspection reporting	Number	Percentage
NO – Jurisdiction does not require inspections to be publically reported	100	22.83%
YES – Other	13	2.97%
YES – Posting on the Internet	219	50.00%
YES – Posting on-site	42	9.59%
YES – Posting on-site and Posting on the Internet	64	14.61%
Total	438	100.0%

Mandatory CFPM requirement	Number	Percentage
NO – Jurisdiction does not have a mandatory Food Protection Manager Certification Requirement	105	23.97%
YES – Based ONLY on successful completion of an ANSI-Accredited Program	282	64.38%
YES – Other AND Reciprocal Acceptance of an ANSI Accredited Program	31	7.08%
YES – Other Food Protection Manager Certification Program (not an ANSI-Accredited Program)	20	4.57%
Total	438	100.00%

Deli

Scope of CFPM Requirement	Number	Percentage
Other	40	12.01%
PIC - One	141	42.34%
PIC - All times	69	20.72%
Supervisor - One	78	23.42%
Supervisor - All times	5	1.50%
Total	333	100.0%

Food handler card and handler training	Number	Percentage
NO – Jurisdiction does NOT require Food Handler Cards	334	76.26%
YES – Other	15	3.42%
YES – Required Test	7	1.60%
YES – Required Training	6	1.37%
YES – Required Training and Test	76	17.35%
Total	438	100.00%

Manager Certification - Store Level Manager

Deli

CFPM PIC	Number	Percentage
NO – The person in charge at the time of the data collection is NOT a certified food protection manager	136	31.1%
YES – Certificate Available - ANSI-Accredited	214	48.9%
YES – Certificate Available - Other	2	0.5%
YES – Certificate NOT Available - ANSI-Accredited	56	12.8%
YES – Certificate NOT Available - Other	0	0.0%
YES – Certificate NOT Available - Unsure	30	6.8%
Total	438	100.00%

CFPM Facility	Number	Percentage
No	390	89.04%
Yes	48	10.96%
Total	438	100.0%

Manager Certification - Store Department / Operation

Deli

CFPM Employed	Number	Percentage
NO – No certified food protection managers are employed at the establishment	118	26.94%
YES – Certificate Available - ANSI-Accredited	203	46.35%
YES – Certificate Available - Other	2	0.46%
YES – Certificate NOT Available - ANSI-Accredited	73	16.67%
YES – Certificate NOT Available - Other	2	0.46%
YES – Certificate NOT Available - Unsure	40	9.13%
Total	438	100.00%

CFPM Present	Number	Percentage
NO – No certified food protection managers are present during the data collection	181	41.32%
YES – Certificate Available - ANSI-Accredited	178	40.64%
YES – Certificate Available - Other	2	0.46%
YES – Certificate NOT Available - ANSI-Accredited	55	12.56%
YES – Certificate NOT Available - Other	3	0.68%
YES – Certificate NOT Available - Unsure	19	4.34%
Total	438	100.0%

Manager Certification - Store Department / Operation continued

Deli

CFPM PIC	Number	Percentage
NO – The person in charge at the time of the data collection is NOT a certified food protection manager	192	43.8%
YES – Certificate Available - ANSI-Accredited	171	39.04%
YES – Certificate Available - Other	1	0.23%
YES – Certificate NOT Available - ANSI-Accredited	53	12.10%
YES – Certificate NOT Available - Other	3	0.68%
YES – Certificate NOT Available - Unsure	18	4.11%
Total	438	100.0%

CFPM Required	Number	Percentage
No	242	55.25%
Yes	196	44.75%
Total	438	100.00%

Employee Health Policy

Deli

eh q1	Number	Percentage
NO – Employees exhibiting illness symptoms or conditions NOT observed within the establishment	435	99.32%
YES – Employees exhibiting illness symptoms or conditions observed within the establishment	3	0.68%
Total	438	100.0%

Employee Health Policy continued

Deli

eh q2	Number	Percentage
NO – Policy only partially developed or non-existent	221	50.46%
YES – Policy is ORAL and based on the current version FDA Food Code	46	10.50%
YES – Policy is WRITTEN and based on the current version FDA Food Code	171	39.04%
Total	438	100.0%

eh q3	Number	Percentage
NO – Policy only partially developed or non-existent	245	55.94%
YES – Policy is ORAL and based on the current version FDA Food Code	27	6.16%
YES – Policy is WRITTEN and based on the current version FDA Food Code	166	37.90%
Total	438	100.0%

eh q4	Number	Percentage
NO – Policy only partially developed or non-existent	288	65.75%
YES – Policy is ORAL and based on the current version FDA Food Code	34	7.76%
YES – Policy is WRITTEN and based on the current version FDA Food Code	116	26.48%
Total	438	100.0%

Deli

eh q5	Number	Percentage
NO – Policy only partially developed or non-existent	282	64.38%
YES – Policy is ORAL and based on the current version FDA Food Code	42	9.59%
YES – Policy is WRITTEN and based on the current version FDA Food Code	114	26.03%
Total	438	100.0%

eh q6	Number	Percentage
NO – Policy only partially developed or non-existent	307	70.09%
YES – Policy is ORAL and based on the current version FDA Food Code	35	7.99%
YES – Policy is WRITTEN and based on the current version FDA Food Code	96	21.92%
Total	438	100.0%

eh q7	Number	Percentage
No	423	96.58%
Yes	15	3.42%
Total	438	100.0%

19 Data Items from the Data Collection Form *(Pages 17-32)*

The following formula calculates the percentage of out-of-compliance observations for each data item:

$$\text{Percent Out-of-Compliance} = \frac{\text{Total Number of Out-of-Compliance Observations for the Data Item}}{\text{Total Number of Observations (IN and OUT) for the Data Item}} \times 100$$

Deli

Data Item	IN	IN%	NA	NA%	NO	NO%	OUT	OUT%
ITEM 1	167	38.13%	0	0.0%	0	0.8%	271	61.87%
ITEM 2	432	98.63%	0	0.0%	0	0.0%	6	1.37%
ITEM 3	302	68.95%	0	0.0%	0	0.0%	136	31.05%
ITEM 4	266	60.73%	0	0.0%	0	0.0%	172	39.27%
ITEM 5	180	41.10%	0	0.0%	0	0.0%	258	58.90%
ITEM 6	220	50.23%	13	2.97%	32	7.31%	173	39.50%
ITEM 7	154	35.16%	4	0.91%	169	38.58%	111	25.34%
ITEM 8	280	63.93%	0	0.0%	2	0.46%	156	35.62%
ITEM 9	302	68.95%	8	1.83%	114	26.03%	14	3.20%
ITEM 10	145	33.11%	51	11.64%	221	50.46%	21	4.79%
ITEM 11	315	71.92%	0	0.0%	0	0.0%	123	28.08%
ITEM 12	387	88.36%	0	0.0%	0	0.0%	51	11.64%
ITEM 13	13	2.97%	409	93.38%	0	0.0%	16	3.65%
ITEM 14	35	7.99%	363	82.88%	5	1.14%	35	7.99%
ITEM 15	275	62.79%	0	0.0%	0	0.0%	163	37.21%
ITEM 16	8	1.83%	426	97.26%	2	0.46%	2	0.46%
ITEM 17	427	97.49%	0	0.0%	0	0.0%	11	2.51%
ITEM 18	356	81.28%	0	0.0%	0	0.0%	82	18.72%
ITEM 19	189	43.15%	0	0.0%	0	0.0%	249	56.85%

Handwashing Frequency Assessment

Deli

Number	Handwash freq c1	Handwash freq c2	Handwash freq c3
0	18	317	194
1	108	64	83
2	99	25	62
3	82	15	43
4	41	5	21
5	41	5	20
6	17	1	3
7	10	1	5
8	9	0	2
9	4	3	2
10	1	2	1
11	2	0	2
12	2	0	0
17	1	0	0

Food Safety Management System Assessment

Deli

PTM	Number	Percentage
N/A	1	0.23%
Non-Existent	27	6.16%
Underdeveloped	210	47.95%
Well developed	159	36.30%
Well developed and documented	41	9.36%
Total	438	100.0%

Summary of cold holding product temperatures

Deli - Data Item 5					
Type	I	II	III	IV	V
Number of Temperatures	5747	491	324	244	90
Percentage	83.34%	7.12%	4.70%	3.54%	1.31%

I. Number of product temperature measurements IN compliance with food code critical limits
II. Number of OUT of compliance product temperature measurements 1 -2 above food code critical limits
III. Number of OUT of compliance product temperature measurements 3 -4 above food code critical limits
IV. Number of OUT of compliance product temperature measurements 5 -9 above food code critical limits
V. Number of OUT of compliance product temperature measurements 10 or more above food code critical limits

Summary of hot holding product temperatures

Deli - Data Item 6					
Type	I	II	III	IV	V
Number of Temperatures	1993	30	40	102	320
Percentage	80.20%	1.21%	1.61%	4.10%	12.88%

I. Number of product temperature measurements IN compliance with food code critical limits
II. Number of OUT of compliance product temperature measurements 1 -2 below food code critical limits
III. Number of OUT of compliance product temperature measurements 3 -4 below food code critical limits
IV. Number of OUT of compliance product temperature measurements 5 -9 below food code critical limits
V. Number of OUT of compliance product temperature measurements 10 or more below food code critical limits

Summary of cooking food product temperatures

Deli - Data Item 9					
Type	I	II	III	IV	V
Number of Temperatures	783	1	2	8	19
Percentage	96.31%	0.12%	0.25%	0.98%	2.34%

I. Number of product temperature measurements IN compliance with food code critical limits
II. Number of OUT of compliance product temperature measurements 1 -2 below food code critical limits
III. Number of OUT of compliance product temperature measurements 3 -4 below food code critical limits
IV. Number of OUT of compliance product temperature measurements 5 -9 below food code critical limits
V. Number of OUT of compliance product temperature measurements 10 or more below food code critical limits

Summary of reheated food product temperatures

Deli - Data Item 10					
Type	I	II	III	IV	V
Number of Temperatures	358	1	0	4	25
Percentage	92.27%	0.26%	0.0%	1.03%	6.44%

I. Number of product temperature measurements IN compliance with food code critical limits
II. Number of OUT of compliance product temperature measurements 1 -2 below food code critical limits
III. Number of OUT of compliance product temperature measurements 3 -4 below food code critical limits
IV. Number of OUT of compliance product temperature measurements 5 -9 below food code critical limits
V. Number of OUT of compliance product temperature measurements 10 or more below food code critical limits

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FDA Retail Food Program
Foodborne Illness Risk Factor Study

Retail Food Store Data Collection Form

Form Approved: OMB No. 0910-0744
Expiration Date: October 31, 2027
See PRA Statement on page 16

FDA

INDUSTRY SEGMENT

Food Safety Management System Risk Factor Category:

Industry Segment: Retail Food Store	Facility Type: Deli Department / Operation

DATA COLLECTION INFORMATION

Date:	Data Collector:
Time In: Time Out:	Total Time in Minutes:

Risk Categorization *(Select **ONE** of the following)*: ☐ 2 ☐ 3 ☐ 4

ESTABLISHMENT INFORMATION

Establishment Name:

Street Address:

City:	State:	Zip:	County:

Maximum Number of Employees Per Shift:	Number of Employees Present at Time of Visit:

Activity level at the time of visit (*Select ONE*): ☐ Light ☐ Moderate ☐ Heavy

ESTABLISHMENTS THAT ARE PART OF MULTI-UNIT OPERATIONS

Establishment is part of a Multi-Unit Operation: ☐ YES ☐ NO

Number of Individual Units that are part of the Multi-Unit Operation *(Enter the number of units provided by the person in charge)*:

Ownership of Establishment *(Select **ONE** of the following)*: ☐ Company-Owned ☐ Franchise ☐ Unsure

If Franchise – number of units owned by the franchisee *(Enter the number of units provided by the person in charge)***:**

INFORMATION ON THE REGULATORY AUTHORITY

Name of Jurisdiction with Regulatory Oversight:

Enrolled in FDA Retail Food Program Standards: ☐ YES ☐ NO

Jurisdiction Meets Standard 1 *(Select **ONE** of the following)*:

☐ YES – Self Reported
☐ YES – Verified by Audit
☐ NO – Jurisdiction does not meet Standard 1

Retail Food Store Data Collection Form *(Continued)*

INFORMATION ON THE REGULATORY AUTHORITY *(continued from previous page)*

Jurisdiction Uses a Grading System *(Select **ONE** of the following)*:

- ☐ YES – Numerical Score
- ☐ YES – Letter Grade
- ☐ YES – Color Graphic
- ☐ YES – Numerical Score and Letter Grade
- ☐ YES – Numerical Score and Color Graphic
- ☐ YES – Letter Grade and Color Graphic
- ☐ YES – Numerical Score, Letter Grade, and Color Graphic
- ☐ NO – Jurisdiction does not have a grading system
- ☐ YES – Other *(If Other, describe)*:

Jurisdiction's Program Includes Public Reporting of Inspection Results *(Select **ONE** of the following)*:

- ☐ YES – Posting on-site
- ☐ YES – Posting on the Internet
- ☐ YES – Posting on-site and Posting on the Internet
- ☐ NO – Jurisdiction does not require inspections to be publically reported
- ☐ YES – Other *(If Other, describe)*:

Jurisdiction Has a Mandatory Food Protection Manager Certification Requirement *(Select **ONE** of the following)*:

- ☐ YES – Based ONLY on successful completion of an ANSI-Accredited Program
- ☐ YES – Other Food Protection Manager Certification Program (not an ANSI-Accredited Program)
- ☐ YES – Other AND Reciprocal Acceptance of an ANSI Accredited Program
- ☐ NO – Jurisdiction does not have a mandatory Food Protection Manager Certification Requirement
- ☐ YES – Other *(If Other, describe)*:

If "Other" *(Select **ONE** of the following)*

- ☐ Other includes a required Training Component
- ☐ Other includes a Test other than exams offered through an ANSI Accredited Programs
- ☐ Other includes a required Training Component AND Test other than exam offered through an ANSI Accredited Program

Scope of Food Protection Manager Certification Requirement *(Select **ONE** of the following)*:

- ☐ Person in Charge – One Per Establishment
- ☐ Person in Charge – Present at All Times
- ☐ Supervisory Employee – One Per Establishment
- ☐ Supervisory Employee – Present at All Times
- ☐ Other *(If Other, describe)*:

Jurisdiction Requires Food Handler Card *(Select **ONE** of the following)*:

- ☐ YES – Required Training
- ☐ YES – Required Test
- ☐ YES – Required Training and Test
- ☐ NO – Jurisdiction does NOT require Food Handler Cards
- ☐ YES – Other *(If Other, describe)*:

MOST RECENT ROUTINE INSPECTIONS

Dates of the Two Most Recent Regulatory Routine Inspections: Date 1: Date 2:

Retail Food Store Data Collection Form *(Continued)*

MANAGER CERTIFICATION – STORE LEVEL MANAGER

1. Is the PERSON IN CHARGE of the retail food store at the time of the data collection a certified food protection manager (*Select* ***ONE***)?

   ☐ YES – Certificate Available
   ☐ YES – Certificate NOT Available
   ☐ NO – The person in charge at the time of the data collection is NOT a certified food protection manager

   If the marking above contains a "YES" response, indicate the Type of Certification below (*Select* ***ONE***)

   ☐ ANSI-Accredited ☐ Other ☐ Unsure

2. Is the PERSON IN CHARGE of the retail food store the same as the PERSON IN CHARGE of the facility type?

   ☐ YES ☐ NO

MANAGER CERTIFICATION FOR THE RETAIL FOOD STORE DEPARTMENT / OPERATION

1. Is there a certified food protection manager EMPLOYED at the department / operation (*Select* ***ONE***)?

   ☐ YES – Certificate Available
   ☐ YES – Certificate NOT Available
   ☐ NO – No certified food protection managers are employed at the establishment

   If the marking above contains a "YES" response, indicate the Type of Certification below (*Select* ***ONE***)

   ☐ ANSI-Accredited ☐ Other ☐ Unsure

2. Is there an employee who is a certified food protection manager PRESENT at the department / operation during the data collection (*Select* ***ONE***)?

   ☐ YES – Certificate Available
   ☐ YES – Certificate NOT Available
   ☐ NO – No certified food protection managers are present during the data collection

   If the marking above contains a "YES" response, indicate the Type of Certification below (*Select* ***ONE***)

   ☐ ANSI-Accredited ☐ Other ☐ Unsure

3. Is the PERSON IN CHARGE at the time of the data collection of the department / operation a certified food protection manager (*Select* ***ONE***)?

   ☐ YES – Certificate Available
   ☐ YES – Certificate NOT Available
   ☐ NO – The person in charge at the time of the data collection is NOT a certified food protection manager

   If the marking above contains a "YES" response, indicate the Type of Certification below (*Select* ***ONE***)

   ☐ ANSI-Accredited ☐ Other ☐ Unsure

4. Is the department's / operation's policy to have a certified food protection manager present at all times?

   ☐ YES ☐ NO

If "Other" for one or more of the responses to questions 1 – 3, *describe*:

Retail Food Store Data Collection Form *(Continued)*

EMPLOYEE HEALTH POLICY

1. Food employees exhibiting certain illness symptoms or conditions that require exclusion or restriction in the *Food Code*, ARE OBSERVED within the establishment during the data collection.

   ☐ YES – Employees exhibiting illness symptoms or conditions observed within the establishment
   ☐ NO – Employees exhibiting illness symptoms or conditions NOT observed within the establishment

2. Are food employees and conditional employees informed of their responsibility to report to the person in charge illness SYMPTOMS as specified in Section 2-201.11 of the *Food Code*?

   ☐ YES – Policy is ORAL and based on the current version of the *FDA Food Code*
   ☐ YES – Policy is WRITTEN and based on the current version of the *FDA Food Code*
   ☐ NO – Policy only partially developed or non-existent

3. Are food employees and conditional employees informed of their responsibility to report to the person in charge diagnosis with, or exposure to, the specific ILLNESSES specified in Section 2-201.11 of the *Food Code*?

   ☐ YES – Policy is ORAL and based on the current version of the *FDA Food Code*
   ☐ YES – Policy is WRITTEN and based on the current version of the *FDA Food Code*
   ☐ NO – Policy only partially developed or non-existent

4. Is management aware of its responsibility to NOTIFY THE REGULATORY AUTHORITY when a food employee is jaundiced or diagnosed with an illness due to a pathogen specified in Section 2-201.11 of the *Food Code*?

   ☐ YES – Policy is ORAL and based on the current version of the *FDA Food Code*
   ☐ YES – Policy is WRITTEN and based on the current version of the *FDA Food Code*
   ☐ NO – Policy only partially developed or non-existent

5. Is the management's employee health policy consistent with 2-201.12 of the *Food Code* for EXCLUDING AND RESTRICTING food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods?

   ☐ YES – Policy is ORAL and based on the current version of the *FDA Food Code*
   ☐ YES – Policy is WRITTEN and based on the current version of the *FDA Food Code*
   ☐ NO – Policy only partially developed or non-existent

6. Is the management's employee health policy consistent with 2-201.13 of the *Food Code* for REMOVAL OF EXCLUSIONS AND RESTRICTIONS of food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods?

   ☐ YES – Policy is ORAL and based on the current version of the *FDA Food Code*
   ☐ YES – Policy is WRITTEN and based on the current version of the *FDA Food Code*
   ☐ NO – Policy only partially developed or non-existent

7. Management has a copy of FDA's *Employee Health and Personal Hygiene Handbook OR cd database*?

   ☐ YES
   ☐ NO

Retail Food Store Data Collection Form *(Continued)*

Risk Factor – Poor Personal Hygiene (Items 1 & 2)

	IN	OUT	NO	NA
1. Employees practice proper handwashing	☐	☐		

Description of HANDWASHING OBSERVATIONS	IN	OUT	NO	NA
A. Hands are cleaned and properly washed using hand cleanser / water supply / appropriate drying methods / length of time as specified in Section 2-301.12 of the *Food Code*	☐	☐		
B. Hands are cleaned and washed when required as specified in Section 2-301.14 of the *Food Code*	☐	☐		

COMMENTS:

HANDWASHING FREQUENCY ASSESSMENT

	C1 Employee observed washing hands properly and when required	C2 Employee observed washing hands improperly	C3 Employee observed failing to wash hand when required
TOTAL COUNT			

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

	IN	OUT	NO	NA
2. Food employees do not contact ready-to-eat foods with bare hands	☐	☐		

COMMENTS:

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

Retail Food Store Data Collection Form *(Continued)*

Risk Factor – Contaminated Equipment / Protection from Contamination (Items 3 & 4)

	IN	OUT	NO	NA
3. Food is protected from cross-contamination during storage, preparation, and display	☐	☐		

Description of FOOD Contamination OBSERVATIONS	IN	OUT	NO	NA
A. Raw animal foods are separated from ready-to-eat foods	☐	☐	☐	☐
B. Different raw animal foods are separated from each other	☐	☐	☐	☐
C. Food is protected from environmental contamination – actual contamination observed	☐	☐		
D. Food is protected from environmental contamination – potential contamination	☐	☐		
E. Other (*describe in the comments section below*)	☐	☐		☐

COMMENTS:

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT								
PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

	IN	OUT	NO	NA
4. Food contact surfaces are properly cleaned and sanitized	☐	☐		

Description of Food Contact Surfaces OBSERVATIONS	IN	OUT	NO	NA
A. Food contact surfaces and utensils are clean to sight and touch and sanitized before use	☐	☐		
B. Equipment food contact surfaces and utensils are cleaned and sanitized properly using manual warewashing procedures	☐	☐	☐	☐
C. Equipment food contact surfaces and utensils are cleaned and sanitized properly using mechanical warewashing equipment	☐	☐	☐	☐
D. Other (*describe in the comments section below*)	☐	☐		☐

COMMENTS:

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT								
PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

Retail Food Store Data Collection Form *(Continued)*

Risk Factor – Improper Holding / Time and Temperature Risk (Items 5-8)

	IN	OUT	NO	NA
5. Foods requiring refrigeration are held at the proper temperature	☐	☐		
Description of Cold Holding Temperature OBSERVATIONS	**IN**	**OUT**	**NO**	**NA**
A. TCS Food is maintained at 41°F (5°C) or below, except during preparation, cooking, cooling, or when time is used as a public health control.	☐	☐		
B. Raw shell eggs are stored under refrigeration that maintains ambient air temperature of 45ºF (7ºC) or less	☐	☐	☐	☐
C. Other (describe in the temperature chart and comments section below)	☐	☐		☐

COMMENTS:

Cold Holding Temperatures Recorded During the Data Collection (List all temperatures taken)

FOOD PRODUCT	FOOD TEMP.	*FOOD CODE* CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT	FOOD PRODUCT	FOOD TEMP.	*FOOD CODE* CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT

SUMMARY COLD HOLDING PRODUCT TEMPERATURE CATEGORIES	NUMBER OF FOOD PRODUCT TEMPERATURES
I. – Number of product temperature measurements **IN** Compliance with *Food Code* critical limits	
II. – Number of **OUT** of Compliance product temperature measurements **1°F - 2°F** above *Food Code* critical limits	
III. – Number of **OUT** of Compliance product temperature measurements **3°F - 4°F** above *Food Code* critical limits	
IV. – Number of **OUT** of Compliance product temperature measurements **5°F - 9°F** above *Food Code* critical limits	
V. – Number of **OUT** of Compliance product temperature measurements **10°F or more** above *Food Code* critical limits	

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

Retail Food Store Data Collection Form *(Continued)*

	IN	OUT	NO	NA
6. Foods displayed or stored hot are held at the proper temperature	☐	☐	☐	☐
Description of Hot Holding Temperature OBSERVATIONS	**IN**	**OUT**	**NO**	**NA**
A. TCS Food is maintained at 135° F (57° C) or above, except during preparation, cooking, cooling, or when time is used as a public health control.	☐	☐	☐	☐
B. Roasts are held at a temperature of 130° F (54° C) or above	☐	☐	☐	☐
C. Other (describe in the temperature chart and comments section below)	☐	☐		☐

COMMENTS:

Hot Holding Temperatures Recorded During the Data Collection (List all temperatures taken)

FOOD PRODUCT	FOOD TEMP.	*FOOD CODE* CRITICAL LIMIT	TYPE OF HOT HOLDING EQUIPMENT	FOOD PRODUCT	FOOD TEMP.	*FOOD CODE* CRITICAL LIMIT	TYPE OF HOT HOLDING EQUIPMENT

SUMMARY HOT HOLDING PRODUCT TEMPERATURE CATEGORIES	NUMBER OF FOOD PRODUCT TEMPERATURES
I. – Number of product temperature measurements **IN** Compliance with *Food Code* critical limits	
II. – Number of **OUT** of Compliance product temperature measurements **1°F - 2°F** below *Food Code* critical limits	
III. – Number of **OUT** of Compliance product temperature measurements **3°F - 4°F** below *Food Code* critical limits	
IV. – Number of **OUT** of Compliance product temperature measurements **5°F - 9°F** below *Food Code* critical limits	
V. – Number of **OUT** of Compliance product temperature measurements **10°F or more** below *Food Code* critical limits	

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

Retail Food Store Data Collection Form *(Continued)*

	IN	OUT	NO	NA
7. Foods are cooled properly	☐	☐	☐	☐
Description of Cooling Temperature OBSERVATIONS	**IN**	**OUT**	**NO**	**NA**
A. Cooked TCS Food is cooled from 135°F (57°C) to 70°F (21°C) within 2 hours **and** from 135°F (57°C) to 41°F(5°C) or below within 6 hours	☐	☐	☐	☐
B. TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours	☐	☐	☐	☐
C. Proper cooling methods/equipment are used	☐	☐	☐	☐
D. Other (describe in the temperature chart and comments section below)	☐	☐		☐
COMMENTS:				

Cooling Temperatures Recorded During the Data Collection (List all temperatures taken)

FOOD PRODUCT	FOOD COOLING TEMP. #1	FOOD COOLING TEMP. #2	TOTAL TIME IN MINUTES	*FOOD CODE* CRITICAL LIMIT	TYPE OF EQUIPMENT USED TO COOL FOOD

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

Retail Food Store Data Collection Form *(Continued)*

	IN	OUT	NO	NA
8. Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening	☐	☐	☐	☐

Description of Date Marking OBSERVATIONS	IN	OUT	NO	NA
A. Ready-to-eat, TCS Food (prepared on-site) held for more than 24 hours is date marked as required	☐	☐	☐	☐
B. Open commercial containers of prepared ready-to-eat TCS Food held for more than 24 hours are date marked as required	☐	☐	☐	☐
C. Ready-to-eat, TCS Food prepared on-site and/or opened commercial container exceeding 7 days at ≤ 41°F is discarded	☐	☐	☐	☐
D. Other (describe in the temperature chart and comments section below)	☐	☐		☐

COMMENTS:

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

Risk Factor – Inadequate Cooking (Items 9 & 10)

	IN	OUT	NO	NA
9. Raw animal foods are cooked to required temperatures	☐	☐	☐	☐

Description of Cooking Temperature OBSERVATIONS	IN	OUT	NO	NA
A. Raw shell eggs broken for immediate service are cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155° F (68°C) for 17 seconds	☐	☐	☐	☐
B. Pork; Fish; Beef; Commercially-raised Game Animals are cooked to 145°F (63°C) for 15 seconds	☐	☐	☐	☐
C. Comminuted Fish, Meats, Commercially-raised Game Animals are cooked to 155°F (68°C) for 17 seconds	☐	☐	☐	☐
D. Poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratite; or stuffing containing fish, meat, poultry, or ratites; wild game animals are cooked to 165°F (74°C) or above for < 1 second (instantaneous).	☐	☐	☐	☐
E. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specifies and according to oven parameters per Chart ***(NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).***	☐	☐	☐	☐
F. Other Cooking Observations (describe in the Comment Section and Temperature Chart below)	☐	☐	☐	☐

COMMENTS:

Cooking Temperatures Recorded During the Data Collection (List all temperatures taken)

FOOD PRODUCT	FINAL COOK TEMP.	*FOOD CODE* CRITICAL LIMIT	CONSUMER ADVISORY		FOOD PRODUCT	FINAL COOK TEMP.	*FOOD CODE* CRITICAL LIMIT	CONSUMER ADVISORY	
			YES	NO				YES	NO
			☐	☐				☐	☐
			☐	☐				☐	☐
			☐	☐				☐	☐
			☐	☐				☐	☐
			☐	☐				☐	☐

SUMMARY COOKING FOOD PRODUCT TEMPERATURE CATEGORIES	NUMBER OF FOOD PRODUCT TEMPERATURES
I. – Number of product temperature measurements **IN** Compliance with *Food Code* critical limits	
II. – Number of **OUT** of Compliance product temperature measurements **1°F - 2°F** below *Food Code* critical limits	
III. – Number of **OUT** of Compliance product temperature measurements **3°F - 4°F** below *Food Code* critical limits	
IV. – Number of **OUT** of Compliance product temperature measurements **5°F - 9°F** below *Food Code* critical limits	
V. – Number of **OUT** of Compliance product temperature measurements **10°F or more** below *Food Code* critical limits	

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

	IN	OUT	NO	NA
10. Cooked foods are reheated to required temperatures	☐	☐	☐	☐
Description of Reheating Temperature OBSERVATIONS	**IN**	**OUT**	**NO**	**NA**
A. TCS Food that is cooked and cooled on premises is rapidly reheated to 165°F (74°C) for 15 seconds for hot holding	☐	☐	☐	☐
B. Commercially-processed ready-to-eat food, reheated to 135°F (57°C) or above **for hot holding**	☐	☐	☐	☐
C. Other Reheating Observations (describe in the Comments Section and Temperature Chart below)	☐	☐		☐

COMMENTS:

Reheating Temperatures Recorded During the Data Collection (List all temperatures taken)

FOOD PRODUCT	FINAL REHEAT TEMP.	*FOOD CODE* CRITICAL LIMIT	FOOD PRODUCT	FINAL REHEAT TEMP.	*FOOD CODE* CRITICAL LIMIT

SUMMARY COOKING FOOD PRODUCT TEMPERATURE CATEGORIES	NUMBER OF FOOD PRODUCT TEMPERATURES
I. – Number of product temperature measurements **IN** Compliance with *Food Code* critical limits	
II. – Number of **OUT** of Compliance product temperature measurements **1°F - 2°F** below *Food Code* critical limits	
III. – Number of **OUT** of Compliance product temperature measurements **3°F - 4°F** below *Food Code* critical limits	
IV. – Number of **OUT** of Compliance product temperature measurements **5°F - 9°F** below *Food Code* critical limits	
V. – Number of **OUT** of Compliance product temperature measurements **10°F or more** below *Food Code* critical limits	

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	COMMENTS:	☐	1	COMMENTS:	☐	1	COMMENTS:
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	
☐	NA		☐	NA		☐	NA	

Other Areas of Interest (Items 11-19)

- **NOTE: This section will be used to develop data items that are not part of the primary research area for Retail Food Risk Factor Study but may provide important information that will assist other food safety initiatives within the agency**

	IN	OUT	NO	NA
11. Handwashing facilities are accessible and properly maintained	☐	☐		
Description of OBSERVATIONS of Handwashing Facilities	**IN**	**OUT**	**NO**	**NA**
A. Handwashing facilities are conveniently located and accessible for employees	☐	☐		
B. Handwashing facilities are supplied with hand cleanser / disposable towels / hand drying devices	☐	☐		
COMMENTS:				

	IN	OUT	NO	NA
12. Employees practice good hygiene	☐	☐		
Description of Good Hygienic Practices OBSERVATIONS	**IN**	**OUT**	**NO**	**NA**
A. Food Employees eat, drink, and use tobacco only in designated areas	☐	☐		
B. Food Employees experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service, or single-use articles	☐	☐		
C. Other (*describe in Comments Section below*)	☐	☐		☐
COMMENTS:				

	IN	OUT	NO	NA
13. Consumers are properly advised of risks of consuming raw or undercooked animal foods	☐	☐		☐
COMMENTS:				

	IN	OUT	NO	NA
14. Time alone is properly used as a public health control	☐	☐	☐	☐
Description of Time as a public health control OBSERVATIONS	**IN**	**OUT**	**NO**	**NA**
A. When time only is used as a public health control for **4 HOURS**, the food establishment follows procedures to serve or discard food as specified in Section 3-501.19 of the *Food Code*	☐	☐	☐	☐
B. When time only is used as a public health control for **6 HOURS**, the food establishment follows procedures to serve or discard food as specified in Section 3-501.19 of the *Food Code*	☐	☐	☐	☐
C. Other (describe in the comments section below)	☐	☐		☐

COMMENTS:

	IN	OUT	NO	NA
15. Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces	☐	☐		
Description of OBSERVATIONS for temperature control	**IN**	**OUT**	**NO**	**NA**
A. Refrigeration / cold holding units have sufficient capacity to maintain TCS Foods at 41ºF (5ºC) or below	☐	☐		
B. Hot holding units have sufficient capacity to maintain TCS Foods at 135ºF (57ºC) or above	☐	☐	☐	☐
C. Refrigeration and hot storage units are equipped with accurate ambient air temperature measuring device	☐	☐		
D. Accurate temperature measuring device, with appropriate probe, is provided and accessible for use to measure internal food temperatures	☐	☐		
E. Accurate temperature measuring devices and/or tests kits provided and accessible for use to measure sanitization rinse temperatures and/or sanitization concentrations	☐	☐		
F. Other (describe in the comments section below)	☐	☐		☐

COMMENTS:

	IN	OUT	NO	NA
16. Special processes are conducted in compliance with issued variance / HACCP Plan, when required	☐	☐	☐	☐
Description of OBSERVATIONS of Specialized Processes	**IN**	**OUT**	**NO**	**NA**
A. Food establishment conducts reduced oxygen packaging without a variance as specified in Section 3-502.12 of the *Food Code*	☐	☐	☐	☐
B. Food establishment performs specialized process in accordance with approved variance and HACCP Plan when required	☐	☐	☐	☐
C. Juice packaged in the food establishment is treated under a HACCP Plan to reduce pathogens or labeled as specified in Section 3-404.11 of the *Food Code*	☐	☐	☐	☐
D. Other (describe in the comments section below)	☐	☐		☐
COMMENTS:				

	IN	OUT	NO	NA
17. Food is received from safe sources	☐	☐		
Description of FOOD SOURCE OBSERVATIONS	**IN**	**OUT**	**NO**	**NA**
A. All food is from regulated food processing plants / No home prepared/canned foods	☐	☐		
B. Shellfish are from NSSP-listed sources. No recreationally caught shellfish are received/sold	☐	☐	☐	☐
C. Food is protected from contamination during transportation/receiving	☐	☐	☐	
D. TCS Food is received at a temperature of 41°F (5°C) or below OR according to Law	☐	☐	☐	
E. Food is safe and unadulterated	☐	☐		
F. Shellstock tags/labels are retained for 90 days and filed in chronological order from the date the container is emptied	☐	☐	☐	☐
G. Written documentation of parasite destruction is maintained for 90 days for fish products	☐	☐	☐	☐
H. Other (*describe in Comments Section below*)	☐	☐		☐
COMMENTS:				

	IN	OUT	NO	NA
18. Toxic materials are identified, used, and stored properly	☐	☐		
Description of Toxic Materials OBSERVATIONS	**IN**	**OUT**	**NO**	**NA**
A. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are properly identified, stored, and used	☐	☐		
B. Other (*describe in the comments section below*)	☐	☐		☐
COMMENTS:				

	IN	OUT	NO	NA
19. Management and food employees are trained in food allergy awareness as it relates to their assigned duties	☐	☐		
Description of Toxic Materials OBSERVATIONS	**IN**	**OUT**	**NO**	**NA**
A. The person in charge accurately describes foods identified as major food allergens and the symptoms associated with major food allergens	☐	☐		
B. Food employees are trained in food allergy awareness as it relates to their assigned duties	☐	☐		
C. Other (describe in the comments section below)	☐	☐		☐
COMMENTS:				

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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For More Information

Additional information on the FDA Report on the Occurrence of Foodborne Illness Risk Factors in Retail Food Stores, 2019 can be accessed at: http://www.fda.gov/retailfoodriskfactorstudy