

STANDARD 1 – REGULATORY FOUNDATION INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

Part III – Compliance and Enforcement

STEP 1 – Review Compliance and Enforcement Administrative Provisions

Part III of the *Standard 1: Self-Assessment Worksheet* contains 12 COMPLIANCE AND ENFORCEMENT categories within a regulatory retail food program. This worksheet is included at the end of these instructions. To meet this element of Standard 1, the jurisdiction’s regulatory requirements must have a corresponding requirement for the *FDA Food Code* sections listed in Items 1 through 12.

In the case of Item 12, pertaining to "Legal Remedies", three *FDA Food Code* sections comprise this COMPLIANCE AND ENFORCEMENT category. A jurisdiction must demonstrate a corresponding regulatory requirement for one of the *FDA Food Code* sections pertaining to criminal, injunctive, or civil penalties. For item 7d, jurisdictions that do not issue variances defaults to a “yes, full intent is met”.

NOTE: *If a jurisdiction adopted the current published edition or one of the two most recent editions of the FDA Food Code by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.*

STEP 2 - Conduct the Self-Assessment for Part III

The self-assessor must compare the jurisdiction’s code, regulation, or ordinance against with the *FDA Food Code* COMPLIANCE AND ENFORCEMENT provisions listed on the SELF-ASSESSMENT worksheets. For each *FDA Food Code* section:

- Record the corresponding jurisdiction requirement; and
- Document his/her determination:
 - If **full intent** of the *FDA Food Code* section is met, place an "X" in the appropriate column.
 - If **partial intent** of the *FDA Food Code* section is met, identify language that is not included with the jurisdiction's requirement. Indicate whether the language is addressed in another jurisdiction statute, ordinance, or regulatory requirement.
 - If **no corresponding regulation exists**, indicate "No Compliance" in the appropriate column and provide any information that may explain why it is not part of the jurisdiction's current requirements.

STEP 3 – Document the Self-Assessment Results for Part III

A summary table is provided at the end of Part III on the *Standard 1: Self-Assessment Worksheet* to document the results of the regulatory foundation SELF-ASSESSMENT for the COMPLIANCE AND ENFORCEMENT *FDA Food Code* provisions. At the bottom of Part III on the *Standard 1: Self-Assessment Worksheet*, record the number of COMPLIANCE AND ENFORCEMENT categories that are met.

To meet the Standard 1, Part III criteria, the jurisdiction must have a “YES” response for all 12 of the listed COMPLIANCE AND ENFORCEMENT categories.

Examples of documents that may be reviewed:

- The jurisdiction’s statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that govern the operation of its food establishments;
- Version of the *FDA Food Code* that was used for the SELF-ASSESSMENT;
- Completed *Standard 1: Self-Assessment Worksheet, Part III – Compliance and Enforcement*; and
- If applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

**STANDARD 1 – REGULATORY FOUNDATION
SELF-ASSESSMENT WORKSHEET**

Part III – *Food Code*: Compliance and Enforcement

<i>FDA Food Code</i> Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	<u>Partial Compliance</u> List what is not covered (Additional sheets can be used for explanations and comments)	<u>NO</u> Compliance with the <i>FDA Food Code</i> section is NOT Met (Indicate the situation)
1a. Hold orders, Embargo, and Destruction of Food 8-901.10 – Conditions Warranting Remedy				
1b. Hold orders, Embargo, and Destruction of Food 8-903.10 – Hold Order, Justifying Conditions and Removal of Food				
1c. Hold orders, Embargo, and Destruction of Food 8-903.30 – Hold Order, Contents				
2a. Permit/License Required; Right to Deny 8-301.11 – Prerequisite for Operation				
2b. Permit/License Required; Right to Deny 8-304.20 – Permits Not Transferable				
3. Plan Review/Pre-operational inspections 8-201.11 – When Plans are Required				
4. Inspection Authority / Right to Access 8-402.20 – Refusal, Notification of Right to Access, and Final Request for Access				
5a. Information Authority; Restriction/Exclusion of Employees 8-501.10 – Obtaining Information: Personal History of Illness, Medical Examination, and Specimen Analysis				

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<i>FDA Food Code Section</i>	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	<u>Partial Compliance</u> List what is not covered (Additional sheets can be used for explanations and comments)	<u>NO</u> Compliance with the <i>FDA Food Code</i> section is NOT Met (Indicate the situation)
5b. Information Authority; Restriction/Exclusion of Employees 8-501.20 – Restriction or Exclusion of Food Employee, or Summary Suspension of Permit				
5c. Information Authority; Restriction/Exclusion of Employees 8-501.30 – Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order				
6. Authority to Require HACCP Plans 8-201.13 – When a HACCP Plan is Required				
7a. Granting of Variances 8-103.10 – Modifications and Waivers				
7b. Granting of Variances 8-103.11 – Documentation of Proposed Variance and Justification				
7c. Granting of Variances 8-103.12 – Conformance with Approved Procedures				
7d. Jurisdiction Does NOT Issue Variances (Variances Prohibited)* Variances Prohibited				
8a. Timely Correction of Critical Violations 8-405.11 – Timely Correction				
8b. Timely Correction of Critical Violations 8-405.20 – Verification and Documentation of Correction				
8c. Timely Correction of Critical Violations 8-406.11 – Time Frame for Correction				

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<i>FDA Food Code Section</i>	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	<u>Partial Compliance</u> List what is not covered (Additional sheets can be used for explanations and comments)	<u>NO</u> Compliance with the <i>FDA Food Code</i> section is NOT Met (Indicate the situation)
9a. Imminent Health Hazard (Summary of Suspension) 8-404.12 – Resumption of Operations				
9b. Imminent Health Hazard (Summary of Suspension) 8-904.10 – Conditions Warranting Action				
10a. License Suspension / Revocation 8-905.10 – Response to Notice of Hearing or Request for Hearing, Basis and Time Frame				
10b. License Suspension / Revocation 8-905.20 - Response to Notice of Hearing or Request for Hearing, Required Form and Contents				
11a. Institution of Proceedings 8-910.10 - Institution of Proceedings				
12a. Criminal Penalties** 8-911.10 - Authorities, Methods, Fines and Sentences				
12b. 8-912.10 - Petitions for Injunction**				
12c. Civil Penalties Provided** 8-913.10 - Petitions, Penalties and Continuing Violations				

NOTE:

1. Meeting the Standard #1 criteria for the “Compliance and Enforcement” component requires a “Yes” for all FDA Food Code Sections listed in Items 1 through 11.
2. *For Item 7d, jurisdictions that do not issue variances defaults to a “yes, full intent is met”.
3. **For Item 12 pertaining to legal remedies, the jurisdiction needs to demonstrate a corresponding regulatory requirement for only one of the sections pertaining to criminal, injunctive, or civil penalties.

STANDARD 1 – REGULATORY FOUNDATION SELF-ASSESSMENT WORKSHEET

Part III – *Food Code*: Compliance and Enforcement Self-Assessment Results

Compliance and Enforcement Category and Description	<u>YES</u> Full Intent is Met	<u>NO</u> Standard Criteria is not Met	Self-Assessor’s General Comments
1. Hold Orders, Embargo, and Destruction of Food			
2. Permit / License Required; Right to Deny			
3. Plan Review / Pre-Operational Inspections			
4. Inspection Authority / Right to Access			
5. Information Authority; Restriction / Exclusion of Employees			
6. Authority to Require HACCP Plans			
7. Granting of Variances / Variances Prohibited			
8. Timely Correction of Critical Violations			
9. Imminent Health Hazard (Summary of Suspension)			
10. License Suspension / Revocation			
11. Institution of Proceedings			
12. Legal Remedies			

Assessment of _____ indicates conformance with _____ out of the 12 Compliance and Enforcement Categories
 (Regulatory Agency) (# Met)