## **Structure of Observations**

**IMPORTANT**: Before documenting preventive controls observations, please ensure: 1) the facility is subject to subparts C and G (e.g. is not a qualified facility, Seafood HACCP/Juice HACCP processor, etc.); 2) you have conducted your own hazard analysis

			quained facility, searood factr/juice factr processor, etc.j; 2) you have conducted your own fazard analysis
1)	Does the facility have a written Food Safety Plan?	No	Use cite 117.126(a)(1) <u>Supporting evidence</u> : • Product description • Lack of conducting a hazard analysis that identifies hazards requiring a preventive control (PC) (include why you think hazards require a PC)
	For each hazard Yes requiring a PC, see Boxes 2-5:		<ul> <li>Lack of conducting a nazard analysis that identifies nazards requiring a preventive control (FC) (include why you think nazards require a FC)</li> <li>Lack of any written PC procedures, including monitoring, corrective actions and corrections, and verification, and a recall plan</li> <li>Lack of records documenting activities performed (or because no activities are performed)</li> <li>Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a public health concern</li> <li>If facility has adequate controls in place, but does not have a written FSP, it might be a discussion item* [no public health concern].</li> <li>No double-dipping! Do not also cite "no hazard analysis", "no adequate written PC programs", "no implemented controls", etc. as standalone cites.</li> </ul>
2)	Did the facility identify the hazard as requiring a preventive control in its hazard analysis?	No	Use cite 117.130(a)(1) <u>Supporting evidence</u> : • Product description • Lack of conducting a hazard analysis, or did not identify a hazard that requires a PC (include why you think hazard requires a PC) • Lack of any/adequate written preventive control procedures, including monitoring, corrective actions and corrections, and verification • Lack of records documenting activities performed (or because no activities are performed)
	Yes		<ul> <li>Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a public health concern</li> <li>If facility has adequate controls in place but misses identifying a hazard requiring a preventive control, this might be a discussion item* [no public health concern].</li> <li>No double-dipping! Do not also cite "no adequate written PC programs", "no implemented controls", etc. as standalone cites.</li> </ul>
3)	Does the facility have a written PC program for the hazard it identified as requiring a PC?	No	Use cite 117.135(a)(1) specific to the PC program [Process, Allergen, Sanitation, Other] or 117.405(a)(1) for Supply-chain <u>Supporting evidence</u> : • Product description • Hazard correctly identified as requiring a PC by the facility at specific step(s) (and why), but there is no written PC program for that hazard • Lack of records documenting activities performed (or because no activities are performed)
	Yes		<ul> <li>Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a <b>public health concern</b></li> <li>If the facility has adequate controls in place, but does not have written PC procedures, this might be a discussion item* [no public health concern].</li> <li>No double-dipping! Do not also cite "no implemented controls", etc. as a standalone cite.</li> </ul>
4)	Is the written PC adequate? [controls the hazard	No	Use cite 117.135(c) specific to the PC program [Process (c)(1), Allergen (c)(2), Sanitation (c)(3), Other (c)(6)] or 117.410(c) for Supply-chain <u>Supporting evidence</u> : • Product description
	and meets regulatory requirements ]		<ul> <li>Hazard correctly identified as requiring a PC by the facility at specific step(s) (and why), there are written procedures, but the procedures are not adequate because: they do not meet regulatory requirements (e.g. missing monitoring, corrective actions and corrections, and verification); or the procedures do not control the hazard (e.g. only using a detergent to sanitize food-contact surfaces; monitoring not done at adequate frequency to ensure hazard is being controlled)</li> </ul>
	Yes		<ul> <li>Records showing that facility is implementing its inadequate procedures and/or lack of records documenting activities performed (or because no activities are performed)</li> <li>Evidence (e.g. in-plant conditions and practices) that the facility is not controlling the hazard and there is a <b>public health concern</b></li> <li>If the facility is controlling the hazard despite having inadequate written PC procedures, this might be a discussion item* [no public health concern].</li> <li>No double-dipping! Do not also cite "no implemented controls", etc. as a standalone cite.</li> </ul>
5)	Is the PC being implemented?	No	Use cite 117.135(a)(1) specific to the PC program [Process, Allergen, Sanitation, Other] or 117.405(a)(1) for Supply-chain <u>Supporting evidence</u> : • Product description
-	Yes	,	<ul> <li>Hazard correctly identified as requiring a PC by the facility at specific step(s) (and why), written procedures are adequate, but procedures are not being implemented</li> <li>Evidence the written procedures are not being implemented based on record review and observation/interview of employees <ul> <li>E.g. Your procedures say [describe procedures]; however, [describe what you see employees do or records show what employees actually did])</li> </ul> </li> </ul>
	٢		NOTES: * Repeat findings that were discussion items in initial inspections may become written observations in subsequent inspections ** If there is no evidence to support a written observation, the observation should not be written!