

1. Has a Hazard Analysis considering each of the following factors been conducted for each of the items supplied to determine if any risks and/or hazards are associated with the listed items?
  - a. Formulation of the food  Yes  No
  - b. Condition, function, design of the establishment and equipment  Yes  No
  - c. Raw materials and other ingredients  Yes  No
  - d. Transportation practices  Yes  No
  - e. Harvesting, manufacturing, processing, and packaging procedures  Yes  No
  - f. Packaging and labeling activities  Yes  No
  - g. Storage and distribution  Yes  No
  - h. Intended or reasonably foreseeable use  Yes  No
  - i. Sanitation, including employee hygiene  Yes  No
2. Were any known or reasonably foreseeable risks and/or hazards identified for each of the items supplied based on this hazard analysis?  Yes  No  Only for \_\_\_\_\_
  - a. If "Yes", please provide the information requested in items A – D for each hazard identified in Appendix One, including the known or reasonably foreseeable hazards associated with each item, classifying each hazard as a Biological (B), Chemical (C) or Physical (P) hazard. Duplicate Appendix One as necessary to address each item supplied and associated hazards identified. Attach additional sheets as necessary.
3. Has an assessment of the probability that the hazard will occur been conducted?  Yes  No
  - a. If "Yes", classify the probability that each identified hazard will occur as "A", "B", "C", or "D" and note where requested in Appendix One (probability classifications defined in note "2" in Appendix One as well as in Appendix Two rubric).
4. Has an assessment of the severity of the illness or injury if the hazard was to occur been conducted?  Yes  No
  - a. If "Yes", classify the severity of each identified hazard as "I", "II", "III", or "IV" and note where requested in Appendix One (probability classifications defined in note "3" in Appendix One as well as in Appendix Two rubric).
5. Record the combined probability and severity code for each identified hazard in the appropriate locations in Appendix One (Example: "I-A").
6. List in the appropriate location in Appendix One any additional controls recommended beyond the prerequisite (cGMP) controls that are in place to reduce or eliminate either the probability that the hazard will occur or the severity of the illness or injury should the hazard occur.
7. What verifications are you proposing for the item supplied to ensure that the controls put in place are appropriate to control the identified hazards (please specify for each hazard identified)?

**FSMA Hazard Analysis  
Appendix One**

<b>Item Supplied:</b>			
Item Hazard Number	1	2	3
Known or Reasonably Foreseeable Hazard Identified			
Hazard Classification (B, C, P) <sup>1</sup>			
Prerequisite programs and/or controls in place that reduce or eliminate the hazard			
Activities which verify that the controls in place are effective at reducing or eliminating the hazard			
Classification of the probability that the hazard will occur in the absence of additional controls <sup>2</sup>			
Classification of the severity should the hazard occur <sup>3</sup>			
Combined probability and severity classification <sup>4</sup>			
Recommended additional controls to reduce the probability of the hazard occurring or the severity of the hazard should it occur			

<sup>1</sup>B=Biological, C=Chemical, and P=Physical




<sup>2</sup>A=Immediate danger that the hazard will occur; B=Probably will occur in time if not corrected; C=Possible to occur in time if not corrected; and D=Unlikely to occur, may assume hazard will not occur.

<sup>3</sup>I=Imminent and immediate danger of death or severe illness. Likely to impact humans and animals; II=Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible human impact; III=Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans; IV=Illness or injury is minor. Possible to impact animals, unlikely to impact humans.

<sup>4</sup>I-A through IV-D from Hazard Evaluation Rubric

**FSMA Hazard Analysis  
Appendix Two  
Hazard Evaluation Rubric**

	Severity	High (I)	Medium (II)	Low (III)	Very Low (IV)
Probability		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
High (A)	Immediate danger that the hazard will occur	I-A	II-A	III-A	IV-A
Medium (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
Low (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
Very Low (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

 Critical: Additional controls required  
 Moderate: Additional controls may be required  
 Negligible: No additional controls necessary

