**Hazard Analysis and Risk-Based Preventive Controls**

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| Proposed § 507. 30--Requirement for a Food Safety Plan  Proposed § 507.30(a) would require that the plan be written as is expressly required by section 418(h).  Proposed § 507.30(b) would specify the food safety plan must be prepared by (or its preparation overseen by) a qualified individual.  Proposed § 507.30(c)(1) through (c)(6) would require that the contents of a written food safety plan include:   * The hazard analysis as required by § 507.33; * The preventive controls as required by § 507.36; * The recall plan as required by § 507.38; * The procedures, and the frequency with which these procedures will be performed, for monitoring the implementation of the preventive controls as required by § 507.39; * The corrective action procedures as required by § 507.42; and * The verification procedures and the frequency with which they will be performed as required by § 507.45. |
| Proposed § 507.33--Hazard Identification  Proposed § 507.33(a) would require that the owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards, for each type of animal food  manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur.  Proposed § 507.33(b) would require that the hazard analysis consider hazards that may occur naturally or may be unintentionally introduced, including:   * Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of animal or human health significance (proposed § 507.33(b)(1)); * Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances (proposed § 507.33(b)(2)); * Physical hazards (proposed § 507.33(b)(3)); and * Radiological hazards (proposed § 507.33(b)(4)).   Proposed § 507.33(c) would require that the hazard analysis contain an evaluation of the hazards identified in § 507.33(b) of this section to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.  Proposed § 507.33(d) would require that, in conducting the hazard evaluation, the qualified individual must consider the effect of the following on the safety of the finished animal food.  Proposed § 507.33(d)(1) would require that the hazard evaluation consider the formulation of the animal food.  Proposed § 507.33(d)(2) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment.  Proposed § 507.33(d)(3) would require that the hazard evaluation consider the effect of raw materials and ingredients on the safety of the finished animal food.  Proposed § 507.33(d)(4) would require that the hazard evaluation consider the effects of transportation practices on the safety of the finished animal food.  Proposed § 507.33(d)(5) would require that the hazard evaluation consider the effects of manufacturing/processing procedures on the safety of finished animal food.  Proposed § 507.33(d)(6) would require that the hazard evaluation consider the effects of packaging activities and labeling activities on the safety of finished animal food.  Proposed § 507.33(d)(7) would require that the hazard evaluation consider the effects of storage and distribution on the safety of finished animal food.  Proposed § 507.33(d)(8) would require that the hazard evaluation consider the intended or reasonably foreseeable use on the safety of finished animal food.  Proposed § 507.33(d)(9) would require that the hazard evaluation consider the effects of sanitation, including employee hygiene, on the safety of finished animal food.  Proposed § 507.33(d)(10) would require that the hazard evaluation consider the effect of any other relevant factors that might potentially affect the safety of the finished animal food. |
| Proposed § 507.36--Preventive Controls for Hazards That are Reasonably Likely to Occur  Proposed § 507.36(a) would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points (CCPs), if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the animal food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act.  Proposed § 507.36(b)--Requirement for Written Preventive Controls for Hazards that are Reasonably Likely to Occur  Proposed § 507.36(c)(1)--Requirement for Parameters Associated with the Control of Hazards That Are Reasonably Likely to Occur  Proposed § 507.36(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the animal food, the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.  Proposed § 507.36(d)(1)--Process Controls  Proposed § 507.36(d)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include process controls that include those procedures, practices, and processes performed on an animal food during  manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur.  Proposed § 507.36(d)(2)--Sanitation Controls  Proposed § 507.36(d)(2)(i)(A) and (B) would establish two requirements for sanitation controls where necessary to significantly minimize or prevent hazards that are reasonably likely to occur.  Proposed § 507.36(d)(2)(ii) would require that the owner, operator, or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures that would be established in proposed § 507.36(d)(2)(i)(A) or (B) or that result in insanitary conditions that could lead to cross-contamination with a hazard.  Proposed § 507.36(d)(2)(iii) would provide that the owner, operator, or agent in charge of a facility is not required to follow the corrective actions that would be established in proposed § 507.42(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with proposed § 507.36(d)(2)(ii), to correct conditions and practices that are not consistent with the procedures in proposed § 507.36(d)(2)(i) (A) or (B).  Proposed § 507.36(d)(3)--Recall Plan  Proposed § 507.36(d)(4)--Other Controls  Proposed § 507.36(e)--Applicability of Monitoring, Corrective Actions, and Verification  Proposed § 507.36(e)(1)(i) through (iii) would specify that, except as provided by proposed § 507.36(e)(2), the preventive controls required under this section would be subject to monitoring as would be required by proposed § 507.39.  Proposed § 507.36(d)(3) would require that preventive controls include, as appropriate, a recall plan as would be required by proposed § 507.38.  Proposed § 507.36(d)(4) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include any other controls necessary to satisfy the requirements of proposed § 507.36(a). |
| Proposed § 507.38--Recall Plan for Animal Food With a Hazard That is Reasonably Likely to Occur  Proposed § 507.38(a) would require that the owner, operator, or agent in charge of a facility establish a written recall plan for animal food with a hazard that is reasonably likely to occur.  Proposed § 507.38(b) would require that the written recall plan include procedures to perform the following actions:   * Directly notify the direct consignees of the product being recalled and how to return or dispose of the affected product (proposed § 507.38(b)(1)); * Notify the public about any hazard presented by the animal food when appropriate to protect animal or human health (proposed § 507.38(b)(2)); * Conduct effectiveness checks to verify that the recall is carried out (proposed § 507.38(b)(3)); and * Appropriately dispose of recalled product, e.g., through destroying the product, reprocessing, or diverting to a use that does not present a safety concern (proposed § 507.38(b)(4)). |
| Proposed § 507.39—Monitoring  Proposed § 507.39(a)--Requirement for written procedures for monitoring.  Proposed § 507.39(b)--Frequency of monitoring. (Required)  Proposed § 507.39(c)--Requirement for records. |
| Proposed § 507.42--Corrective Actions  Proposed § 507.42(a)--Corrective Action Procedures  Proposed § 507.42(b)--Corrective Action in the Event of an Unanticipated Problem  Proposed § 507.42(c)—Documentation |
| Proposed § 507.45—Verification  Proposed § 507.45(a)--Validation that preventive controls are adequate to control the hazard  Proposed § 507.45(a)(2)--Validation based on scientific and technical information  Proposed § 507.45(a)(3)--Preventive controls for which validation is not required  Proposed § 507.45(b)(1)--Verification of Monitoring  Proposed § 507.45(b)(2)--Verification of Corrective Actions  Proposed § 507.45(b)(3)--Implementation and Effectiveness  Proposed § 507.45(b)(4)--Calibration  Proposed § 507.45(c)--Records review  Proposed § 507.45(e)--Reanalysis  Proposed § 507.45(e)(1)(vi)--Reanalysis on the initiative of FDA  Proposed § 507.45(e)(2)--Implementation of additional controls  Proposed § 507.45(e)(3)--Revision of the food safety plan  Proposed § 507.45(e)(4)--Requirement for a qualified individual  Proposed § 507.45(f)--Requirement for Records for Verification |
| Proposed § 507.48--Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Animal Food That is Not Exposed to the Environment  Proposed § 507.48(a) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment conduct certain activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin  production by, microorganisms of animal or human health significance. |
| Proposed § 507.50--Requirements Applicable to a Qualified Individual |
| Proposed § 507.55--Records Keeping |

**Withdrawal of an Exemption Applicable to a Qualified Facility**

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| Proposed § 507.60--Circumstances That May Lead FDA to Withdraw an Exemption Applicable to a Qualified Facility  Proposed § 507.62--Issuance of an Order to Withdraw an Exemption Applicable to a Qualified Facility  Proposed § 507.65--Contents of an Order to Withdraw an Exemption Applicable to aQualified Facility  Proposed § 507.67--Compliance With, or Appeal of, an Order to Withdraw an Exemption Applicable to a Qualified Facility  Proposed § 507.69--Procedure for Submitting an Appeal  Proposed § 507.71--Procedure for Requesting an Informal Hearing  Proposed § 507.73--Requirements Applicable to an Informal Hearing  Proposed § 507.75--Presiding Officer for an Appeal and for an Informal Hearing  Proposed § 507.77--Timeframe for Issuing a Decision on an Appeal  Proposed § 507.80--Revocation of an Order to Withdraw an Exemption Applicable to a Qualified Facility  Proposed § 507.84--Final Agency Action |

**Requirements Applying to Records That Must Be Established and Maintained**

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| Proposed § 507.100--Records Subject to the Requirements of this Subpart F  Proposed § 507.102--General Requirements Applying to Records  Proposed § 507.106--Additional Requirements Applying to the Food Safety Plan  Proposed § 507.108--Requirements for Record Retention |