



**CERTIFICATION
INSTRUCTION**

D-CI-01.01

ISSUE: 3/2013-03-18

Page 1 of 2

CERTIFICATION INSTRUCTION NUMBER	CI-19-01
ISSUED BY	Emmanouil Geneiatakis Issue date: 2019-03-04
TYPE OF INSTRUCTION	<input type="checkbox"/> Immediate Implementation <input type="checkbox"/> Information <input type="checkbox"/> Interpretation <input type="checkbox"/> FAMI-QS Awareness
APPLICABLE FOR	<input checked="" type="checkbox"/> Certification Bodies <input checked="" type="checkbox"/> Feed Business Operators <input checked="" type="checkbox"/> Accreditation Bodies <input type="checkbox"/> Authorised Training Organisations Starting date:
PURPOSE	Provision of FSMA PCAF Addendum to FAM-QS V 6.0
SUBJECT	

CERTIFICATION INSTRUCTION	<p>The aim of the addendum is to assist FAMI-QS certified feed business operators to understand the prescriptive elements within the FSMA Preventive Controls for Animal Food that are not explicitly covered in the FAMI-QS Code Version 6.0.</p> <p>Certification Bodies may offer provision of audits against the FSMA Preventive Controls for Animal Food with the use of FSMA PCAF Addendum to FAM-QS V 6.0.</p> <p>In order for the FSMA Preventive Controls Preparedness Module to be included within the audit program, additional time will be needed for the audit. The amount of additional time will depend on several factors, primarily the organization, knowledge and preparedness of the facility personnel. The Certification Body shall indicate the expected additional time requirements at the time of planning the audit.</p> <p>The Certification Body may offer the addendum in combination with a scheduled FAMI-QS audit or independently.</p> <p>During the process of auditing the following regulatory requirements shall be reviewed :</p> <ul style="list-style-type: none">• Bovine Spongiform Encephalopathy• Veterinary Feed Directive• Food Safety Modernization Act Preventative Controls for Animal Food (507: CGMPs, Hazard Analysis and Risk Based Preventive Controls for Animal Food)• Food Facility Registration• Recalls• FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals <p>In addition, the following regulatory requirements shall be taken into account:</p>
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ISSUE: 3/2013-03-18

Page 2 of 2

- 509: Unavoidable contaminants in animal food and food-packaging material
- 556: Tolerances for residues of new animal drugs in food
- 570: Animal Food additives
- 573: Food additives permitted in feed and drinking water of animals
- 579: Irradiation in the production, processing, and handling of animal feed and pet feed
- 582: Animal Substances generally recognized as safe
- 584: Food substances affirmed as generally recognized as safe in feed and drinking water of animals
- 589: Substances prohibited from use in animal food or feed

These regulatory requirements can be found:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

Additional information on FSMA:

<https://www.fda.gov/food/guidanceregulation/fsma/>

**Auditors
Requirements**

For the provision of an audit against the FSMA PCAF Addendum to FAM-QS V 6.0 it is required from the auditors to have attended a FDA Approved Training on the Food Safety Modernization Act - Preventive Controls for Animal Food. The training module shall be the one developed by Food Safety Preventive Controls Alliance (FSPCA).

Certification Bodies shall notify the qualified auditors for FSMA PCAF Addendum FAM-QS V 6.0 to FAMI-QS Secretariat at audit@fami-qs.org