

	<b>Certification Instruction</b>	D-CI-01.01
		ISSUE: 2019-11-28
		Page 1 of 4

<b>CI NUMBER</b>	CI-22-02
<b>ISSUED BY</b>	Giacomo Sisinni, FAMI-QS Scheme Manager 2022-12-29
<b>APPROVED BY</b>	Emmanouil Geneiatakis, FAMI-QS Secretary General 2022-12-29
<b>CONTACT PERSON FOR CLARIFICATION</b>	Giacomo Sisinni <a href="mailto:gsi@fami-qs.org">gsi@fami-qs.org</a>
<b>TYPE OF INSTRUCTION</b>	<input checked="" type="checkbox"/> Immediate Implementation <input type="checkbox"/> Information <input type="checkbox"/> Interpretation <input type="checkbox"/> FAMI-QS Awareness
<b>APPLICABLE FOR</b>	<input checked="" type="checkbox"/> Certification Bodies  <input checked="" type="checkbox"/> Feed Business Operators (EU and non-EU) placing on the EU Market Vitamins obtained from animal origin and gelatine-coated Vitamins and Pigments.  <input checked="" type="checkbox"/> Accreditation Bodies  <input checked="" type="checkbox"/> Authorised Training Organizations: update with regard to the compliance with the regulatory requirements. This case can be used as an example.  <b>Starting date: asap</b>
<b>SUBJECT</b>	Placing Vitamins obtained from animal origin and gelatine-coated Vitamins and Pigments on the EU Market
<b>PURPOSE</b>	<p>To inform the FAMI-QS Certified Organizations about the condition for placing on the market:</p> <ul style="list-style-type: none"> <li>• Vitamins from animal origin (i.e., A, D3, Vitamin AD3-mixture)</li> <li>• Gelatine-coated Vitamins (i.e., Vitamin A, Vitamin D3, Vitamin AD3-mixture)</li> <li>• Gelatine-coated Pigments (i.e., Canthaxanthin, Ethyl ester of <math>\beta</math>-apo-8'-carotenoid acid, Astaxanthin, Citranaxanthin)</li> </ul> <p>Note: The same product categories are treated differently for other grades such as Food or Pharma. This is not to be used as an argument for deviation from the applicable regulatory requirements for these product groups.</p>

**Certification  
Instruction**

Vitamins obtained from animal origin, classified as rendered fats, and gelatine-coated Vitamins and Pigments fall under the regulations relating to the placing on the EU market of products containing animal by-products not intended for human consumption.

For non-EU Feed Business Operators:

Ingredients/Products consisting of or containing animal by-products or derived products can be imported in the EU only if the below conditions are met:

- The country of origin shall be an authorised third country
- The ingredient/product is coming from an organization registered or approved in the TRACES NT
- The shipment is accompanied by a health certificate

All non-EU FAMI-QS Feed Business Organizations placing on the EU market Vitamins obtained from animal origin, gelatine-coated Vitamins and Pigments produced in third countries shall be registered and approved in the Traces NT <https://webgate.ec.europa.eu/tracesnt/login>.

The product shall be accompanied by a health certificate:

<b>Product Group</b>	<b>Type of Certificate</b>
Containing Gelatine	Certificate for Gelatine as per the Certificate set out in Annex XV Chapter 11 of Reg.142/2011.
Containing rendered fats	Health Certificate for imports of rendered fats, as per the Certificate set out in Annex XV Chapter 10(A) of Reg.142/2011.
Containing Gelatine and rendered fats	For gelatine-coated Vitamins, two (2) Health Certificates: Certificate 1 for Gelatine (as per the Certificate set out in Annex XV Chapter 11 of Reg.142/2011) and Certificate 2 for Vitamin (A, D3, AD3-mixture)) (Certificate for imports of rendered fats, as per the Certificate set out in Annex XV Chapter 10(A) of Reg.142/2011).

For EU Feed Business Operators:

Ingredients/Products consisting of or containing animal by-products or derived products produced in the EU may be placed on the EU market if the below conditions are met:

- The ingredient/product is produced by an establishment approved or registered as ABP processing plant as appropriate
- The consignment is accompanied by a commercial document.

EU FAMI-QS Feed Business Organizations placing on the EU market EU-produced Vitamins obtained from animal origin, gelatine-coated Vitamins and Pigments shall be registered/approved in the Traces NT <https://webgate.ec.europa.eu/tracesnt/login>.

Consignments shall be accompanied by a commercial document in accordance with the model set out in Annex VIII Chapter III, under point 6 of Reg. (EU) 142/2011

FAMI-QS Certified Organizations shall:

- Update any information with regard to §8.2. Determination of requirements for products
- Review all current documentation and make the necessary changes
- EU-based FAMI-QS feed business organizations that import or produce gelatine-coated Vitamins, Pigments and Vitamin D3 shall ensure that they have provided all the necessary information to their supplier. This shall be part of the contract or purchase order.
- Non-EU FAMI-QS certified producers and traders of gelatine-coated Vitamins, Pigments and Vitamin D3 shall ensure that their customers include these requirements on their purchase order. In case it does not, the purchase order shall be rejected and sent back to their client for an update.

FAMI-QS Process Documents (HACCP Plan): A review of the HACCP plan is required in order to ensure that any hazards relating to animal by-products for ingredients like gelatine, lanolin, cholesterol (dehydrocholesterol) are included. Minutes of the HACCP team meeting(s) shall be maintained.

**Certification Bodies** of FAMI-QS Certified Organizations who place gelatine-coated Vitamins, Pigments and Vitamin D3 on the EU market shall ensure that during the next FAMI-QS audit, they will design a focus area

	<p>specifically for this topic and review the actions as described in the instruction.</p> <p>Certification Bodies shall ensure that all auditors receive and understand the current Certification Instruction.</p>
<b>References</b>	<p>Reg. (EC) 1069/2009 on animal by-products: <a href="http://data.europa.eu/eli/reg/2009/1069/2019-12-14">http://data.europa.eu/eli/reg/2009/1069/2019-12-14</a></p> <p>Reg. (EU) 142/2011 on import of animal by-products <a href="http://data.europa.eu/eli/reg/2011/142/2022-04-17">http://data.europa.eu/eli/reg/2011/142/2022-04-17</a></p> <p>Reg. EU) 2017/625 on official controls <a href="http://data.europa.eu/eli/reg/2017/625/2022-01-28">http://data.europa.eu/eli/reg/2017/625/2022-01-28</a></p>