

# FAMI-QS Process Document Bioprocess | New version published

The FAMI-QS Secretariat is pleased to announce the publication of the revised Process Document for Bioprocess. The document can be found at: [https://fami-qs.org/PD-01\\_Bioprocess\\_V3.pdf](https://fami-qs.org/PD-01_Bioprocess_V3.pdf)

For the past 2 years, quality and regulatory experts have worked extensively to put in place a robust document which will further support the production and trade of specialty feed ingredients coming from bioprocess.

Following the RASFF (notification) in 2019 (2019.3216-unauthorised genetically modified bacteria (*Bacillus subtilis*) in vitamin B2), the FAMI-QS Secretariat initiated a systematic review of the FAMI-QS Bioprocess. Given that the FAMI-QS Certification plays an important role in the global trade of specialty feed ingredients coming from bioprocess, the review of the Process Document Bioprocess was necessary with a view to identifying any missing points and building further trust in the global feed value chain.

The FAMI-QS Process Document Bioprocess includes, apart from the implementation of the HACCP System, an additional set of requirements which can be used as input to the FAMI-QS Vulnerability Assessment with regard to the regulatory requirements. Furthermore, the definitions and HACCP System have been adapted to reflect the latest changes in the HACCP, following the 2020 revision of the

## The importance of the FAMI-QS Process Documents:

With the launch of the FAMI-QS Certification Version 6.0, among the main changes was also the adaptation of our scope for global implementation. The driving force for this adaptation was the fact that the same ingredient/mixture has a different regulatory classification depending on the country of destination. This approach may also create confusion in the industry with regard to the risks/hazards that need to be managed depending on the classification of the feed additive or feed ingredient.

To overcome this, we focused on the common denominator which is the production process. This allows for a better management of the risks/hazards.

In this context we have developed, with the support of the industry, the well-known Process Documents, an add-on document with a dedicated HACCP plan for each process covered under the FAMI-QS

*CODEX General Principles of Food Hygiene CXC 1-1969.*

To reinforce further the transparency, and support the feed purchasing process in identifying the regulatory status of the product and the eligible markets for products coming from bioprocess, a certification instruction which requires the listing of the microorganism and strain number was issued in 2019. In addition, with the listing of the microorganism and strain number, we minimize the occurrence of feed fraud issues.

This additional control measure (listing of the microorganism and strain number) was possible due to the new approach to the FAMI-QS scope with the publication of the complete list of single ingredients of the FAMI-QS Certified Feed Business Organization's certificate. The certification instruction can be found at: [https://fami-qs.org/Certification%20Instructions/CI-19-04\\_Bioprocess\\_public\\_list.pdf](https://fami-qs.org/Certification%20Instructions/CI-19-04_Bioprocess_public_list.pdf)

A self-study guide to support the industry and the auditors to further understand the changes in the document will be available to all our members and Certification Bodies by the end of September 2021. The guide will be provided free of charge.

In addition, a feedback mechanism will be set up in order to ensure that any questions or clarifications will be addressed adequately.

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Certification. The quality and safety of feed for animals intended for human consumption have a direct impact on the quality and safety of the food manufactured from these animals. Primary goal of the implementation of HACCP System under FAMI-QS is to identify, evaluate, and controls hazards which will not cause harm to animals and/or lead to contamination (Feed Safety Concept).

The process documents serve a triple purpose:

1. To support the FAMI-QS Feed Business Organisation in developing their HACCP System
2. To facilitate the training and approval of the FAMI-QS auditors with a view to providing a robust and competent audit
3. To allow FAMI-QS Certification to react proactively and more efficiently in the event of emerging risks/hazards.

## FAMI-QS Feed Fraud Prevention and Defence Module

In 2018, FAMI-QS carried out the challenging task to incorporate the requirements for Feed Fraud Prevention and Defence under its third-party certification system by creating an additional mandatory add-on module for the FAMI-QS Certification System Version 6.

The goal of the Feed Fraud Prevention and Defence module is to ensure that FAMI-QS Certified Feed Business Operators will implement an auditable system that demonstrates their ability to manage and effectively mitigate the risk of feed fraud and terrorism, and comply with §4.6 *Quality and Safety*.

With the incorporation of the FAMI-QS Feed Fraud Prevention and Defence requirements, FAMI-QS will be the first Scheme to officially introduce Fraud and Defence as an object of conformity and not just as a requirement. As an object of conformity, feed fraud will be shown on the certificate.

The complete module consists of the following elements:

### FAMI-QS Feed Fraud and Defence Module

The document contains two types of text:

- **Requirements:** These are mandatory measures that the FAMI-QS Feed Business Operator shall comply with.
- **Guidance:** The guidance section, following the requirements, includes background information, additional explanations and methods to support operators in implementing the requirements.

### FAMI-QS Feed Fraud and Defence Templates

For the development of the FAMI-QS Feed Fraud Prevention and Defence system, specific templates were created that the FAMI-QS Certified Feed Business Operators shall use. The use of the FAMI-QS templates is **mandatory**. The templates will guide you through the process for developing your vulnerability and threat assessments and can support integrated management systems of feed and food. Furthermore, with the use of the templates, we will achieve a harmonised auditing approach at global level.

For organisations that have already developed their own templates or have already a Fraud Prevention and Defence System in place, they can continue using their current templates; in this case, however, they have to make sure that all the FAMI-QS requirements are included therein. The templates will be redesigned to allow a more user-friendly navigation and structure. Previous versions will remain valid. The updated templates are expected to be circulated by end of June 2021.

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### FAMI-QS Feed Fraud and Defence Audit Guidance

Over the past year, the FAMI-QS Secretariat worked hand in hand with our Authorised Certification Bodies to develop the competence of our the FAMI-QS Authorised Auditors and define an effective audit approach. The status of the document is still in draft form. Conduction of the first audits against the module will offer us a better insight on what actually can or cannot be checked by the auditor compared to what is described in the audit guidance.

All documents are available at: <https://fami-qs.org/feed-fraud-prevention-and-defence-module.html>

#### Scope

The Feed Fraud Prevention and Defence module requires operators seeking certification to FAMI-QS to apply the scope as defined for the FAMI-QS 6.0 Certification. The Certification Body should place particular focus on the specific requirements on defining the scope for feed fraud prevention and defence as defined in sections 6.1.2. and 7.1.2 of the Feed Fraud Prevention and Defence module. Due to the nature of the topic, the FAMI-QS Certified Organisation shall review the suitability of their current assessment on an annual basis in the framework of their actions for continuous improvement. The annual review does not indicate that an update of assessments is required.

#### Audit Duration

For the initial assessment of the implementation of the FAMI-QS Feed Fraud Prevention and Defence Module, the Certification Body shall allocate (as a minimum) 0.5 man-days as an add-on to the auditing time already allocated. For the subsequent surveillance audits, the necessary additional audit time will be defined by the Certification Body.

#### Compliance dates

All current FAMI-QS Certified Organisations shall complete the implementation of the module by the **1<sup>st</sup> of September 2022**. As from the 2<sup>nd</sup> of September 2022, all audits shall include the audit of the FAMI-QS Feed Fraud and Defence Module in their audit plan.

## Fake Certificates Issued by non-Authorised Certification Bodies

Over the past months, we have been confronted with a new "experience", this of fake FAMI-QS certificates issued by non-authorised Certification Bodies. The circulation of fake certificates could be also linked to the circulation of non-compliant specialty feed ingredients and/or mixtures. These notifications are available at: <https://fami-qs.org/communication-notifications.html>.

Based on our understanding, there are no real Certification Bodies behind this, just an address in a business centre that supposedly provides the FAMI-QS Certification Services at an extremely low price. This information reaches our desk when organisations relying on the FAMI-QS Certification check our database and cannot find the certificate.

As always, we encourage all stakeholders relying on the FAMI-QS Certification to check the validity of the certificate in our list of FAMI-QS Certified Feed Businesses at: <https://www.fami-qs.org/certified-companies-6-0.html>

The list with the current FAMI-QS Authorised Certification Bodies can be found at <https://www.fami-qs.org/certification-bodies-6-0.html>. Only these Certification Bodies are approved for issuing a FAMI-QS Certificate.

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## Consultancy Services for the FAMI-QS Certification

The FAMI-QS Secretariat has been identifying on a regular basis a number of organisations on the Internet which provide consultation services for the implementation of FAMI-QS services.

We would like to highlight the fact that FAMI-QS has no direct communication with any consultancy organisations. When selecting your partner to implement the FAMI-QS Code, it is important that you verify the consultancy organisation's competence in understanding the FAMI-QS Certification System.

## New Certification Bodies for the FAMI-QS Scheme

The FAMI-QS Secretariat is pleased to welcome IFC Global and WCS Certification Services to the FAMI-QS System.



IFC Global  
Adalet Mahallesi 2132/2 Sokak  
No:3 Daire:45 Bayraklı İzmir Turkey  
[info@ifcglobal.de](mailto:info@ifcglobal.de)



WCS Certification Services (M) Sdn Bhd  
B-5-8, Plaza Mont Kiara, Mont Kiara  
50480 Kuala Lumpur Malaysia  
[amie.wsm@gmail.com](mailto:amie.wsm@gmail.com)

## Communication with the FAMI-QS Secretariat

Topic	Email Address
General Enquiries, Trainings, Events (Ms. Danai Konti, Mr. Alexandre Catudal)	<a href="mailto:fffs_info@fami-qs.org">fffs_info@fami-qs.org</a>
Application Forms and Approval Letters (Mr. Giacomo Sisinni)	<a href="mailto:fffs_apply@fami-qs.org">fffs_apply@fami-qs.org</a>
Accounting (Ms. Danai Konti)	<a href="mailto:accountingfffs@fami-qs.org">accountingfffs@fami-qs.org</a>
International Cooperation and Mutual Recognition (Mr. Emmanouil Geneiatakis)	<a href="mailto:fffs@fami-qs.org">fffs@fami-qs.org</a>
Missing Certificates on the Website and Certificates' Validity (Ms. Sofia Poucha)	<a href="mailto:audit@fami-qs.org">audit@fami-qs.org</a>
Members and Stakeholders support for Asia Pacific (Ms. Wendy Yap)	<a href="mailto:wya@fami-qs.org">wya@fami-qs.org</a>
Feed Safety Incidents, Crisis Management	<a href="mailto:notification@fami-qs.org">notification@fami-qs.org</a>

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## EU Feed Legislation

Commission Implementing Regulation (EU) 2021/329 of 24 February 2021 concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase for chickens for fattening (holder of the authorisation: AVEVE NV), and repealing Regulation (EC) No 1091/2009

[http://data.europa.eu/eli/reg\\_impl/2021/329/oj](http://data.europa.eu/eli/reg_impl/2021/329/oj)

Commission Implementing Regulation (EU) 2021/330 of 24 February 2021 concerning the authorisation of a preparation of 3-phytase produced by Komagataella phaffii CECT 13094 as a feed additive for pigs for fattening, minor porcine species, turkeys for fattening and reared for breeding (holder of authorisation: Fertinagro Biotech S.L.)

[http://data.europa.eu/eli/reg\\_impl/2021/330/oj](http://data.europa.eu/eli/reg_impl/2021/330/oj)

Commission Implementing Regulation (EU) 2021/343 of 25 February 2021 concerning the authorisation of a preparation of Lactobacillus buchneri DSM 29026 as a feed additive for all animal species

[http://data.europa.eu/eli/reg\\_impl/2021/343/oj](http://data.europa.eu/eli/reg_impl/2021/343/oj)

Commission Implementing Regulation (EU) 2021/344 of 25 February 2021 concerning the authorisation of sorbitan monolaurate as a feed additive for all animal species

[http://data.europa.eu/eli/reg\\_impl/2021/344/oj](http://data.europa.eu/eli/reg_impl/2021/344/oj)

Commission Implementing Regulation (EU) 2021/346 of 25 February 2021 concerning the authorisation of a preparation of Lactobacillus parafarraginis DSM 32962 as a feed additive for all animal species

[http://data.europa.eu/eli/reg\\_impl/2021/346/oj](http://data.europa.eu/eli/reg_impl/2021/346/oj)

Commission Implementing Regulation (EU) 2021/363 of 26 February 2021 concerning the authorisation of a preparation of fumonisin esterase produced by Komagataella phaffii DSM 32159 as a feed additive for all animal species

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/363/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/363/oj)

Commission Implementing Regulation (EU) 2021/367 of 1 March 2021 concerning the renewal of the authorisation of a preparation of Saccharomyces cerevisiae CNCM I-4407 as a feed additive for calves for rearing and repealing Regulation (EU) No 883/2010 (holder of authorisation S.I. Lesaffre)

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/367/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/367/oj)

Commission Implementing Regulation (EU) 2021/412 of 8 March 2021 amending Implementing Regulation (EU) 2017/962 as regards the review of the suspension of the authorisation of ethoxyquin as a feed additive

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/412/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/412/oj)

Commission Implementing Regulation (EU) 2021/420 of 9 March 2021 correcting Implementing Regulation (EU) 2020/1097 concerning the authorisation of lutein-rich and lutein/zeaxanthin extracts from Tagetes erecta as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/420/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/420/oj)

Commission Implementing Regulation (EU) 2021/421 of 9 March 2021 concerning the authorisation of tincture derived from Artemisia vulgaris L. (mugwort tincture) as a feed additive for all animal species

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/421/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/421/oj)

Commission Implementing Regulation (EU) 2021/422 of 9 March 2021 concerning the authorisation of a preparation of Enterococcus faecium DSM 7134 as a feed additive for laying hens (holder of authorisation: Lactosan GmbH & Co KG)

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/422/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/422/oj)

Commission Implementing Regulation (EU) 2021/426 of 10 March 2021 correcting Implementing Regulation (EU) No 1263/2011 as regards the authorisation of Lactococcus lactis (NCIMB 30160) as a feed additive for all animal species

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/426/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/426/oj)

Commission Implementing Regulation (EU) 2021/485 of 22 March 2021 concerning the authorisation as feed additives of ginger essential oil from Zingiber officinale Roscoe for all animal species, ginger oleoresin from Zingiber officinale Roscoe for chickens for fattening, laying hens, turkeys for fattening, piglets, pigs for fattening, sows, dairy cows, veal calves (milk replacers), cattle for fattening, sheep, goats, horses, rabbits, fish and pets and ginger tincture from Zingiber officinale Roscoe for horses and dogs

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/485/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/485/oj)

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Commission Implementing Regulation (EU) 2021/505 of 23 March 2021 concerning the denial of authorisation of phosphoric acid 60 % on silica carrier as a feed additive belonging to the functional group of preservatives

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/505/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/505/oj)

Commission Implementing Regulation (EU) 2021/506 of 23 March 2021 concerning the authorisation of methanethiol as a feed additive for all animal species

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/506/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/506/oj)

Commission Implementing Regulation (EU) 2021/507 of 23 March 2021 concerning the renewal of the authorisation of pyridoxine hydrochloride (vitamin B6) as a feed additive for all animal species and repealing Implementing Regulation (EU) No 515/2011

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/507/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/507/oj)

Commission Implementing Regulation (EU) 2021/508 of 23 March 2021 concerning the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for weaned piglets and repealing Regulation (EU) No 170/2011 (holder of authorisation: Prosol S.p.A.)

[https://eur-lex.europa.eu/eli/reg\\_impl/2021/508/oj](https://eur-lex.europa.eu/eli/reg_impl/2021/508/oj)

## OUR VISION

Excellence and Trust in Specialty Feed Ingredients

## OUR MISSION

We set the worldwide leading accredited scheme for the feed industry contributing to safe food. We facilitate trade, driven by uncompromised focus on risk management, safety and quality. With our collective experience, knowledge, and expertise, we proactively respond to the emerging challenges for specialty feed ingredients and their mixtures.

### About FAMI-QS

FAMI-QS is a preeminent quality and feed safety management system for the sector of specialty feed ingredients and their mixtures. We are the worldwide leading accredited scheme for the feed industry contributing to safe food. Accreditation is an important pillar for the credibility of our scheme. It gives assurance to governments, supply chains and consumers that organisations providing FAMI-QS certification have the required competence and impartiality to do so. FAMI-QS is operating under IAF MLA <https://www.iaf.nu/articles/Scopes/16>.

The FAMI-QS Certification System proactively responds to the emerging feed-related challenges in our sector. The FAMI-QS Certification Scheme addresses safety, quality and address the challenging topics of integrity (fraud), defence and regulatory compliance. The system is specifically designed for global implementation.

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