Newsletter Issue 20
July 2020

Public Consultation on PD-01 Bioprocess

In 2019, FAMI-QS carried out a systematic review of the Process Document Bioprocess (PD-Bioprocess). The systematic review of the PD-Bioprocess was triggered by the latest regulatory developments in the European Union, at that time, in regard to the authorisation of ingredients obtained from bioprocessing.

Following extensive discussions and an exchange of collective experience, knowledge, and expertise at global level among the members of the Task Force (TF) Bioprocess, the PF Bioprocess was revised in order to respond to and address the emerging challenges relating to bioprocess. The collective work of the TF Bioprocess is presented in the below document. On behalf of FAMI-QS, we would like to thank all the members of the TF for their commitment and support.

Objective of the revision

To address all the known hazards/risks relating to bioprocess and manage these hazards/risks under the current methodology of HACCP. The management of these risks and the content of the preventive or control measures may differ from region to region, taking also into consideration the different regulatory/statutory background. In line with the FAMI-QS Requirements, hazards/risks shall be treated always based on the regulatory/statutory requirements where the FAMI-QS Certified Organisation is located and the regulatory/statutory requirements of the country of destination.

The document **PD-01 Bioprocess Version 3** is available at: https://fami-qs.org/public-consultation.html

The consultation for the Process Document Bioprocess will remain open until **2020-09-30**. We invite you to share with us your comments on the document by using this template.

For the submission of the comments please use the relevant form favailable on our website and submit it to the following email address: revision@fami-qs.org

Feel free to share this information with colleagues or any other partners in the feed chain.

Comments evaluation

Once the consultation period has concluded, the FAMI-QS Secretariat will compile the comments received in one document. Following an initial review of the comments by the FAMI-QS Secretariat, the TF Bioprocess will assess the content and provide feedback on each comment. Once this process has been completed, the comments with the responses provided by the TF will be made available on the FAMI-QS Website for a period of two (2) months. In the event that there will be comments that may have a significant impact on the document, the document will be submitted for a short comment period of thirty (30) days.

In this issue:

FAMI-QS Management of Extraordinary Events: Covid-19 Updated Policy

Current Valid Version 5.1 Certificates

The surveillance audit can be skipped in order to schedule the recertification audit under V6.0. The transition period will end on **2020-10-01. No extension will be granted. On 2020-10-02 the version 5.1 list of certified organisations will be no longer available on our website.**

Surveillance Audits under Version 6.0

Option 1: Postponement of the surveillance audit for three months. If it's not possible for the audit to be conducted after three months, then the certificate shall be suspended for the following three months. After that period, the certificate shall be withdrawn.

Option 2: The surveillance audit can be conducted remotely on the due date. Pre-requisite: the initial or recertification audit must have been conducted on-site. If not, then Option 1 applies.

Note: The combination of the two options is not possible. The Feed Business Operator shall choose one of the two options.

Recertification Audits (certificate validity will not be extended)

Option 1: In the event that a FAMI-QS Certified Feed Business Operator based in one of the affected areas is in process of recertification (certificate approaching its expiration date), the certificate validity will not be extended.

However, for these audits, Certification Bodies can apply only a Stage 2 Audit for when the audit will be scheduled (after the expiry of the certificate).

Option 2 (measure applicable until 2020-10-30): Certification Bodies can issue a certificate valid for three years based on the review of the audit findings from the remote audit and the previous experience with the organisation. The Certification Body shall have a minimum of three years' experience with the organisation in any standard. Auditing time shall be equal to recertification.

After 2020-10-30, the audits will be designed based on the proposal of the "Revamping the Audit Process" project. More information on this will be made available through our next newsletter.

Initial Certification

For initial FAMI-QS audits (newcomers), even if the Certification Body has experience with the feed organisation for three years on other standards, a **combination of a remote and an on-site audit** shall apply. A remote audit can only support the initial audit process and cannot replace the initial audit in its entirety. The remote audit shall be a tool to support the audit planning.

For initial FAMI-QS audits (newcomers): A full remote audit can be accepted only for those feed organisations with no physical handling of the product (brokers).

In the event that you will face any issues with your Certification Body, please submit your case at fffs@fami-qs.og, to the attention of Mr. Emmanouil Geneiatakis.

FAMI-QS Supported Events

Beyond 2020 – Feeding the Future Conference by PIX/AMC 11.04-13.04.2021, Gold Coast, Australia
https://www.pixamc.com.au/

Feedinfo Summit 2021 by Feedinfo, 28.04-29.04.2021, Geneva, Switzerland
https://summit.feedinfo.com/content-feedinfo-summit/

7th International FEED Conference by Ages 23.06.-24.06.2021, Vienna, Austria
https://feed2021.ages.at/home/

EU Feed Legislation

Commission Implementing Regulation (EU) 2020/378 of 5 March 2020 concerning the authorisation of L-leucine as a feed additive for all animal species
https://eur-lex.europa.eu/eli/reg_impl/2020/378/oj

Commission Implementing Regulation (EU) 2020/377 of 5 March 2020 concerning the authorisation of sodium selenate as a feed additive for ruminants
https://eur-lex.europa.eu/eli/reg_impl/2020/377/oj

Commission Implementing Regulation (EU) 2020/376 of 5 March 2020 concerning the authorisation of Norbixin (annatto F) as a feed additive for cats and dogs
https://eur-lex.europa.eu/eli/reg_impl/2020/376/oj

Commission Implementing Regulation (EU) 2020/997 of 9 July 2020 concerning the authorisation of L-lysine base, liquid, L-lysine sulphate and L-lysine monohydrochloride, technically pure, as feed additives for all animal species
http://data.europa.eu/eli/reg_impl/2020/997/oj

Commission Implementing Regulation (EU) 2020/1033 of 15 July 2020 concerning the renewal of the authorisation of L-arginine produced by Corynebacterium glutamicum ATCC 13870 and the authorisation of L-arginine produced by Corynebacterium glutamicum KCCM 80182 as feed additives for all animal species, and repealing Regulation (EC) No 1139/2007
http://data.europa.eu/eli/reg_impl/2020/1033/oj