

REGULATORY COMPLIANCE FOR PLACING ON THE MARKET FEED ADDITIVES UNDER FAMI-QS CERTIFICATION



"...only ingredients/substances which are listed in the Feed Additive Register and meet the authorisation requirements (e.g. specified production strain) are allowed to be placed on the EU market."

We would like to bring to the attention of our **FAMI-QS** certified feed business operators the fact that, for the scope of Feed additives, only ingredients/substances which are listed in the Feed Additive Register and meet the authorisation requirements (e.g. specified production strain) are allowed to be placed on the EU market.

According to the requirements of the **FAMI-QS** Code of Practice:

7.1.1. Determination of requirements related to the product

7.1.2. Compliance of the product to the requirements

7.4.1. Sourcing of incoming materials,

FAMI-QS certified feed business operators shall ensure that the product meets the regulatory requirements of the country of destination. Please note that the situation is evolving on a very regular basis due to the ongoing re-authorisation process of all feed additives, so **FAMI-QS** certified feed business operators must be attentive to changes. Failure to comply with these requirements is considered as a critical non-conformity and leads to the immediate suspension of the certificate.

Special attention shall be given to products that are produced by fermentation process. **FAMI-QS** certified feed business operators

also need to ensure that the strain that is used is the same as the one defined by the authorisation process. More detailed information on the next article "*Fermentation Products: what's to come*".

We invite all **FAMI-QS** feed business operators that place their products on the EU market to increase their attention on the authorisation requirements, as they are outlined in the EU Feed Additive Register. Feed additives that do not meet the authorisation requirements are considered to be illegal.



FERMENTATION PRODUCTS: WHAT'S TO COME



Continuing the previous topic, on 5th September 2014 an “alert” (information for follow-up) on Vitamin B2 was posted on the RASFF portal further to a notification from Germany (industry’s own check). This notification concerned the detection of unauthorised Genetically Modified *Bacillus subtilis* strain in a consignment imported from China. While this case is essentially a problem of non-compliance with Regulation (EC) 1829/2003 on GM food and feed in particular, it bears in background an important issue on EU market access for additives produced by fermentation.

During the September meeting of the Standing Committee on Animal Nutrition, the European Commission has drawn Member States’ attention to another issue: a batch of L-Lysine sulphate imported from China was confirmed to have been produced with *Escherichia coli*, while only *Corynebacterium glutamicum* is authorised for the production of L-Lysine sulphate in Europe. This is a clear breach of the Feed Additive Regulation (EC) No. 1831/2003 and, to a certain extent, of the Feed Hygiene Regulation (EC) No. 1831/2005.

In the first case, the problem with the production strain is latent (the authorisation of Vitamin B2 does not include yet provisions on the production strain, but this will be the case once the re-authorisation of this additive will

be finalised), while it is established in the second case.

This demonstrates the emergence of a new attention by the Commission and the control authorities regarding the identity the feed additives as described in the authorisations. It is anticipated that this situation will amplify.

THE ANALYSIS AND CONSEQUENCES

The evaluation of the safety of the production strain is an integral part of the EFSA assessment on the safety of feed additives produced by fermentation, and conclusions in EFSA opinions are restricted to the strains that are described in the application.





"...we remind our members to check in due time if their source(s) of additives produced by fermentation are involved in the re-authorisation process. "

Several authorisations granted under the Feed Additives Regulation are already mentioning the production strain(s) for fermentation additives, disregarding the fact that the strain is genetically modified or not. So far, such authorisations mainly concerned holder-specific authorisations and a few 'non-holder-specific' additives.

After the reauthorisation process, the link of the active substance to the producing strain will become the rule for all additives produced by fermentation. This concerns important products in the amino acid, vitamin and organic acid groups. This is a fundamental change since all the sources of a given fermentation additive that do not fulfil the authorisation, i.e. that are produced with a strain not referenced in the authorisation, will be illegal on the EU market.

Besides the official control, it is also important to bear in mind that - under the Feed Hygiene Regulation - it is a responsibility for both the supplier and the user of a feed to make sure that it fulfils the legal requirements. It will then be the responsibility of each producer/ importer/ user to secure the fact that the given additive was produced with an authorised strain. Operators could follow that up with a simple traceability document - including the production strain(s) - as the vast majority of the strains used in fermentation processes are proprietary and identified through a culture collection number.

Hence, we remind our members to check in due time if their source(s) of additives produced by fermentation are involved in the re-authorisation process. This can be done through direct questioning of the suppliers/ supply chain, but also by checking in the EFSA database of applications under the Feed Additives Regulation which strain have been notified (this information is often included in the public summary).



CONSULTANCY SERVICES FOR THE FAMI-QS CERTIFICATION



The **FAMI-QS** secretariat has identified a number of organisations on the Internet, which provide consultation services for the implementation of **FAMI-QS** services.

We would like to draw your attention on 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 Code, the EU Feed Safety concept and the EU regulatory framework.

FAMI-QS BECOMES AN ASSOCIATED MEMBER OF THE INTERNATIONAL ACCREDITATION FORUM

On 12 April 2014, **FAMI-QS** officially became an associated member of the International Accreditation Forum (IAF). The latter is the world association of Conformity Assessment Accreditation Bodies, as well as of other bodies that are interested in conformity assessment, in the fields of management systems, products, services, personnel and other similar conformity assessment programmes. Its primary function is to develop a single worldwide conformity assessment programme, which reduces risk for business and its customers by assuring them that accredited certificates may be relied upon. Accreditation assures users of the competence and impartiality of the accredited body.

FAMI-QS is committed to supporting the IAF's activities and actively contributes to it. **"We are committed to promote accreditation activities. We believe that accreditation is the best way in which mutual recognition arrangements can be achieved, among the sector specific certification programmes."** - stated by our Secretary General, Dr. Didier Jans.

In this context, the IAF has an important role to play.

FAMI-QS is also among the first sector specific schemes to have applied for a formal evaluation at

European Level. Over the past few years, the European cooperation for the Accreditation (EA) has worked very intensively, both to revise its current procedures for assessing sector specific schemes and to reinforce harmonization and consistency among their members.



IAF/ILAC Joint General Assembly and Signing Ceremony, Vancouver 16 Oct 2014.

From the left: Mr. Randy Dougherty- IAF Chairman, Mr. Emmanuel Geneiatakis - FAMI-QS Quality Manager.

EUROPEAN COMMISSION CORNER

Feed additives Authorisations

Nutritional additives

Vitamins, provitamins and chemically well-defined substances having similar effect:

[Commission Implementing Regulation \(EU\) No 1249/2014 of 21 November 2014 concerning the authorisation of inositol as a feed additive for fish and crustaceans](#)
(OJ L 335, 2014-11-22)

Compounds of trace elements:

[Commission Implementing Regulation \(EU\) No 1230/2014 of 17 November 2014 concerning the authorisation of copper bilysinate as a feed additive for all animal species](#)
(OJ L 331, 2014-11-18)

Amino acids, their salts and analogues:

[Commission Implementing Regulation \(EU\) No 1236/2014 of 18 November 2014 concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* \(DSM 25202\) as a feed additive for all animal species](#)
(OJ L 332, 2014-11-19)

Import controls

[Commission Implementing Regulation \(EU\) No 1295/2014 of 4 December 2014 amending Annex I to Regulation \(EC\) No 669/2009 implementing Regulation \(EC\) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin](#)
(OJ L 349, 2014-12-05)

Protection measures

[Commission Implementing Regulation \(EU\) No 1306/2014 of 8 December 2014 amending Implementing Regulation \(EU\) No 750/2014 by extending the period of application of the protection measures in relation to porcine epidemic diarrhoea](#)
(OJ L 351, 2014-12-09)





2015

FAMI_{QS}

As the Holiday Season is upon us, we find ourselves reflecting on the past year and on those who have supported us. We value our relationship with all our Members and Partners and look forward to working with you in the year to come.

FAMI-QS wishes you a Happy Holiday Season and a New Year filled with Peace and Prosperity!

About FAMI-QS

FAMI-QS Asbl is the management and coordination center for the FAMI-QS code of practice. It is the only certifiable code specifically aimed at Specialty Feed Ingredients and Their Mixtures (feed additives, functional feed ingredients, premixtures, specialty complementary feed, specialty complementary dietetic feed) for animal nutrition. The code addresses safety, quality and regulatory compliance in order to minimize the risk that unsafe specialty feed ingredients enter the food and feed chain. It offers independent certification for all operators placing these products on the market. Based on partnership with international certification bodies and third countries institutional partners, it includes more than 850 certified sites spread across more than 52 countries. The current FAMI-QS President is Mrs. Bernadette Okeke, Lallemand.

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