Welcome!

We are pleased to bring you the third edition of the FAMI-QS Newsletter.

With the year coming to an end, the FAMI-QS team wanted to take this opportunity to thank all our Members and Partners for their support. We’ve really enjoyed working with you and look forward to continuing to do so in 2014.

With 2014 on the horizon, it’s a great time to continue our support and to inform you on the latest developments.

Specially, FAMI-QS places the highest priority on the safety of feed and health of animals.

We wish you a Merry Christmas and Happy New Year!
FAMI-QS Team.

Latest News

Undesirable Substances in Animal Feed (EU)

With more and more globalisation, the Operator’s supply chain has become extensive and complex. FAMI-QS certified companies need to follow robust safety validated procedures. Safe product is the highest priority of FAMI-QS and every Operator’s quality and safety management system(s).

Undesirable substances are substances which can endanger animal health or because of their presence in livestock products, human health or the environment. Their presence can’t be eliminated fully but they may be present in products intended for animal feed only in accordance with the conditions laid down in the Directive 2002/32/EC on undesirable substances in animal feed and may not be used in any other way for the purposes of animal feed.

Goal of the directive

The aim of EU legislation on undesirable substances in animal nutrition is to ensure that feed materials, feed additives and feedingstuffs are put into circulation only if they are sound, genuine and of merchantable quality and, when correctly used, do not represent any danger to human health, animal health or the environment or do not adversely affect livestock production.

Directive (2002/32/EC) is intended to control undesirable substances which can occur naturally in feedingstuffs, such as heavy metals, dioxins, toxic weed seeds, mycotoxins, etc. Since it is impossible to eliminate most of these substances from feedingstuffs, maximum permitted levels are fixed at a level which should prevent adverse effects on animal or consumer health.
Scope
The scope of Directive 2002/32/EC covers feed materials, feed additives, premixtures, compound feed, complete feed, compound feedingstuffs, complete feedingstuffs and complementary feedingstuffs. The Directive applies to all feeds fed to all animals, including pets and animals in the wild.

This Directive includes maximum limits for heavy metals such as arsenic, lead, mercury and cadmium as well as for dioxin, aflatoxin, certain pesticides, and botanical impurities in certain feed materials, feed additives and feedingstuffs. Maximum levels are not set for all the substances in feed additives and premixtures. A general principle of food law (EC 178/2002) is that feed and food operators have the primary responsibility for feed and food safety. In case of absence of maximum levels, it is the responsibility of the company to establish the internal control level to guarantee the compliance when the product is used in animal feed.

What is an undesirable substance?
"Undesirable substances" in EU legislation on animal nutrition means any substance or product, with the exception of pathogenic agents, present in and/or on the product intended for animal feed which presents a potential danger to human health, animal health or the environment or adversely affects livestock production.

How to use the Directive 2002/32?
The maximum levels of undesirable substances are set down in Annex I of the directive 2002/32. Annex II set down the action thresholds where investigations shall be carried out to identify the sources of undesirable substance when the maximum levels are exceeded. Until now, the directive has been amended 17 times since 2003. The consolidated version (including all amendments) shall be used as reference.
One of the most important aspect is the prohibition of the dilution of contaminated products intended for animal feed. For example, if the melamine contained in a feed material or additive exceeds the maximum level defined in annex I, it is not allowed to be diluted or mixed with other products and used in the animal feed.

If the limit is exceeded...
Where a feedingstuff contains an undesirable substance in excess of the maximum permitted level, it must be removed from the feed chain.

The Directive also introduces a provision designed to reduce or eliminate certain sources of contamination. When the background level for an undesirable substance is exceeded Member States are required to investigate the cause of the contamination and take appropriate action. In order to ensure a harmonized approach between Member States, provision is made in the Directive for the fixing of Action Thresholds in certain cases.

Regulation (EC) No 178/2002 establishes general principles and requirements of food/feed law. It contains general provisions for traceability, risk analysis, and precautionary principle. This regulation gives legal effect to Rapid Alert System for Food and Feed (RASFF). RASFF notifications shown in the RASFF portal represent new cases reported on a health risk detected in one or more consignments of a food or feed. Information on substance/hazard, product category, analytical result, country of origin and countries to which the product is distributed is reported in RASFF notifications, which is a tool for EU control authorities coordination.
What's more?

More generally, FAMI-QS would like to stress the fact that the EU legislation on animal nutrition:
- banned the use and market of antibiotics (growth promoters) as feed additive since January 2006 (Art. 11 of Regulation (EC) N° 1831/2003),
- established maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (Council Regulation EEC 2377/90 with all amendments) which can have impacts on the feed industry,
- laid down a Community procedure for the undesirable substances (EC 2002/32 with all amendments),
- established a list of materials whose circulation or use for animal nutrition purposes is prohibited (Commission Decision 2004/217/EC).

The Key Obligations of Food and Feed Business Operators (FBOs)

Safety

FBOs shall not place on the market unsafe food or feed

Responsibility

FBOs are responsible for the safety of the food and feed which they produce, transport, store or sell

Traceability

FBOs shall be able to rapidly identify any supplier or consignee

Transparency

FBOs shall immediately inform the competent authorities if they have reason to believe that their food or feed is not safe

Emergency

FBOs shall immediately withdraw food or feed from the market if they have reason to believe that it is not safe

Prevention

FBOs shall identify and regularly review the critical points in their processes and ensure that controls are applied at these points.

Cooperation

FBOs shall cooperate with the competent authorities in actions taken to reduce risks.

These obligations derive from the EU food safety legislation. They are further detailed in the guidance document on the implementation of the main General Food Law requirements.
For more information, see:
http://ec.europa.eu/food/food/foodlaw/guidance/index_en.htm

Document of the "Key Obligations" available in different languages on:
http://ec.europa.eu/food/food/foodlaw/responsibilites/index_en.htm
(from European Commission - Health & Consumer Protection Directorate-General)
EXTRACT FROM FAMI-QS RULES FOR OPERATORS

2.1 - Evaluation procedure of the application

2.1.1 - Feed Additives

For the approval of the application for feed additives, it is required that the ingredient is listed on the European Union Register of Feed Additives. As feed additives can be considered only those that are included under the European Feed Additives Register.

The current version of the register can be found under:

2.1.2 - Functional Feed Ingredients

Following the Operator’s application for Functional Feed Ingredients, FAMI-QS Process Manager will send a Product Classification questionnaire (D-SCD-01-01) to be filled in by the Operator.

Process manager FAMI-QS will test the received questionnaire with the FEFANA Classification Tool. http://www.fefana.org/ClassTool/

To get an application’s approval, the result of the classification tool shall be “Functional Feed Ingredients”. Any other result will lead to the rejection of the application.

2.1.3 - Premixtures

For the approval of Premixtures, Regulation EC 1831/2003 applies. Premixture means “mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals”. As feed additives can be considered only those that are included under the European Feed Additives Register (see section 2.1.1)

2.1.4 - Specialty Complementary Feed & Specialty Complementary Dietetic Feed

FAMI-QS will maintain a list with the approved Specialty Complementary (Dietetic) Feeds.

The status of these products will be individually assessed using the information from the Operator covering:

a. Composition (mg / kg or % for each component)
b. Functionality, use
c. Species (s) animal (s)
d. How is the product delivered? in water or in the feed?
e. Dosage in the total ration of “complete feed”
f. Do you have a risk assessment for this type of product? yes or no.

The company shall provide an excel file and attach documentation which can facilitate the evaluation (e.g. product data sheet, labels, MSDS). Any communication between Operator and FAMI-QS is strictly confidential.

Key points to obtain your approval letter

1. Clearly define your scope. see Scope Description Document.
2. Know Your Products: it is important to have an updated list of ingredients.
3. Send the application form with all sections filled in ONLY to apply@fami-qs.org
4. Ask your approval letter on time and not during the audit.
5. Validity of the approval letter is for 3 years.
6. Avoid many revisions of your approval letter. It should be once each 3 years or maximum once a year before the audit.
7. When to ask an approval letter: initial certification - scope extension - New site - Recertification see the certification instruction CI-13-06
8. Check and read documents available on our website - see 10 steps toward FAMI-QS certification documents.
FAMI-QS Certification: The Values

Nowadays, International Trade occurs in a rather complex legal and business environment. As far as the sector of Specialty Feed Ingredients and their Mixtures is concerned, Third Party Certification (TPC) is becoming an important tool, for supporting market access at a global level. This is particularly true of FAMI-QS.

When operating on such a large (global) scale, a Conformity Assessment Scheme is required, in order to respect the rules of international trade. Given that compliance with the International Accreditation Standards and the respect of the WTO/TBT agreement have become a must, both elements have been integrated in FAMI-QS, this precursor scheme’s structure.

Besides its market value, a credible Third Party Certification could also be a useful tool for the competent authorities, e.g. to plan official controls, or to “grant” market access, either to products or to operators. Although Third Party Certification is not meant to substitute the competent authorities’ responsibilities, a number of them increasingly recognise it as an important element, which not only supports their enforcement role, but can also help to set state-of-the-art practices at a global level and, as such, facilitate understanding and exchanges, also on an international level.

On the 29th January 2007, the Standing Committee on the Food Chain and Animal Health formally adopted FAMI-QS, the Community Guide to Good Practice for Feed Additive and Premixture Operators. In this way, the competent authorities recognised FAMI-QS as a suitable reference, for implementing the Feed Hygiene Regulation’s ambitious requirements.

The FAMI-QS system’s implementation supports feed business operators’ upgrade, by improving their production process, as well as their products’ quality and safety. A FAMI-QS audit doesn’t only focus on the final product’s safety but rather, it ensures that the entire process is a controlled one. The management system approach ensures that the final product will constantly meet both the regulatory and the customer’s requirements. Given that FAMI-QS auditors regularly undergo training, they are in a position to provide feed business operators with an audit that has real added value, rather than with a mere compliance one.

The above-mentioned elements constitute the basic pillars for creditable Third Party Certification, and FAMI-QS is taking all the necessary steps to maintain the highest level of confidence in it.
CAUTION: USE OF FAKE FAMI-QS CERTIFICATES OR LOGO

We ask all FAMI-QS Operators and Partners to remain alert and always consult the FAMI-QS database of certified companies on our website (http://www.fami-qs.org/certifiedcompanies). Only FAMI-QS certified companies are listed in our certified companies database (and if they are not listed, they are not certified).

All FAMI-QS Members and Partners must report to FAMI-QS any unlawful use of FAMI-QS designations and/or collective logo by third parties.

This announcement is made in accordance with the provisions laid down in section 4.3 “FAMI-QS logo” and section12 "Exclusions on certificates" of FAMI-QS Rules of Certification Bodies AND also sections 12 "Transparency" and 15 on the "use of the logo" of FAMI-QS Rules for the Operators.

The FAMI-QS name and logo may only be used by operators that have obtained certification from a certification body recognised by FAMI-QS Asbl. The right to use the FAMI-QS logo and/or name is exclusively granted by FAMI-QS Asbl, and can be withdrawn at any moment in the event of non-compliance with certification requirements or when the certificate is expired.

Furthermore, let us advise you to always consult the FAMI-QS certified companies database if you have any doubt about a company’s FAMI-QS certification.

FAMI-QS will celebrate its 10 years anniversary in 2014!

FAMI-QS will celebrate its 10 Year Anniversary with a public event on 5th of may 2014. During the past 10 years, FAMI-QS has experienced year-on-year growth. We have listened to our members and our Industry sector and delivered groundbreaking advancements in ensuring your products meet the requirements of the 21st century. The launch of this event is just the start of a new chapter in our history that you will see develop over the coming months ahead.

“We are very proud of the journey we have undertaken over the last 10 years. We have experienced many high points, have met wonderful people, and have supported our members for an unparalleled experience. The next 10 years will see greater enhancements and expansion of our global presence.”

FAMI-QS team.
THINGS YOU MIGHT’VE MISSED!

- New FAMI-QS code version 5.1 ➤ coming soon
- FAMI-QS and GMP+ International move ahead with a Memorandum of Understanding ➤ Link
- Public consultation on F50 project launched! ➤ Link
- Launch of FAMI-QS Awareness training in 2014! ➤ Limited places! if you are interested, PLEASE CONTACT US QUICKLY.

CHECK OUT OUR LATEST "NEWS" ON THE OFFICIAL FAMI-QS WEBSITE! ➤ Link

EUROPEAN COMMISSION CORNER

Here is the link pointing to the latest version of the Community Register of Feed Additives pursuant to Reg. (EC) 1831/2003 and released on 2013-12-16 (Appendices 3 and 4, Annex: List of additives - Rev. 177):

Community Register of Feed Additives [Rev. 177]

From now on, the Annex II will be in a separate file due to the increasing number of pages:

Direct link to new separate file for Annex II

Feed additives

- Commission Implementing Regulation (EU) No 1113/2013 of 7 November 2013 concerning the authorisation of preparations of Lactobacillus plantarum NCIMB 40027, Lactobacillus buchneri DSM 22501, Lactobacillus buchneri NCIMB 40788/CNCM I-4323, Lactobacillus buchneri LN 40177/ATCC PTA-6138, and Lactobacillus buchneri LN 4637/ATCC PTA-2494 as feed additives for all animal species (OJ L 298, 2013-11-08)


Other European news

FVO --- reports made available here.
RASFF --- alerts made available here.
**Other International news**

- **FDA Food Safety Modernization Act (FSMA)** --- FDA has extended the comment period on several proposed rules.

  - Foreign Supplier Verification Programs (FSVPs) ➤ January 27, 2014
  - Accreditation of Third-Party Auditors/Certification Bodies ➤ January 27, 2014
  - Preventive Controls for Animal Food ➤ February 26, 2014

- **Canadian Food Inspection Agency** --- Consultations on Proposed Regulatory and Policy Changes

  - Feed Ingredient Assessment and Authorization - Regulatory Framework Proposal ➤ December 20, 2013
  - Feed Labelling - Regulatory Framework Proposal ➤ December 20, 2013

**SPECIAL THANKS TO**

Xuelei Wang, FAMI-QS Expert (Adisseo)

for her contribution.

**Would you like to know more about FAMI-QS? Would you like to bring a topic to our attention? Would you like to participate?**

**Please contact us for more information. Our team will be pleased to help you.**

**For more information, please contact the editor:**

Laetitia Cirilli, PhD
FAMI-QS Process & Communication Manager
Avenue Louise 130 A – BOX 1
1050 Brussels – Belgium
Tel.: + 32 2 639 66 69
Fax: + 32 2 640 41 11
E-mail us at: [laetitia@fami-qs.org](mailto:laetitia@fami-qs.org)