Regulatory Developments in USA

The FDA Food Safety Modernization Act (FSMA) aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

Both FAMI-QS and FSMA rule share a common philosophy of a “Risk based and system based approach” and the overarching policy requirement for staff and management commitment to food safety. All the applicable requirements were incorporated into our latest FAMI-QS Code Version 6.

In order to support its members to comply with the Food Safety Modernization Act (FSMA) and with the Current Good Manufacturing Practices (CGMP) for animal food, FAMI-QS prepared – in cooperation with our partner in the US – a GAP Analysis against the FAMI-QS Code version 5.1 and the Food Safety Modernization Act rule on Current Good Manufacturing Practices and Preventive Controls for Animal Food (cGMP PCAF). Soon, FAMI-QS will launch a full FSMA package, including the benchmark against Version 6 as well.

HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

According to FDA, a Food Safety Plan (FSP) consists of the primary documents in a preventive controls food safety system that provides a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne illness or injury. It contains a collection of written documents that describes activities that ensure the safety of food during manufacturing, processing, packing, and holding.

A “preventive controls qualified individual” (PCQI) must develop the FSP. A PCQI is a person with the education, training, or experience to develop and apply a food safety system. A PCQI can be qualified through job experience or by completing training equivalent to the standardized curriculum recognized as adequate by FDA.
DIFFERENCES BETWEEN A HACCP PLAN AND A FOOD SAFETY PLAN

Hazard Analysis and Critical Control Points (HACCP) is a preventive food safety strategy that is a systematic approach to the identification and assessment of the risk of hazards from a particular food or food production process or practice and the control of those hazards that are reasonably likely to occur.

The preventive controls approach to controlling hazards used in an FSP incorporates the use of risk-based HACCP principles in its development. Although an FSP and a HACCP plan are similar, they are not identical. Table 1 compares what is required for the elements of each type of plan.

<table>
<thead>
<tr>
<th>ELEMENT</th>
<th>HACCP PLAN</th>
<th>DIFFERENT IN FOOD SAFETY PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Analysis</td>
<td>Biological, chemical, physical hazards</td>
<td>Chemical hazards include radiological hazards, consideration of economically motivated adulteration</td>
</tr>
<tr>
<td>Preventive Controls</td>
<td>CCPs for processes</td>
<td>Process CCPs + controls at other points that are not CCPs</td>
</tr>
<tr>
<td>Parameters and values</td>
<td>Critical limits at CCPs</td>
<td>Parameters and minimum/maximum values (equivalent to critical limits for process controls)</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Required for CCPs</td>
<td>Required as appropriate for preventive controls</td>
</tr>
<tr>
<td>Corrective actions and Corrections</td>
<td>Corrective actions</td>
<td>Corrective actions or corrections as appropriate</td>
</tr>
<tr>
<td>Verification (including validation)</td>
<td>For process controls</td>
<td>Verification as appropriate for all preventive controls; validation for process controls; supplier verification required when supplier controls a hazard</td>
</tr>
<tr>
<td>Records</td>
<td>For process controls</td>
<td>As appropriate for all preventive controls</td>
</tr>
<tr>
<td>Recall plan</td>
<td>Not required in the plan</td>
<td>Required when a hazard requiring a preventive control is identified</td>
</tr>
</tbody>
</table>

For more information on this topic, please consult the publicly available document: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry.

Call for Experts: Working Group Process Documents

FAMI-QS recently launched a call for interest for the participation of experts on the Working Group Process Documents. This group will be responsible for the review of the FAMI-QS Process Documents and will be divided into the following Task Force (TF) Groups: TF Bioprocess, TF Chemical, TF Extraction, TF Formulation, TF Mining and TF Mixing.

The Process Documents are provided as add-ons to the FAMI-QS Code. These are auditable documents, established in line with Codex Alimentarius (including HACCP programme) principles, for each process described in the Scope. The Process Documents are meant to check for specific risks per process and to provide information on how to deal with particular issues in a more detailed and practical way.

The Process Documents will have their own dynamics and will be adapted according to the needs of the industry, which will vary. Participation on the Working Group Process Documents will be on a voluntary basis, therefore commitment of organisations and individuals is vital.

There are no geographical restrictions for the participation in the Task Forces. Each individual may choose more than one TF to participate and contribute. The only prerequisite for the participation in the TF is the proven experience on the selected topic related to the TF.
Each TF will be convened by a member of the industry and co-convened by a FAMI-QS manager.

Any interested party wanting to join the Working Group Process Documents shall express its interest by filling the following online questionnaire https://pt.surveymonkey.com/r/22XXFLF. We will then contact you for the next steps.

Top 10 FAMI-QS non-conformities in 2017

Each year, FAMI-QS collects data and information from certification audits. In 2017, over 1200 sites in 51 countries were assessed and analysed to identify key findings together with trends and developments. The purpose of this analysis is to provide an overview of findings, allowing operators to benchmark sector performance on a global scale.

Across the sites assessed, consistent patterns of non-conformities emerged. The most dominant non-conformities were concerned with the following requirements:

- §7.4: Handling of Incoming Materials (18%);
- §7.5: Production of finished goods (14%);
- §6.3: Infrastructure (10%).

The above percentage figures are based on the totality of non-conformities. Starting off with §7.4: Handling of Incoming Materials, the most frequent non-conformity was the incomplete supplier evaluation review. This was followed by non-complaint limits for undesirable substances and missing inspection records at raw material receipt.

As for §7.5: Production of finished goods, missing working instructions, inconsistent parameters in production records and lack of traceability emerged as the top 3 non-conformities. Last but not least, auditors commonly reported faulty doors, damaged windows, cracked walls and ceiling during the site tour – requirements applicable to §6.3: Infrastructure.

We went a step further and analysed the ranking of FAMI-QS Code sections by comparing the number of non-conformities logged in 2017 in relation to 2015. All registered data was taken into consideration for the purpose of this study. §7.4 Handling of incoming materials and §7.5 Production of finished goods retained the top spots in the list. We saw a significant increase in number of non-conformities with respect to §6.3 Infrastructure, which jumped from 6th place to 3rd place in the ranking. Another notable increase can be observed with respect to §6.5 Cleaning moving up from 8th place to 5th place. On the other hand, we saw a drop in the number of non-conformities in relation to requirements linked to §6.4 Maintenance and control of monitoring and measuring device and §6.6 Pest Control.

<table>
<thead>
<tr>
<th>FAMI-QS CODE SECTION</th>
<th>RANK 2017</th>
<th>RANK 2015</th>
<th>CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.4 Handling of incoming materials</td>
<td>1</td>
<td>2</td>
<td>▲</td>
</tr>
<tr>
<td>7.5 Production of finished goods</td>
<td>2</td>
<td>1</td>
<td>▲</td>
</tr>
<tr>
<td>6.3 Infrastructure</td>
<td>3</td>
<td>6</td>
<td>▲</td>
</tr>
<tr>
<td>7.2 HACCP programme</td>
<td>4</td>
<td>3</td>
<td>▲</td>
</tr>
<tr>
<td>6.5 Cleaning</td>
<td>5</td>
<td>8</td>
<td>▲</td>
</tr>
<tr>
<td>6.6 Pest control</td>
<td>6</td>
<td>4</td>
<td>▲</td>
</tr>
<tr>
<td>6.2 Human resources</td>
<td>7</td>
<td>7</td>
<td>▲</td>
</tr>
<tr>
<td>6.4 Maintenance and control of monitoring and measuring devices</td>
<td>8</td>
<td>5</td>
<td>▲</td>
</tr>
<tr>
<td>4.3 General documentation requirements</td>
<td>9</td>
<td>9</td>
<td>▲</td>
</tr>
<tr>
<td>8.2 Internal audits</td>
<td>10</td>
<td>11</td>
<td>▲</td>
</tr>
</tbody>
</table>

The trend and development of non-conformities described here will continue to inform future policies and practices, enhancing the already rigorous safety regime which FAMI-QS promotes. In the near future, FAMI-QS is committed to analyse and monitor regional performance in further depth. Our aim is to pinpoint areas of strength and weakness, identify challenges and suggest next steps to ensure the highest quality and safety standards in our sector.
# FAMI-QS Certification Bodies

The presently acknowledged Certification Bodies and their contact agents are listed below.

<table>
<thead>
<tr>
<th>Certification Bodies</th>
<th>Contact Person</th>
<th>Phone Numbers and Email Addresses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BUREAU VERITAS CERTIFICATION</strong></td>
<td>Jean-Christophe LEVESCOT</td>
<td>+33 (0) 1 41 97 58 41 <a href="mailto:jean-christophe.levescot@fr.bureauveritas.com">jean-christophe.levescot@fr.bureauveritas.com</a></td>
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<td></td>
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<td>+33 (0) 4 75 61 13 04 <a href="mailto:elodie.gouvernel@fr.bureauveritas.com">elodie.gouvernel@fr.bureauveritas.com</a></td>
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<td>+39 0 4453 130 11 <a href="mailto:g.battistella@csqa.it">g.battistella@csqa.it</a></td>
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<td>+39 02 86968602 <a href="mailto:i.dadda@certiquality.it">i.dadda@certiquality.it</a></td>
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</tr>
<tr>
<td>Organization</td>
<td>Address</td>
<td>Contact Information</td>
</tr>
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<td>------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>HSL CERTIFICATION SERVICE</td>
<td>Room 408, No.55, Nongzhan North Road, Chaoyang District, Beijing 100125 - China</td>
<td>Hou XIANGYU +86 (0) 10 5919 5185 <a href="mailto:housy@hslcs.org.cn">housy@hslcs.org.cn</a>, Dong XIAOLING <a href="mailto:info@hslcs.org.cn">info@hslcs.org.cn</a></td>
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<td>KIWA PAI</td>
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</tr>
<tr>
<td>LRQA NEDERLAND</td>
<td>PO Box 701, 3000 AS Rotterdam - The Netherlands</td>
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<tr>
<td>SGS</td>
<td>SGS Nederland B.V., Malledijk 18, P.O. Box 200, NL-3200 AE Spijkenisse</td>
<td>Erik Verweij +31 (0) 181 69 32 97 <a href="mailto:erik.verweij@sgs.com">erik.verweij@sgs.com</a></td>
</tr>
<tr>
<td>SGS</td>
<td>Bernstrasse 103, 3052 Zollikofen - Switzerland</td>
<td>Christine PRIDAL +41 58 710 34 09 <a href="mailto:christine.pridal@sqs.ch">christine.pridal@sqs.ch</a>, Karin SCHULZE <a href="mailto:karin.schulze@sqs.ch">karin.schulze@sqs.ch</a></td>
</tr>
<tr>
<td>SWISS CERT PVT. LTD</td>
<td>412, Best Sky Tower, Netaji Subhash Place, Pitampura, Delhi - 110 034 - India</td>
<td>Pramod GUPTA +91 11 41539720 <a href="mailto:info@swissoindia.com">info@swissoindia.com</a></td>
</tr>
<tr>
<td>TÜV NORD CERT GMBH</td>
<td>Geschäftstelle Hannover, Am TÜV 1, 30519 Hannover, Germany</td>
<td>Elke BRAUTLECHT +49 511/ 9986 2516 <a href="mailto:ebrautlecht@tuev-nord.de">ebrautlecht@tuev-nord.de</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LOCAL OFFICES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INDIA - TÜV NORD India Pvt Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>801, Raheja Plaza – 1, L.B.S Marg, Ghatkopar (W) Mumbai 400086, India</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+91 (22) 66477099</td>
</tr>
</tbody>
</table>
Certification Bodies willing to be licensed to perform FAMI-QS audits, please fill in the application form for CBs and send it by e-mail to ffs@fami qs.org. We will contact you and inform you on the steps to be followed afterwards.

FAMI-QS Accreditation Bodies

The FAMI-QS Certification Scheme has been endorsed as an IAF MLA sub-scope under the Main Scope of Management Systems Certification – ISO/IEC 17021-1 and the Level 4 Sub-scope – ISO/TC 22003. The following Accreditation Bodies are providing FAMI-QS Accreditation Services:

COFRAC – COMITÉ FRANÇAIS POUR L’ACCREDITATION

52, rue Jacques Hillairet, 75012 PARIS France
https://www.cofrac.fr/
European Commission Corner

FEED WITHDRAWAL REGULATION

To check the Commission Implementing Regulation (EU) 2017/1145 of 8 June 2017 on the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives, please click here.

FEED ADDITIVES AUTHORISATIONS

• Commission Implementing Regulation (EU) 2018/250 of 15 February 2018 concerning the authorisation of methyl 2-furoate, bis-(2-methyl-3-furyl) disulfide, furfural, furfuryl alcohol, 2-furanmethanethiol, 5-furfuryl acetothioate, difurfuryl disulfide, methyl furfuryl sulfide, 2-methylfuran-3-thiol, methyl furfuryl disulfide, methyl 2-methyl-3-furfuryl disulfide and furfuryl acetate as feed additives for all animal species – OJ L 53/166, 2018-02-23


• Commission Implementing Regulation (EU) 2018/248 of 15 February 2018 concerning the authorisation of 2,3-diethylpyrazine, 2,5 or 6-methoxy-3-methylpyrazine, 2-acetyl-3-ethylpyrazine, 2,3-diethyl-5-methylpyrazine, 2-(sec-butyl)-3-methoxypyrazine, 2-ethyl-3-methoxypyrazine, 5,6,7,8-tetrahydroquinoxaline, 2-ethylpyrazine and 5-methylquinoxaline as feed additives for all animal species – OJ L 53/120, 2018-02-23

• Commission Implementing Regulation (EU) 2018/240 of 15 February 2018 concerning the authorisation of trimethylamine, trimethylamine hydrochloride, 3-methylbutylamine for all animal species except laying hens and 2-methoxyethyl benzene, 1,3-dimethoxy-benzene, 1,4-dimethoxy-benzene, 1-isopropyl-2-methoxy-4-methylbenzene as feed additives for all animal species – OJ L 53/14, 2018-02-23

• Commission Implementing Regulation (EU) 2018/243 of 15 February 2018 concerning the authorisation of 3-hydroxybutan-2-one, pentan-2,3-dione, 3,5-dimethyl cyclopentan-1,2-dione, hexan-3,4-dione, sec-butan-3-onyl acetate, 2,6,6-trimethylcyclohex-2-en-1,4-dione and 3-methylnona-2,4-dione as feed additives for all animal species – OJ L 53/69, 2018-02-23


• Commission Implementing Regulation (EU) 2018/238 of 15 February 2018 concerning the authorisation of disodium 5’-ribonucleotides, disodium 5’-guanylate and disodium 5’-inosinate as feed additives for all animal species – OJ L 53/1, 2018-02-23

• Commission Implementing Regulation (EU) 2018/239 of 15 February 2018 concerning the authorisation of methyl N-methylanthranilate and methylanthranilate as feed additives for all animal species except avian species – OJ L 53/9, 2018-02-23

• Commission Implementing Regulation (EU) 2018/246 of 15 February 2018 concerning the authorisation of linalool oxide as a feed additive for all animal species except fish – OJ L 53/105, 2018-02-23

• Commission Implementing Regulation (EU) 2018/247 of 15 February 2018 concerning the authorisation of 2,4,5-trimethylthiazole, 2-isobutylthiazole, 5-(2-hydroxyethyl)-4-methylthiazole, 2-ethylthiazole, 2-ethyl-4-methylthiazole, 5,6-dihydro-2,4,6,tri(2-methylpropyl)4H-1,3,5-dithiazine and thiamine hydrochloride as feed additives for all animal species – OJ L 53/109, 2018-02-23

• Commission Implementing Regulation (EU) 2018/244 of 15 February 2018 concerning the authorisation of vanillyl acetone and 4-(4-methoxyphenyl) butan-2-one as feed additives for all animal species and the denial of 1-phenylethanol-1-ol – L 53/81, 2018-02-23

• Commission Implementing Regulation (EU) 2018/242 of 15 February 2018 concerning the authorisation of hex-3(cis)-en-1-ol, non-6-en-1-ol, oct-3-en-1-ol, non-6(cis)-enol, hex-3(cis)-enol, hept-4-enal, hex-3(cis)-enyl acetate, hex-3(cis)-enyl formate, hex-3-enyl butyrate, hex-3-enyl hexanoate, hex-3(cis)-enyl isobutyrate, citronellol, l-3,7-dimethyl-6-octen-1-ol, citronellal, 2,6-dimethylhept-5-enal, citronellic acid, citronellyl acetate, citronellyl butyrate, citronellyl formate, citronellyl propanoate, 1-ethoxy-1-(3-hexenyloxy)ethane and hex-3-enyl isovalerate as feed additives for all animal species – OJ L 53/36, 2018-02-23

• Commission Implementing Regulation (EU) 2018/183 of 7 February 2018 concerning the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers – OJ L 34/6, 2018-02-08
Future Events

27 March 2018
Awareness in Feed Safety Training
Bangkok, Thailand

4 April 2018
FAMI-QS Workshop
Jakarta, Indonesia

16-18 May 2018
Feed Additives Asia 2018 *(sponsored by FAMI-QS)*
Bangkok, Thailand

18-19 September 2018
FDA Approved Training on the Food Safety Modernization Act - Preventive Controls for Animal Food
Brussels, Belgium

For more information regarding FAMI-QS future events, please check our webpage: http://www.fami-qs.org/events.htm.

About FAMI-QS
FAMI-QS is the only global Quality and Feed Safety Management System for the sector of Specialty Feed Ingredients. The code addresses safety, quality and regulatory compliance in order to minimize hazards and ensure the placing on the market of safe and legal Specialty Feed Ingredients. FAMI-QS is operating under IAF MLA.

Member of: [IAF logo] [IFIF logo] [EA logo]

Recognized Stakeholder: