



GMP⁺ FC AUDIT REPORT

Surveillance audit

Company Name	- Eurofins Food Chemistry Testing Madison, Inc.
Registration n° GMP⁺	- GMP052818
Audit date(s)	- 04/09/2024

General data

Site address	6304 Ronald Reagan Avenue, Madison, WI 53704		
Legal registration n°			
e-mail	Carrie.Abrath@ft.eurofinsUS.com		
Representative/position	Mrs. Carrie Abrath / Senior Quality Specialist		
Organisational structure			
Activity/process of site(s)	Laboratory testing		
Products/volumes/#trucks	n/a		
N° of involved FTE		N° of shifts	
Total time (onsite+reporting)	10	N° of HACCP-studies	n/a
Lead auditor	Marcel Naber	Team members	n/a
Additional attendee(s)	n/a	Role of attendee(s)	n/a
Accreditation body	Unaccredited	Non-GMP ⁺ FC Standard(s) covered in this audit	n/a
Applied standard(s) FSA	TS4.2, 01 January 2022	Certificate expiry date	21/09/2026
Applied standards) FRA	n/a		
Fixed certification scope	See paragraph 2.		
Free certification scope	n/a		
Excluded from certification	n/a		

Audit objectives

The objectives of this audit were to determine conformity of the feed management system, or parts of it, with audit criteria and its:

- ability to ensure applicable statutory, regulatory and contractual requirements are met,
- effectiveness to ensure the organisation is continually meeting its specified objectives,
- ability to identify as applicable areas for potential improvement.

1. Current audit findings and conclusions

Nonconformities					
Critical:	0	Major:	0	Minor:	0

This was a process-based audit focusing on significant aspects, risks and objectives required by the standard(s). A sampling process was used, based on the information available at the time of the audit.

Methods of assessment included interviews, observation and review of documentation.

The audit team concludes that the organization **HAS** established and maintained its management system in line with the requirements of the standard and/or demonstrated the ability of the system to systematically achieve agreed requirements for products or services within the scope and the organization's policy and objectives.

**Based on the result of this audit, the audit team recommends that certification or temporary acceptance be
CONTINUED**

2. Scope of the audit

No	Operation	Material / Matrix		
		Feed material	Feed additives and premixtures	Compound feed and complementary feed
1. Aflatoxin B1				
1.01	Aflatoxin B1	x		
2. Dioxins and dioxin-like PCBs				
2.01	Sum of dioxins and dioxin-like PCBs			
2.02	Dioxins			
2.03	Dioxin-like PCBs			
2.04	Non-dioxin-like PCBs			
3. Heavy Metals and Fluorine				
3.01	Arsenic	x	x	x
3.02	Lead	x	x	x
3.03	Cadmium	x	x	x
3.04	Mercury	x		
3.05	Fluorine			

The certification scope was amended based on the results of this audit.

Yes ☐ No ☒

The auditor is qualified for the new scope and audit time was found to be sufficient.

n/a ☒ Yes ☐ No ☐

Details on amendments to previous scope and motivation of amendments

3. Nonconformities

Major nonconformities

Requirement	3.3		
Scope	Aflatoxin B1 and Heavy metals		
Standard(s)	TS4.2		
Details nonconformity	Action/correction	Corrective measures	Implementation date
The internal audit report does not demonstrably cover the verification of the compliance with the requirements as laid down in chapters 4 from this standard.	Eurofins will make sure the Aflatoxin and Heavy Metals proficiency testing and annual review will contain a matrix match test.	The internal audit for Aflatoxin and Heavy Metals will be reviewed annually and as part of the review matrix match proficiency testing will be done at least once per calendar year	21/10/2024

Reviewed and accepted by:	Carrie Abrath	Date:	16/10/2024
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UPDATE 29-10-2024: The laboratory provided additional information (SGS.doc of 28-10-2024) and demonstrated the verification of the compliance with the requirements as laid down in chapter 4 from this standard.

This major nonconformity is resolved.

4. Follow-up on nonconformities of previous audit

There was no follow-up during the suggested time frame of the minor noticed during last year's audit. So, this Minor is aggravated to a Major NCF.

Minor nonconformities

Requirement	3.3		
Scope	Aflatoxin B1 and Heavy metals		
Standard(s)	TS4.2		
Details nonconformity	Action/correction	Corrective measures	Implementation date
The internal audit report does not demonstrably cover the verification of the compliance with the requirements as laid down in chapters 4 from this standard.	Eurofins Food Chemistry will evaluate adding additional review criteria to the annual audit	If it is, agree upon by Eurofins management to include additional review topics during the annual audit these topics will be added to the annual auditor checklist.	First Quarter of 2024

Reviewed and accepted by:	Carrie Abrath	Date:	04/09/2023
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5. Audit Attendance Record

Name	Position
Mrs. Carrie Abrath	Senior Quality Specialist

6. Audit findings

Assessed documentation

Document name	Document code / version
SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017	Certificate Number: 2918.01, Valid to: October 31, 2025
A2LA ISO17025 QMS Internal Audit Checklist	Completed 08 and 09/2022
Performance criteria for laboratory testing	
MYCO_REG: Regulated Mycotoxins in Raw Materials Using UHPLC-MS/MS	R-ME-CT-TM4470, version 6, 04/08/2023
Method Validation Report Addendum 9 MYCO_REG	02/09/2021
Method Validation Report MYCO_REG MYCO_AFL	14/04/2016
MYCO_REG AFB1 Cereal Flour	July-September 2024
ICP_MS: Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)	R-ME-IN-TM4079, version 6, 01/02/2023
Method Validation Report Addendum 9 ICP-MS	10/05/2022
Method Validation Report ICP_MS	08/08/2014
ICP_MS Dirty4	June-September 2024
SGS.DOC	28-10-2024
Eurofins TS4.2 092024 GMP+ CAR UK v2020-1 (002).pdf	16-10-2024
Improvement	
PT Spreadsheet	2020 - September 2024
FAPAS PT report 04508 Multi Mycotoxins in Oat Flour	March-May 2024
FAPAS PT report 07512 Metallic Contaminants in Milk Powder	January-February 2024
FAPAS PT report 07512 Metallic Contaminants in Coffee (Ground)	January-February 2024

3. Registration process

The laboratory complies with the requirements for registration and assessment.

The laboratory operates an ISO/IEC 17025:2017 accredited quality management system. The accreditation scope covers Mycotoxins (of which Aflatoxin B1) and Heavy Metals.

There was no follow up on last year's Minor CAR 1: The internal audit report does not cover demonstrably the verification of the compliance with the requirements as laid down in chapters 4 and 5 from this standard.

Therefore, this Minor was aggravated to Major CAR 1: No implementation of last year's audit of the minor NCF:

The Internal audit report does not cover demonstrably the verification of the compliance with the requirements as laid down in chapters 4 from this standard.

UPDATE 29-10-2024: The laboratory provided additional information and demonstrated the verification of the compliance with the requirements as laid down in chapter 4 from this standard. This major nonconformity is resolved.

4. Performance criteria for laboratory testing

The analytical methods are accordingly the guides from this standard.

Aflatoxin B1 is determined by UHPLC-MS/MS. The content is quantified against an internal standard. Immunoaffinity clean-up is applied if needed. The instruction prescribes a recovery determination during each series. There are no changes implemented since the previous audit. No additional validation was needed.

The reproducibility and bias calculated on results for control analysis is below the limit from this standard.

Heavy Metals are determined by ICP/MS after digestion. Calibration by means of an internal standard. The method is derived from AOAC 2011.19, 993.14 and 2015.01. There are no changes implemented since the previous audit. No additional validation was needed.

No further changes concerning laboratory equipment, chemicals or laboratory area were occurred since the previous audit.

The reproducibility calculated on results for control analysis is below the limit from this standard.

5. Improvement

The laboratory takes part in several inter-laboratory tests for Aflatoxins and Heavy Metals. The results over the past years are registered in an Excel overview. The results from the provided original proficiency testing report were registered correctly. All results retrieved since the previous audit are satisfactory.