Guidance

S9.94 - Transition Certification Bodies - List of changes

Version EN: 1 March 2021

GMP+ International

gmpplus.org

Index

Welcome

This Feed Certification scheme document supports you to contribute to feed safety worldwide. By assessing and complying with the requirements set by GMP+ International together with its stakeholders, we aim to provide safe and responsible feed for the GMP+ community. Please read the information in this document carefully.

Let's make this work together!

1. About this document

The GMP+ Feed Certification scheme (GMP+ FC scheme) has developed over time, to adapt to changes in legislation, the feed market and feed safety management. With this development, the GMP+ FC scheme also became complex. During the past years, together with our stakeholders, we also gained new insights in our scheme.

This was our motivation to remove the complexity and apply these new insights via a systematic redesign of the GMP+ FC scheme. Together with our stakeholders, we have created scheme principles to keep ourselves focused and guide us through the process of achieving feed safety for our customers all over the world.

We are proud of the result! The structure of the GMP+ FC scheme has been simplified with completely rewritten standards, intended for both GMP+ certified companies and Certification Bodies. It is important to know that no concessions have been made in terms of feed safety!

A few topics of the GMP+ FC scheme could not be rewritten without changing the content. This document provides an overview of the changes in certification requirements.

2. Changes in certification requirements

The changes in the certification requirements are mainly based on:

- ISO/IEC 17021-1:2015 and NPR-ISO/TS 22003:2013 requirements
- Combining requirements from different documents into one paragraph
- Restructuring the order of the requirements based on the audit process

2.1. Certification requirements

Certification Requirements (CR)	GMP+ FC scheme 2020	GMP+ FC scheme 2010	Change
CR1.0 – Acceptation requirements	1. Scope of this document	• §1.3, C10	• Audit duration: *1 day equals 8 hours*
	2. Normative references	• Not applicable	• Listing of the documents that are mandatory to comply with
	3. Principles	• Not applicable	• The principles must be applied for decisions that need to be made for unanticipated situations
	4.3.1. Accreditation requirements	• §3.3, C10	• Removed: the reference to ISO/IEC17021
	4.3.2. Management of impartiality	• §3.4, C10	• There is a more robust set of requirements to manage the impartiality
	4.3.3. Confidentiality	• §3.7, C10	• More detailed requirements regarding confidentiality
	4.3.5. Structural requirements	• Not applicable	• More detailed requirements regarding organisational structure, top management and operational control
	4.3.6.1. Competence of personnel	• §3.5, C10	• Inclusion of witness audits to comply with the audit experience requirements for the GMP+ auditor FSA and FRA • Internal harmonisation requirement for the GMP+ auditor FSA and FRA of maximum time is reduced to 24 hours/year
	4.3.7.1. Public information	• Not applicable	• Maintenance of public information about audit processes, handling requests for information, complaints, appeals and policy on impartiality
	4.3.7.2. Information exchange between Certification Bodies and its Clients	• §3.7, C10	• List of information that must be provided to clients and also by clients
	4.3.9. Procedures / Documents for GMP+ certification	• §3.8, C10	• Implementation date of new certification requirements is changed
	5.2.3.2. Overall analysis	• §2.2, C11	• Obligation of sending the action/improvement plan on the request of GMP+ International
	5.2.5. Report assessment	• §2.2, C11	• The Certification Body must provide the information immediately on request

Certification Requirements (CR)	GMP+ FC scheme 2020	GMP+ FC scheme 2010	Change
	Appendix 4: Procedure for the Acceptance and Assessment of Certification Bodies	• Annex 3: Procedure for the acceptance and assessment of certification bodies, GMP+ C10	• The steps *'assessment documentation'* and *'acceptation audit'* are separate steps
	Appendix 6: Assessment criteria	• Annex 1: Assessment criteria, GMP+ C11	• The column of descriptions of nonconformities has been updated
CR2.0 – Assessment and Certification	1. Scope of the document	• C7	• Country Notes are included under the scope of this document
	2. Normative reference	• §2.1, C12	• Listing of the documents that are mandatory to comply with
	4. Principles	• Not applicable	• The principles must be applied for decisions that need to be made for unanticipated situations
	5.1.1 Application	• §2.2, C12	• New information must be provided by the applicant organisation to the Certification Body
	5.1.2 Application review	• §3.1, A1 • §2.2, C12	• A procedure for the application review is required
	5.1.4 Audit programme	• Not applicable	• A procedure and specific topics for audit programme are required now
	5.1.5 Audit team assignment	• Not applicable	• New conditions for auditors-in-training • New audit role
	5.1.6 Audit plan	• Not applicable	• An audit plan with minimum required information must be provided to the company and audit team
	5.2.1.2 Opening meeting	• Not applicable	• An opening meeting with minimum required topics must be held
	5.2.1.3 Initial certification audit	• §2.2, C6 • §2.2, C12	• The initial audit must be conducted in two stages • There are specific requirements for the Stage 1 and the Stage 2 audit
	5.2.1.3.1 Temporary acceptance	• §2.2, C6 • §2.2, C12	• The temporary acceptance must be conducted in two stages • There are specific requirements for the Stage 1 and the Stage 2 audit
	5.2.1.4 Surveillance audit	• §2.3, C12	• Not necessary full system audit (based on risk assessment) • Mandatory topics to be assessed during the surveillance audits • Whole system must be assessed throughout the certification cycle
	5.2.1.4.1 Announced surveillance audits	• §2.3, C6 • §2.3, C12	• New requirements regarding announced surveillance audits have been established

Certification Requirements (CR)	GMP+ FC scheme 2020	GMP+ FC scheme 2010	Change
	5.2.1.4.2 Unannounced surveillance audit	• §2.4, C6	• New requirements regarding unannounced surveillance audits have been established
	5.2.1.5 Recertification audit	• §2.5, C6 • §2.4, C12	• Requirements for recertification audit planning • Specific topics to be assessed during the recertification audit
	5.2.1.6 Expansionaudit	• §2.2, C6	• Stage 1 and Stage 2 are required
	5.2.2.2 Repeat audit	• §2.7, GMP+C6 • §2.5, GMP+C12	• Physical and/or administrative checks and a sampling may be carried out.
	5.2.4 Identifying and recording audit findings	• §2.9, C6 • Annex 4, C6 • §2.7, C12	• There are new requirements regarding establishing, recording and communicating opportunities of improvement, conformity and nonconformity (identification, classification)
	5.2.5 Closing meeting	• Not applicable	• A closing meeting with minimum topics must be held
	5.2.6 Audit report	• §2.9, C6 • §2.7, C12	• Extension of the deadline for uploading the audit findings/checklist, nonconformities and final assessment in the GMP+ database • Extension of the deadline for sending the audit report/checklist to the applicant organisation/ GMP+ Certified company • New information must be included in the audit report. • For stage 1 audits, documented conclusions do not need to meet the full requirements of a report
	5.2.7 Review	• §2.9, C6 • §2.7, C12	• The Certification Body must have a process to conduct an effective review of all GMP+ audit reports/checklist
	5.2.8 Certification decision	• §2.9, C6 • §2.7, C12	• The individual(s) appointed to conduct the certification decision must have appropriate competence and employed by Certification Body or an entity under the organisational control of the Certification Body • The Certification Body must record each certification decision to grant an initial certification, the audit team must provide specific minimum information

Certification Requirements (CR)	GMP+ FC scheme 2020	GMP+ FC scheme 2010	Change
	5.2.9.1 Certificates	• §2.10, C6 • §2.8, C12	• In the event of issuing any revised certification documents, there must be a means to distinguish the revised documents from any prior obsolete documents • Within 8 weeks following the execution of the audit on site, the Certification Body must send the certificate to the applicant organisation/GMP+ Certified Company
	5.2.9.3 Certificate/temporary acceptance templates	• §2.10, C6 • §2.8, C12	• The GMP+ FSA logo must be on the certificate
	5.3 Suspension or withdrawal of a certificate/temporary acceptance	• §8.2.1 e), A1 • §2.11, C6 • §2.9, C12	• The change on the deadline of informing GMP+ International and adapting in the GMP+ database is renewed • Documented procedure(s) for suspension, withdrawal and reduction of the scope of certification
	Appendix 1: Assessment criteria and sanctions for audits GMP+ FSA	• Annex 1, C6 • Annex 1, C12	• The descriptions of nonconformities have been updated • In case of less than 10 minor nonconformities, the maximum period to close is extended
	Appendix 2: Frequency and Audit times	• Annex 2, C6 • Annex 2, C12	• The minimum required audit time is modified. • The audit time calculation is modified.
	Appendix 4: Multi-site certification	• Annex 4, C6 • Annex 4, C12	• The audit duration calculation and sampling of sub-locations are modified
	Appendix 5: Announced surveillance audit – not at GMP+ Certified Company	• Annex 7, C6	• Added requirements for announced surveillance audit– not at GMP+ Certified Company location for *'paper trade'* within the scope of trade in feed
CR3.0 – Assessment and Certification for additional scopes	1. Scope	• §1.3, C7	• FRA module, Inland waterway transport and short sea shipping of feed, and Laboratory testing and registered laboratories are described in the scope of this document (not accredited)
	2. Normative reference(s)	• §1.1, C12	• Listing of the documents that are mandatory to comply with
	4.1.1. Application	• §2.2, C12	• New information must be provided by the applicant organisation to the certification body

Certification Requirements (CR)	GMP+ FC scheme 2020	GMP+ FC scheme 2010	Change
	4.1.2. Application review	• §2.2, C12	• A procedure for the application review is required.
	4.1.6. Audit plan	• Not applicable	• For FRA and Laboratory testing an audit plan must be sent to the company
	4.2.1.1. General	• §2.1, C6 • §2.1, C12	• For laboratory testing, there are specific requirements of on-site assessment depending on the scope(s) under ISO17025 accreditation
	4.2.1.2. Initial certification audit/inspection	• §2.2, C6 • §2.2, C12	• All analyses must be assessed during the certification cycle
	4.2.1.3. Temporary acceptance	• §2.2, C6 • §2.2, C12	• The temporary acceptance must be conducted in two stages • There are specific requirements for the Stage 1 and the Stage 2 audit
	4.2.1.6. Unannounced surveillance audits	• §2.4, C6	• If the FRA module is audited together with the FSA module the audit will be unannounced for all scopes
	4.2.1.7. Recertification audit	• §2.5, C6 • §2.4, C12	• Certification Body can decide to have Stage 1 and Stage 2 audits in order to extend the certificate/statement
	4.2.1.8. Expansion audit	• §2.2, C6	• Application review • Determining if any audit activity is necessary • Possibility to conduct an expansion audit in conjunction with a surveillance/recertification audit
	4.2.2.2. Repeat audit / Inspection	• §2.7, C6 • §2.5, C12	• Physical and/or administrative checks and a sampling may be carried out
	4.2.5. Audit report	• §2.9, C6 • §2.7, C12	• Extension of the deadline for uploading the audit findings/checklist, nonconformities and final assessment in the GMP+ database • Extension of the deadline for sending the audit report/checklist to the applicant organisation/ GMP+ Certified company • There is new information that must be included in the audit report.
	4.2.6. Review	• §2.9, C6 • §2.7, C12	• The Certification Body must have a process to conduct an effective review of all GMP+ audit reports/inspection checklists

Certification Requirements (CR)	GMP+ FC scheme 2020	GMP+ FC scheme 2010	Change
	4.2.7. Certification decision	• Not applicable	• Three criteria for certification decision have been established
	4.2.8.1. Certificates	• §2.10, C6	• The deadline of sending the certificate and statement to the applicant organisation/GMP+ Certified Company is renewed
	4.2.8.3. Certificate / temporary Acceptance Templates	• §2.10, C6	• GMP+ FSA/FRA logo must be on the certificate/statement
	4.3. Suspension or withdrawal of a certificate/Temporary acceptance	• §8.2.1 e), A1 • §2.11, C6 • §2.9, C12	• The deadline of informing GMP+ International and adapting in the GMP+ database is renewed • Documented procedure(s) for suspension, withdrawal and reduction of the scope of certification
	Appendix 1: Frequency and Audits/ Inspection Duration	• Annex 2, C6 • Annex 2, C12	• The minimum required audit duration is modified • The audit duration calculation is modified • Audit time reduction is not applicable for the FRA module, Laboratory testing, Registered laboratory, and Inland waterway transport and short sea shipping of feed
	Appendix 2: FRA Multi-site certification	• Annex 4, C6 • Annex 4, C12	• The audit duration calculation and sampling of sub-locations are modified

At GMP+ International, we believe everybody, no matter who they are or where they live, should have access to safe food.

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