Description of the TÜV NORD CERT certification procedure GMP+ FC (Feed Certification scheme) of GMP+ International B.V. (NL)

Certification

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If you should require any further information then please do not hesitate to contact us. We will be please to help you.

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Description of the TÜV NORD CERT certification procedure
GMP+ FC (Feed Certification scheme)
of GMP+ International B.V. (NL)

Rules and performance descriptions with regard to certification according to GMP+ FC

The rules and the performance descriptions regarding certification according to the GMP+-Standard are an integral part of the offer or proposal. They supplement the general conditions of certification (allgemeine Bedingungen zur Zertifizierung).

Upon signing of the contract, the Company warrants that it complies with all applicable requirements in the GMP+ FC scheme. The GMP+ FC scheme is part of this agreement.
The most recent version of the GMP+ FC scheme is publicly accessible at the Website www.gmpplus.org.
By signing the contract, the Company expressly agrees to the above ways to take note of the GMP+ FC scheme and declares that prior to signing it has read and understood these documents.

Rules of the TÜV NORD CERT Certification Procedure according to GMP+

The customer has the obligation to adhere to the provisions of the respective valid certification rules of the GMP+ FC (Feed Certification scheme) of GMP+ International B.V. (NL) which apply to him based on the respective standards on which the rules are based.

The requirements in the GMP+ FC documents are obligatory.

These are in particular:

- The certification body is entitled to issue information regarding the certification procedure according to the provisions of the respective GMP+ standard to Stand GMP+ International B.V. (NL). This also includes application for a registration number from GMP+ International B.V. (NL) for each operating site and the uploading of reports in the GMP+-database.
- The customer is obliged to inform the certification body about changes in their company datas which are needed according the GMP+ C documents.
- In a situation where the customer is confronted with an Extraordinary event, he is obliged to inform the Certification Body.
- In case of signals or perceived facts which indicate that the safety of a product is not in compliance with the legal product standards or with the product standard laid down in GMP+ BA1 Specific Feed Safety limits, the customer has to notify GMP+ International and the certification body in accordance with the GMP+ BA5 Minimum Requirements EWS in between of 12 hours. If it is a legal obligation the participant needs also to notify the non-conformity to the competent authority in the country or region of residence. In each case the participant should fill in the *EWS Notification Form GMP+ Feed Safety Assurance* or otherwise use the notification form prescribed by the competent authority in question.
- The customer will inform the certification body in writing in the case of a product recall, and will provide details of what has occurred.

  Therefore send an e-mail at the following mailbox: tncert-food-recall@tuev-nord.de

  From its side, the certification body will take appropriate steps in order to assess the situation and its effect on the certification and will take suitable measures.
- The customer declares that he agrees to the analysis results being entered into the database for undesired substances of GMP+ International B.V. (NL) within the framework of product monitoring.
- The customer is aware of his obligation to support the performance of witness audits, parallel audits and additional audits (improvement controls, stronger controls and repeat controls). GMP+

International is authorized to carry out a compliance audit as well as to take samples and laboratory testing.

- The customer is aware of his obligation to inform the certification body of any misuse of the GMP mark or offence against the GMP+ FSA which becomes known to him. The certification body communicates the information to GMP+ International B.V. (NL).
- GMP+ International may at any time make any necessary amendments to the contents of the GMP+ FC scheme

1 CERTIFICATION PROCEDURE

1.1 Audit Preparation

The audit preparation serves to assess the readiness of the customer for certification. In preparation of the audit the company can describe itself and its activities using a questionnaire.

In order to prepare, the customer receives the questionnaire for preparation for a TÜV NORD CERT Audit. The completed questionnaire is returned to the certification body and serves to establish if the FSM system of the customer fulfils the basic requirements for a certification audit. If the scope was not clarified in the previous discussion, the scope of the certificate is laid down.

In addition, the customer names a contact person appointed by the top company management as responsible for the audit. This is generally the quality management representative.

1.2 Establishment of readiness for certification

In the case of a positive result, the audit plan is drafted, which contains all the GMP$^+$ requirements to be audited, the affected processes and the organisation units of the customer, as well as a schedule for the audit. This plan is sent to the customer two weeks before the audit.

The lead auditor agrees the plan with the employee of the customer responsible for the audit and informs the other auditors in the team.

1.3 Temporary approval

Based on a positive evaluation of the QM documentation for a certification audit, it is possible to issue a certificate for time-limited approval (maximum 4 months) to a company which begins GMP$^+$- activities in the feed industry.

If a company carries out production and/or (simple) processing and/or storage and/or transport activities, a part of the evaluation of the QM documentation must take place at the site or sites.

The additional certification audit must take place on site within the 4 months, and the entire certification process, including updating of the database of GMP+ International B.V. (NL) by the certification body, must also be completed within 4 months.

1.4 Audit Stage 2 – Certification Audit

The document review can take place before the audit. Following this, individual employees are questioned at their workstations and other relevant documents, records, orders, guidelines etc. are viewed.

The task of the organisation during the audit is to demonstrate the practical application of its documented procedures. Following the end of the audit, the customer is informed of the result in a closing meeting. The auditor can provide an estimate of the result of the audit, but cannot state the

final result itself. The result is documented in a report and nonconformities are documented in an action plan. The customer receives the action plan following the audit in order to specify the corrective actions. Within 14 days of receipt, the customer sends the action plan with the corrective actions and suitable evidence to the Audit. The auditor verifies the corrective actions based on the evidences provided or by means of a follow-up audit (improvement control), i.e. a new inspection on site, and notes this in the action plan. The scope of the follow-up audit is decided by the lead auditor. However, only the requirements of the standard for which a nonconformity or nonconformities were identified are subject to re-audit.

In the case of a critical non-conformity (Category 1) result, in accordance with GMP+ rules an immediate report must be made to GMP+ International B.V. (NL).

If one or more critical nonconformities are observed during an initial certification audit, surveillance audit and recertification audit or a re-view of the quality documentation, then the GMP+ certificate or the temporary approval may not be issued or extended.
The requirement of GMP+ C6 are applicable.

1.5 Award of Certificate

The certificate is issued following successful review of the audit procedure by TÜV NORD CERT If the contract regarding certification has been signed and is available at TÜV NORD CERT, the certificates (if required in several languages) are sent to the customer along with the Audit Report. The certificate is only issued if the corrective actions listed in the action plan have been positively assessed by the auditor and the certification body. The period of validity of the GMP+ certificate is 3 years, provided that surveillance audits are performed each year. Certificates for time-limited approval are issued for a maximum of 4 months.

The owner of a GMP+ certificate of TÜV NORD CERT GmbH is entitled to make use of the corresponding “GMP+ Feed Safety Assurance” trade mark of GMP+ International B.V. in accordance with GMP A3 in the current version.

Owners of certificates for temporary approval are not permitted to advertise with the GMP+ trade mark.

The right of the customer to make use of the TÜV NORD CERT Certificate and/or to make use of the trade mark „GMP+ FC“ of GMP+ International B.V. for GMP+-certified companies ends with immediate effect without the need for a period of notice if

- the applicant does not immediately report changes to aspects of his operation which are decisive for the certification, or indications of such changes, to the certification body;
- the certificate or the trade mark “GMP+ FC” of GMP+ International B.V. is used in an incorrect manner;
- the results of the surveillance audits no longer justify maintenance of the certificate;
- insolvency proceedings are opened with regard to the assets of the applicant, or if an application for insolvency proceedings applied for against him is refused due to lack of assets;
- the fee is not paid within the period of time set by the certification body;
- surveillance audits cannot be carried out for reasons for which the applicant is responsible;
- the certification or the continued existence of the certificate is prohibited for legal reasons or official administrative reasons.

2 SURVEILLANCE AUDIT

The time when the surveillance audit is due depends on the date of the certification audit and must be performed 12 or 24 months after the certification audit.

Before the surveillance audit, the data of the company are updated in order to take changes which have a significant influence on the area of activity or the way of working of the customer into consideration..

3 RECERTIFICATION AUDIT

Before the recertification audit, the data of the organisation are updated in order to take changes which have a significant influence on the area of activity or the way of working of the customer into consideration, and a new offer is submitted to the customer.

In good time before the period of validity of a certificate has expired, a recertification audit must be carried out. Normally the recertification audit has been carried out 36 months after the certification audit.

In addition, before expiry of the period of validity of the certificate, the entire certification process, including updating of the database of GMP+ International B.V. (NL) must have been completed by the certification body. If the recertification audit is not carried out before expiry of the period of validity of the certificate, a certification audit has to be performed. During this period, the customer is not GMP$^+$-certified.

4 UNANNOUNCED AUDITS

4.1 Option A: Temporary reinstallation of the voluntary add on unannounced surveillance audit, valid till 15th of November 2019

The voluntary unannounced surveillance audit only applies to the customer certified for the production scopes.

The unannounced audit is an extra audit carried out during the certification cycle and can be requested by the customer.The unannounced audit cannot replace other audits. Per certification cycle, the customer may request one unannounced surveillance audit.

As soon as the customer chooses to have unannounced surveillance audits, it becomes compulsory during the certification cycle. A customer may not refuse the conduction of an unannounced surveillance audit. The customer can only refuse the unannounced surveillance audit by means of a legitimate motivation.

4.2 Option B: Unannounced audit program valid from 22nd of February 2018

The voluntary unannounced surveillance audit program is applicable for all customer outside the Netherlands certified for at least one GMP+ scope, all scopes.

Those who apply for the unannounced audit will be obliged to participate during the certification cycle. In this case, the unannounced surveillance audit shall replace one of the announced surveillance audits during the certification cycle.

Every twelve months, each customer can specify 15 days in that year during which the unannounced surveillance audit cannot be performed. If not indicated in advance the unannounced surveillance audit cannot be refused.

In principle, all requirements and obligation of the GMP+ FC scheme must be assessed.

Customer that already apply voluntary add on unannounced audit will be changing to the replacement unannounced surveillance audit in the new certification cycle

5 ADDITIONAL AUDITS

If the results of the audit indicate it then an additional audit should be carried out.

Compliance audit
If major- nonconformities (Category 2) shortcomings are observed then the certification body may carry out a compliance audit. This audit is in addition to the normal audit cycle and is aimed at specific aspects related to the observed nonconformity and the improvement measures taken. A major- nonconformity (Category 2) nonconformity can also be handled administratively on the basis of compliance measures formulated by the company.

Stricter supervision
In the event of the observation of one or more critical- nonconformity (Category 1) a certification body may decide to withdraw the certificate or temporary approval of the company, to suspend the company or to place the company under stricter supervision. This last will only be done if unsatisfactory improvement measures are taken. The stricter supervision will take place for the period determined in appendix 1 and will be a minimum of 3 months and a maximum of 6 months.

At least one on-site stricter supervision audit must be conducted. For the rest of the monthly stricter supervision audits, the certification body can decide to conduct an audit on site or not on-site.

Repeat audit
In special circumstances there may be a repeat audit. This audit is aimed in principle at all the requirements of the GMP+ FC scheme. The reason for a repeat audit may be an EWS alert, complaints or incidents, or something else. The costs of the repeat audit will be met in principle by GMP+ International. However, if it appears that one or more critical or major nonconformities are observed then the costs will be charged to the company.

6 TRANSFER OF CERTIFICATION FROM OTHER CERTIFICATION BODIES

During the term of their GMP+ certificate, the customer can transfer to another certification body accepted by GMP+ International.

This transfer is carried out under the following conditions:

- All contractual obligations following from the (departing) certification body and the customer should be performed until the moment of termination of the certification agreement.
- The departing certification body remains responsible for GMP+ certification of the customer until the termination of certification.
- Prior to the moment of transfer of the customer, all outstanding non conformities (third, second and first category) should be closed.
- After transfer the new certification body is responsible for GMP+ certification of the customer.

- The new certification body always has to enter a new GMP+ agreement
- The certification cycle between the new certification body and the customer always has to start with an initial audit. To transfer a GMP+ certificate from the old certification body to the new certification body is not allowed.

7 CERTIFICATION OF COMPANIES WITH MULTIPLE LOCATIONS (MULTI-SITE)

Multi site certification is possible:
a. At a company with a main office with 100% subsidiaries, or
b. At a group of companies which have joined together as a quality community.

This applies for the activities:
a. Transport
b. Trade
c. Storage
d. Transhipment
e. Collection
f. affreightment

The requirements of GMP+ C6 has to be considered.

8 MANAGEMENT OF NON-CONFORMITIES

Audit nonconformities are to be classified on the basis of the general assessment criteria stated below. In addition the specific assessment criteria shown in the checklists remain in force. The measures specified should be imposed as a minimum. A certification body is able to impose stricter measures.

Minor- Nonconformity (category 3):

Any nonconformity which does not adversely affect the health or safety of a product.

Conclusion:
Where 10 or more minor nonconformities are observed during an audit, an additional audit or the assessment of quality documentation, the company does not meet the requirements for GMP+ certification or temporary approval.

Major-Nonconformity (category 2):

Any nonconformity other than critical, which may result in failure for health or safety and which cannot be completely eliminated by re-work or reduced to a minor nonconformity.

When a requirement of the GMP+ normative document has been addressed but there is in-sufficient evidence to demonstrate that it has been properly controlled or implemented.

Conclusion:
The company does not meet the requirements for GMP+ certification or temporary approval.

If major-nonconformities are observed during an initial certification audit or recertification audit or a review of the quality documentation, then the GMP+ certificate or the temporary approval may not be issued or extended.

Critical-Nonconformity (category 1):

Any nonconformity which may result in hazard-ous or unsafe for individuals and animals.
A regulatory violation or a complete feed safety failure to implement a requirement of the GMP+ normative document.
Conclusion:
The company does not meet the requirements for GMP+ certification or temporary approval.

If one or more citical nonconformities are observed during an initial audit, an extension audit or a review of the quality documentation, then the GMP+ certificate or the temporary approval may not be issued or extended.

The critical non-conformity has to be announced to GMP+ International B.V.

9 MEASURES AND SANCTIONS

If the certification body as a result of an audit or in some other way establishes that the customer does not comply in fully or partly with what is determined in or by virtue of the GMP+ FC scheme or the GMP+ agreement, then measures will be taken or sanctions applied to the participant by the certification body. Nonconformities must be classified according these criterias.

Measures or sanctions are the following:

a) Compliance audit at the customer. The cost for this audit is at the expenses of the customer.
b) A stricter supervision audit at the customer. The cost for this audit is at the expenses of the customer
c) Suspension of the GMP+ Certificate for of maximum of three months
d) Withdrawal of the GMP+ Certificate for a minimum period of at least one year. The customer is excluded for at least twelve month from reapplying for participation in the GMP+ FSC scheme.
e) Publication by GMP+ International of the suspension and the withdrawal

During Suspension, the Company shall not use the Trademarks and Documentation. The Company shall temporarily remove all references made to the Trademarks. In case the Company has affixed the Trademarks to its products, during suspension it will refrain from bringing these products into the market.

The Certification Body is entitled to inform GMP+ International and the relevant government authorities of any Measures or Sanctions taken against the Company.

The Certification Body or GMP+ International are entitled to publish any Measures or Sanctions taken against the Company. GMP+ International is also entitled to inform the Participants or other certification bodies in the GMP+ FC scheme or any other scheme holder with which it has a mutual recognition, about any Measures or Sanctions imposed on the Company.

10 TRADEMARKS

Upon the terms and conditions of this Agreement, the Company is entitled to use the Trademarks and the Documentation under the condition that it meets all requirements for Participants incorporated in the GMP+ FC scheme.

The Trademarks shall only be used exactly as registered in the relevant trademark register(s). In any case, the Company is not permitted to alter the Trademarks or to use the Trademarks as part of a new logo. The Trademarks may be:
a. affixed to the walls and/or on signs around the premises or on transport vehicles of the Company;
b. affixed to documents of the Company;
c. used on the website of the Company.

The Documentation shall not be published nor modified in any way by the Company. The Company has the right to reproduce the Documentation for its own use.

The Company does not have the right to license or transfer the rights granted in this Agreement to a third party.

The Company has the duty to immediately report to the Certification Body any infringement of the Trademarks or Documentation which comes to the notice of the Company.

Upon termination of this Agreement, the Company loses its right to use the Trademarks and Documentation. The Company shall permanently remove all references made to the Trademarks and shall destroy the Documentation as well as all materials depicting the Trademarks.