GMP+ Integrity Policy ~~2014~~

CONTENT

1 Introduction

The overall aim of any kind of certification is to give confidence to all parties that a system fulfils specified requirements. The value of certification is the degree of public confidence and trust that is established by means of an impartial, objective and competent assessment conducted by a third-party.

GMP+ International carries out several supervision activities to monitor the compliance of the certification process of third parties (certification bodies) with the rules of certification laid down in the GMP+ Feed certification scheme. ~~During 2014, GMP+ International has carried out a reevaluation of it supervision activities and other aspects related to integrity. The result is the current Integrity Policy 2014. It will be implemented step-by-step in 2015.~~

The ~~This~~ Integrity Policy aim~~s~~ is to ensure the confidence and trust about certification regarding the GMP+ Feed Certification scheme. The first Integrity Policy document was established in 2014.

The purpose of this document is to provide a second version of Integrity Policy, after evaluation of the previous one in 2016, and to define the general aims, principles, methods, procedures and organization of the management of the three cornerstones of the Integrity Policy. It is also the intention to apply the principles regarding the development of policies relating the organization and its operations, as laid down in the ISO 17021 standard.

In advance, first we pay attention to the roles and responsibilities of involved parties and the perceived attitudes regarding compliance. Those are important determining factors for the Integrity Policy.

2 Aim Integrity Policy

GMP+ International applies an Integrity Policy with the aim to ensure the confidence that the certified companies comply with the principles and requirements of the applicable GMP+ normative standards in a proper and unimpaired manner and to improve the quality of the certification.

Therefore, GMP+ International wants to evaluate the effectiveness of its Integrity Policy from time to time and to improve it. Above, it has to find the right balance regarding nature and extent of efforts (cost) to obtain optimal results. This policy document~~s~~ is implemented in an annual Integrity Program.

~~At this moment, GMP+ International has 30 accepted Certification Bodies with about 350 qualified auditors in charge with the certification against the standards of the GMP+ Feed Certification scheme. There are over 13,300 certified companies.~~

With the following objectives the Integrity Policy seeks to achieve:

a. To guarantee consistent implementation of the GMP+ FC scheme worldwide
b. Encourage the improvement of certification bodies
c. Give feedback to GMP+ International
d. Determine the ambiguous points in our normative documents
e. Follow up of complaints, rumors and investigate frauds
f. Achieving a continuous improvement of the certification process

3 Roles and responsibilities

The GMP+ Integrity Policy is not a stand-alone item, but part and breech block of a coherent set of roles and responsibilities of the involved parties.

The involved parties are the certified company, the Certification Body and GMP+ International (as scheme manager). Each involved party has a responsibility for the credibility of a certificate but together there is a common responsibility. Therefore GMP+ International is constantly working together with the Certification bodies to improve the effectiveness of the measures especially for the compliance assessments, and on a regular basis the companies are asked for input in surveys/meetings, etc.

Certified company
First of all, the certified company is responsible for compliance with the requirements appropriately. The management's responsibility is to propagate adherence to compliance and to evaluate the implementation and compliance regularly. Accurate compliance is also crucial; otherwise it will fuel a tendency of indolence. Feed safety culture is management's responsibility.

Certification Body
Secondly, the Certification Body has the responsibility for assessing and certifying companies. Issuing a certificate expresses a justifiable confidence that the company complies with the applicable requirements regarding of the GMP+ Feed Certification scheme. Therefore, the Certification Body needs to ensure skills, knowledge and competences of auditors and technical reviewers, to act impartially and also to assess company's compliancey with the normative standards in a consistent way and to assess nonconformity fully in accordance with ~~of~~ the rules of certification, set by the scheme manager. It is recognized that the source of revenue for a Certification Body is its clients paying for certification, and that this is a potential threat of impartiality. To obtain and maintain confidence, it is essential that a Certification Body's decisions are based on obtained *objective evidence* of (non)conformity, and that its decisions are not influenced by other interests or by other parties (ISO 17021, par. 4.2).

Scheme manager
Finally, also the scheme manager has its responsibility. It is about setting normative standards or certification criteria, about setting rules of certification and about an Integrity Policy and related program.

Regarding the determination of the content of the certification scheme, the scheme manager has established the International Expert Committee. In this IEC all stakeholders in the feed chain and following links in the animal production sector are represented in a well-balanced way via so-called partnership of trade associations and food companies. The IEC has the right to give a binding advice to GMP+ International regarding the content of the international standards of the certification scheme, including the rules of certification. Proposal for the IEC are prepared in collaboration with a number of subcommittees for specific scopes (production, trade & collection, transport, certification & compliance).

Setting normative standards: it is important that the requirements for participating companies as well as involved Certification Bodies in the certification scheme are achievable and relevant. Validation, prior to implementation, is an important tool. Well-balanced multi-stakeholders participation is also important for setting achievable and relevant requirements. GMP+ International aims to apply the principles of ISO/IEC 17007:2009 *Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment*.

Setting rules of certification: it is also important that the scheme manager defines a coherent set of rules for certification. For GMP+ International, first it is about accreditation. It is also about skills, knowledge and competence requirements of auditors and technical reviewers and regular examination of auditors and technical reviewers to prove ongoing knowledge of the applicable standards. Additionally, it is about audit frequency, minimum audit time, rules for classification of nonconformities and imposing the related measures, corrective actions and sanctions. Accreditation of the Certification Body according ISO 17021 / ISO 220003 will be a condition[1].

GMP+ International has also a dispute procedure and an independent Dispute Committee for disputes between a company and GMP+ International. Besides that, GMP+ International has a complaint procedure (see par. 6).

In the framework of critical self-reflection, GMP+ International carries out regular assessments of the effectiveness and achievability of the certification scheme by means of evaluations and customers' satisfaction. ~~New standards and adaptations are implemented after a certain time of implementation, which can result in adaptations.~~ After any feed safety emergency, an extended evaluation is carried out to identify improvements in the content of the scheme, the certification and compliance assessment process, communication and other operations.

The third responsibility of the scheme manager is to have a proper Integrity Policy and a related program. The GMP+ Integrity Policy has three cornerstones: (i) Compliance Assessments, (ii) Complaint Management and (iii) Management of the Early Warning Notifications. The following in this policy document is addressing these topics.

In the framework of accreditation, we are regularly ~~audited~~ assessed by the Dutch Accreditation Council ~~(until 2015) and representing~~ the European Accreditation Council ~~(2015 onwards)~~ as home accreditation body ~~o~~ in compliance with criteria applicable for scheme holders. In 2014, we applied for acceptance by the Dutch Food Safety Authority (NVWA). Part of the acceptance procedure ~~will be audits~~ is to assess compliance with the criteria. This kind of ~~audits~~ assessment is also triggers for improvement of performance.

[1] Until ~~2015~~ mid-2016, accreditation according NEN 45011 / ISO 17065 is applicable, ~~in 2015~~ afterwards it will moves to accreditation according ISO 17021

4 Attitudes regarding compliance

Concerning participating *feed companies*, at least we can characterize two kinds of attitudes regarding compliance with the GMP+ requirements:

a. a commitment and adherence to work accurately and to meet the requirements because of the conviction of the need of operating credibly and mitigating risks (product safety risks as well as financial risks);
b. participation in the scheme because the market forces the company to be certified, with a lack of or with a weak commitment to comply with the requirements for risks mitigation, at the lowest cost resulting in minimal compliance ('operating on the border') and showing critical nonconformities regularly.

Crucial are the values, the attitude and behavior of the management. When the management propagates and carries out a weak Feed Safety Culture, the employees will follow in the same way.

The determining factor for a weak or strong Feed Safety Culture is how feed safety control is considered[2]: as a priority or as a company value. In the event it is a priority, it can be higher or lower, depending on the (financial) situation. A value is always at the same level of urgency, because it is a driving force for daily operations. That makes the difference.

Concerning participating *Certification Bodies*, we can also characterize two types of attitudes regarding compliance with the GMP+ requirements:

a. a commitment to work accurately and to carry out the certification in a credible, which means impartial, competent and consistent way;
b. a limited commitment as mentioned under a. which is showed in weak assessment of companies ('lack of depth during auditing'), resulting in non-observation and/or non-recording of nonconformities, or in classifying nonconformities less strict than laid down in the GMP+ Feed Certification scheme.

As mentioned before, the source of revenue for a Certification Body is its client paying for certification, which is a potential threat of impartiality. Therefore, an important touchstone of the attitude of a Certification Body and the Auditors is the extent to which the Certification Body's decisions are demonstrably based on *objective evidence* of (non)conformity and that its decisions are not influenced by other interests (ISO 17021, par. 4.2).

Inaccurate assessment by an auditor results in inaccurate operations of an assessed feed company regarding feed safety control. The consequence is that it can lead to further stretching of deviant behavior and non-compliancy in the operations.

Concerning *GMP+ International* as scheme holder and in supervisor of the compliance of the certification process, the attitude of involved people at several levels is also important. To ensure proper development of standards, the principles of ISO/IEC 17007 need to be applied. Compliance assessments need to be carried out by competent employees in an objective, consistent and impartial way and measures against certification bodies must be imposed in a careful and reliable way according defined criteria. GMP+ International's decisions have to be based on objective evidence.

[2] "Food Safety Culture - Creating a Behavior-Based Food Safety Management System" (2010) - Frank Yiannas

Therefore, it is important to operate according a quality management system (ISO 17021, ISO 9001), including carrying out internal audits. Additionally, the performance of GMP+ International is assessed regularly by the accreditation council[3] and possibly by more independent parties in the near future.

5 Compliance Assessments

5.1 Aim

The primary aim of a Compliance Assessment, as part of the Integrity Policy, is to assess the compliance of the performance of a Certification Body and the auditors in charge with the certification of companies against the GMP+ FC scheme in order to give all interested parties:

a. *Confidence* that the Certification Body conducts the audits and manages the GMP+ FC certification process in accordance with the requirements and applicable criteria and carries out the assessment of the companies in an impartial, competent and consistent way.
b. Proper assessment and certification must result in *trust* that the GMP+ certified companies fulfil the applicable requirements regarding feed safety assurance.

Interested parties are: the clients of the Certification Body, the clients of the GMP+ certified companies and other downstream (food) companies, governmental authorities, non-governmental organizations and finally the consumers of animal products.

5.2 Principles

The following principles are important:

a. The management and effectuation of Compliance Assessments are based on the following principles: impartiality, competence, responsibility, openness, confidentially and responsiveness to complaints (~ ISO 17021, par. 4.1.3).
b. The assessments and decisions of GMP+ International must be demonstrably based on obtained objective evidence of (non)conformity (~ ISO 17021, par. 4.2.3).

5.3 Compliance Assessment Methods

5.3.1 Introduction

GMP+ International will apply the following Compliance Assessment Methods in a systematic way:

a. Compliance Audits:
    a. Witness Audits (WA report)
    b. Parallel Audits (PA report)
    c. CB office audits (CB report)
    d. Chain-oriented Audits (COA report)
b. Retrospective analysis of the:
    a. certification process of a specific company (RAC report)
    b. performance of an individual Auditor (RAA report)

[3] ~~At this moment by the Dutch Accreditation Council and in the future by or on behalf of the European co-operation for Accreditation~~

c. Overall analysis of the performance of a Certification Body (OACB report)
d. Examination of auditors.
e. CB Audit Report assessment

All compliances assessment methods are documented in the GMP+ C11 “Method of and Criteria for the Compliance Assessment of Certification Bodies”.

~~5.3.2 Compliance Audits~~

~~First of all, it is necessary to realize the relation of the Compliance Audits with the Internal Audit, carried out by or on behalf of the entrepreneur and the Certification Audit carried out by or on behalf of the Certification Body.~~

~~*Witness Audit* is a Compliance Audit carried out by accompany an (accepted) Auditor of a Certification Body in order to supervise the CB auditors by assessing his / her working method and the way in which they categorize their findings during the execution of the Certification Audit.~~

~~A *Parallel Audit* is a Compliance Audit carried out at a GMP+ certified company to verify the method by which an audit has been planned, executed and reported to the certification body and how the report has been reviewed and assessed. This parallel audit will take place as quick as possible after a Certification Audit has been carried out and reported to GMP+ International.~~

~~A *CB office Audit* is a Compliance Audit carried out at the Certification Body’s office to assess the compliance with all applicable requirements in the GMP+ Feed Certification scheme audits.~~

~~A *Chain-oriented Audit* is a Parallel Audit at a certain company and its supplier(s) and / or client(s) with a focus on specific requirements and consistency regarding labelling, information in purchase and sales contracts or delivery orders, information on transport documents, etc. The big advantage of this type of auditing is to assess the process consecutively.~~

~~A *Retrospective analysis of the certification process of a specific company* is an analysis of the reports of all Certification Audits and if available also of Compliance Audits, conducted at a specific company during the last 36 months.~~

~~A *Retrospective analysis of the performance of an individual auditor* is an analysis of the reports of all Certification Audits conducted by a certain Auditor during the last 36 months.~~

~~5.3.3 Overall analysis~~

~~An *Overall analysis of the performance of a certification body* (OACB) is an annual analysis of performance of a Certification Body during the last three calendar years, based on at least:~~

~~a. Identified nonconformities per auditor~~
~~b. Findings of CB office Audits;~~
~~c. Findings of Parallel and Witness Audits;~~
~~d. Participation and input in harmonization meetings;~~
~~e. Exam results of the Auditors;~~

~~Final aim is to deliver input for rating of Certification Bodies which will be relevant for the development of a risk-based Compliance Audit Program.~~

~~5.3.4 Examination of auditors~~

~~Annual examination of auditor is a tool for assessing auditors' compliance with the condition of having enough knowledge of the normative standards and rules of certification, including the classification of nonconformities as well as the characteristics of the production processes in the feed chain.~~

5.4 Frequency

~~Until 2014, only the Witness Audits, Parallel Audits and CB office audits were carried out regularly. The overall analyses (OACB) were carried out on ad hoc base. From 2015 onwards,~~ a All methods of Compliance Assessment will be carried out on a structural base. The Compliance Audits, parallel and witness audits, are risk based selected; ~~Regarding the frequency of the Compliance Audits, the following criteria are applicable:~~

~~a. The Compliance Audits at certified companies is partly ad random and mostly risk based selected;~~

b. The number of Compliance Audits conducted annually at certified companies (Parallel and Witness Audits) is established the fourth quarter of each year and based on the results of the annual audit risk assessment ~~determined by a sample size calculation based on (i) 95% confidence level, (ii) 2% confidence interval and (iii) number of CB auditors[4] at end October in the previous calendar year;~~

c. The CB office audit is conducted ~~one time (2 days audit)~~ annually at least~~, the office audit of a Sub-contractor every two years at least~~ but it will depend on the results of the compliance audits conducted to the CB.

d. Overall analysis of the performance of a certification body is carried out annually.

e. The Chain-oriented Audits and the retrospective analysis are carried out systematically and will be determined by GMP+ International ~~in accordance with the guidelines of the Managing Director~~.

6 Complaints

Parties expect that complaints will be investigated properly and that a reasonable effort will be made to resolve them. Effective responsiveness to complaints is an important means of protection for GMP+ International, the accepted Certification Bodies, GMP+ certified companies and other users of certification against errors, omissions or unreasonable behavior.

Confidence in certification activities is safeguarded when complaints are processed by clear and transparent procedures.

GMP+ International ~~The Quality Manager~~ will report:

a. regularly about the received complaints and the progress and results of the handling of them to management of GMP+ International;

[4] ~~http://www.calculator.net/sample-size-calculator.html?type=1&cl=95&ci=2&ps=350&x=51&y=9~~

b. annually ~~(in April)~~ about the analysis of the complaints in the previous calendar year. The aim of these analyses is to provide input for the risk based planning of ~~the parallel~~ compliance audits and CB office audits.

7 Early Warning notifications

Companies are obliged to notify perceived exceeding of the maximum permitted level of undesirable substances in feed lots. The involved company is primary responsible for taking the proper control measures, to communicate with customers downstream and to trace back to the source and cause of contamination, in order to limit the distribution of contaminated lots of feed products.

For GMP+ International, a EWS notification can result in Compliance Assessments, like a Repeat Audit, but also in Parallel Audits and sometimes also Chain-oriented Audits.

The EWS team will report:

c. regularly about the received EWS notifications and the progress and results of the handling of them;
d. annually ~~(in April)~~ about the analysis of the EWS notifications in the previous calendar year. This can provide input for a risk-based Compliance Audit program as well as for the generic risk analysis of feed materials (FSP)
e. monthly the results of the points a and b are assesses/discussed by the EWS team ~~annually (in April) an analysis of feed related RASFF notifications~~.

8 Communication

GMP+ International wants to show openness as much as possible to the public and to be accountable to stakeholders. It is about providing public disclosure of appropriate and timely information about its audit and certification process, and about the certification status of participating companies and acceptance of Certification Bodies in order to gain confidence in the integrity and credibility of the certification.

The following communication activities ~~were~~ are carried out ~~until 2014~~[5]:

a. Public: the status of the certification of companies and acceptance of a Certification Body (a public accessible company database).
b. Public: publication of a newsletter in case of suspension or withdrawal of a certificate of a company or of the acceptance of a Certification Body.
c. Public: under certain conditions it could also be possible to make public the observed critical non-conformity ~~(category 1)~~, the imposed measure(s) or sanction(s), and the name and location of the involved Participant.
d. GMP+ Community: EWS messages as a result of EWS notifications.
e. Competent authority / Certification Body: findings about breach of statutory requirement on the basis of Audits and EWS notifications to the concerned Certification Body as well as to competent authorities.
f. Partners, IEC: in case of a feed safety disruption, reporting to partners and IEC about actions and progress regarding the management of the disruption (by means of letter and / or teleconferences).

g. Other certification scheme managers: in case of EWS notifications and disruptions with other scheme managers (with mutual recognition) about actions, progress and sometime details in case of delivery by GMP+ certified companies to companies certified against the other's certification scheme, by letter, mail, teleconferences.
h. Public: 'focus' newsletter about specific requirements and clarifications and interpretations of specific requirements of the GMP+ standards, in response to perceived misunderstandings, nonconformities during Compliance Audits, received questions, discussions during harmonization meetings, etc.
i. IEC: An annual overall report of the results of the Integrity Program in the previous calendar year.
j. Public: a summary of the annual report about the Integrity Program.
k. Certification Bodies: When perceived audit results are relevant for compliance assessment of a supplying company, it shall be shared with the involved Certification Body with taking into account the confidentiality restrictions.

~~Additionally, GMP+ International will also carry out the following communication:~~
~~a. Public: Publication of the Integrity Policy document.~~
~~b. Public: A monthly 'focus' newsletter about specific requirements and clarifications and interpretations of specific requirements of the GMP+ standards, in response to perceived misunderstandings, nonconformities during Compliance Audits, received questions, discussions during harmonization meetings, etc.~~
~~c. IEC: An annual overall report of the results of the Integrity Program in the previous calendar year.~~
~~d. Public: a summary of the annual report about the Integrity Program.~~
~~e. Certification Bodies: When perceived audit results are relevant for compliance assessment of a supplying company, it shall be shared with the involved Certification Body with taking into account the confidentiality restrictions.~~

9 Internal organization

GMP+ International will apply the principles, mentioned in ISO 17021, par. 6 in a comparable way, regarding the organizational structure concerning the implementation and execution of the Integrity Policy. Additionally, the principles of ISO 9001~~:2008~~ Quality management systems will be applied. ~~Certification against ISO 9001 is considered in the future~~.

The different roles and responsibilities regarding the Integrity Policy must be clear. The following roles and responsibilities are distinguished and documented in the internal quality system of GMP+ International:

Roles, tasks, responsibilities	Organizational units
• Overall supervision on implementation of policies and procedures[6] • Allocation of financial and human resources • Development of policies • Decisions about imposing measures on Certification Bodies, including contract extension • Decisions about acceptance of applicant Certification Bodies • Decisions about appointment of CA Auditors • Decisions about guidelines for Compliance Assessments	~~Managing~~ Operations Director
• Carrying out internal audits • Handling of complaints	Quality Manager
• Monitoring performance of Compliance Assessments (CA) and responsiveness to noticed nonconformities • Monitoring Complaints Management (CM), EWS Management (EM) and Exemptions • Assuring impartiality, competence and consistency regarding CA, CM, EM, Exemptions, and of acceptance assessment of CB's, and of CB and CA Auditors • Decisions about actions regarding Compliance Assessments	Internal Integrity Committee (Managing Director/Operations Director, Program Manager Normative Standards and Program Manager Certification & Compliance)
• Handling and management of EWS notifications	EWS team
• Planning & control Compliance Assessments • Technical review Compliance Audit reports • Carrying out retrospective analysis and overall analysis • Harmonization of CB auditors as well as the Compliance Auditors • Assessment of applications of new Certification Bodies • Acceptance / examination[3] CB auditors	Certification & Compliance Assessment team
• Conducting Compliance Audits (by own GMP+ International auditors and hired auditors)	

10 Implementation

~~This Integrity Policy will be implemented in the GMP+ C2 document before summer 2015.~~

~~Additionally, based on the Integrity Policy, the Certification & Compliance team will develop an annual *Compliance Audit Program*, which will be approved by the Managing Director in December of the previous year at the latest.~~

The Compliance Audit Program will be based on partly ad random selection and partly risk assessment results. The risk assessment will be carried out annually with an extra check every six months if it is necessary. It must be defined on the base of several sources of information (i.e. results of audits, results of examination, complaints, EWS, notifications from external sources).

The Certification & Compliance team will transfer the Compliance Audit Program in two Operational Compliance Audit Plans for a period of 6 months each (January – June and July – December).

~~End 2015, this Integrity Policy should be fully implemented.~~

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