

BT-12

Ver 0.5

Execution of internal audits





DOCUMENT HISTORY

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0.0 03/07/2008	Launch of the new GMP: New provisions.	Entire document	01/01/2009
0.1 23/12/2010	Planning of internal audits: clarification regarding the period	Point 6	08/02/2011
	Frequency and contents of the recall exercise Amendments and clarification	Point 9	
0.2 19/12/2012	Indication of a time frame regarding the availability of information related to a product recall.	Point 9	1/03/2013
0.3 02/05/2013	Adaptation of a reference to an existing document	Point 5	02/05/2013
0.4 22/10/2015	Change of name	Entire document	01/01/2016
	Addition of determination regarding control of incidents and crises	Point 10	
0.5 21/10/2016	New lay-out	Entire document	21/10/2016



Table of contents

1. INLEIDING	FOUT! BLADWIJZER NIET GEDEFINIEERD.
2. TOEPASSINGSGEBIED.....	FOUT! BLADWIJZER NIET GEDEFINIEERD.
3. PRINCIPE VAN DE VOLGORDE EN REINIGINGSREGIMES	FOUT! BLADWIJZER NIET GEDEFINIEERD.
3.1. PRINCIPE.....	FOUT! BLADWIJZER NIET GEDEFINIEERD.
3.2. MOGELIJKE SITUATIES	FOUT! BLADWIJZER NIET GEDEFINIEERD.
3.3. REINIGINGSREGIMES	FOUT! BLADWIJZER NIET GEDEFINIEERD.
3.3.1. <i>Afwezigheid van reiniging</i>	<i>Fout! Bladwijzer niet gedefinieerd.</i>
3.3.2. <i>Reinigingsregime A (droge reiniging)</i>	4
3.3.3. <i>Reinigingsregime B (reiniging met water) of C (reiniging met water + reinigingsmiddel)</i>	5
3.3.4. <i>Reinigingsregime D (reiniging met water + reinigingsmiddel + desinfectie)</i>	<i>Fout! Bladwijzer niet gedefinieerd.</i>
4. LIJST VAN TOEGELATEN EN VERBODEN VOORGAANDE PRODUCTEN EN AANVERWANTE REINIGINGSREGIMES	FOUT! BLADWIJZER NIET GEDEFINIEERD.
4.1. PRODUCTEN VERMELD IN TABEL 1	FOUT! BLADWIJZER NIET GEDEFINIEERD.
4.2. PRODUCTEN NIET VERMELD IN TABEL 1.....	FOUT! BLADWIJZER NIET GEDEFINIEERD.
5. TOELATINGSPROCEDURE VOOR DE INSTALLATIE NA OP- OF OVERSLAG VAN EEN VERBODEN PRODUCT	FOUT! BLADWIJZER NIET GEDEFINIEERD.
5.1. PROCEDURE A : VISUELE CONTROLE DOOR EEN EXTERNE INSTELLING, GOEDGEKEURD DOOR OVOCOM VZW	FOUT! BLADWIJZER NIET GEDEFINIEERD.
5.2. PROCEDURE B : ANALYSE VAN HET SPOELWATER.....	FOUT! BLADWIJZER NIET GEDEFINIEERD.



BT-12 : Execution of internal audits

1. Introduction

Point 2.13 of document 'AC-01: General Provisions' states that:

- An internal audit must be planned and performed annually by a person independent of the activity to be controlled;
- A report must be drawn up and registered; and
- Appropriate measures for non-conformities, identified during the audit, will be taken.

This document indicates the way as to how an internal audit should be performed.

2. Scope

The requirements, included in this document are specific to Feed Chain Alliance Standard, and are applicable to all FCA-certified companies.

3. Qualification of the Internal auditor

The internal auditor must be sufficiently qualified. This means that he should have:

- An adequate technical knowledge regarding the activities performed by the company;
- An active knowledge of requirements linked to the application as regards the legislation and FCA Standard;
- A practical experience in terms of audit.

The qualifications of the auditor are registered in the company's quality system, e.g. in a function sheet. The company will define the qualifications of the internal auditor.

4. Independence of the internal auditor

The internal auditor should be independent in relation to the activity to be controlled. This independence requirement will ensure the prevention of a certain "blindness" by the auditor. After all, how can a person keep sufficient distance in order to evaluate his own work, while performing this same work the whole year through.

The entire system must not necessarily be audited by one and the same person. A part of the system (e.g. the "production" part) may be audited by a staff member, active in another department of the company (e.g. purchase), having the requisite skills.

It goes without saying that it is impossible for a quality manager to audit the system's "quality aspects" implemented in the company.

Who can be an Internal Auditor in practice ?

As mentioned above, there is no specific profile type for an internal auditor. It is of the utmost importance that this person satisfies the criteria regarding knowledge and independence, and has adequate knowledge of the FCA Standard and the company's activities, and is independent of the activity to be audited.

Here below you will find a few examples showing a wide range of potential internal auditors:

- A staff member from another 'department' (e.g. purchase);
- A family member (e.g. husband);
- A 'colleague' from another FCA certified company;
- A consultant;
- Etc.

« Internal auditor » versus « external auditor »

Certain external auditors, working for certification bodies, may offer their services and perform consultancy assignments for the company. The participant must always inform the certification body, when calling upon a consultant. This way, the certification body can define with certainty, which external auditor should they send in order to avoid creating a conflict of interest.

An inspection or an audit, performed by a competent authority (e.g. FASFC inspector) cannot be compared with an internal audit, performed in the framework of FCA Standard. Only the aspects relating to compliance with the existing legislation, are treated in this type of audit. On the other hand the results of the inspection, both positive and negative, must be analyzed by the company, who will then respond accordingly.

5. Evaluation of the internal auditor

If the internal auditor is a staff member, a yearly verification is recommended in order to verify whether the internal auditor is still compliant with the requirements (e.g. in relation with the independence criteria).

If the internal auditor is not part of the company, he will need to be evaluated as a service provider (point 6 of document 'BC-01: General Provisions'). This evaluation will take place at least once a year.

The evaluation should at least cover the relevance of the work performed. An internal audit, showing no non-conformities is irrelevant, when the certification body on the other hand, reveals problems with the quality system and the animal feed safety.

In this case, an appropriate training or a replacement of the internal auditor, must be on the agenda.

6. Planning and frequency of the internal audit

The time frame between the internal audit and the external certification audit (initial audit, intermediate audit or renewal audit) must at least be 2 months (see Figure 1).

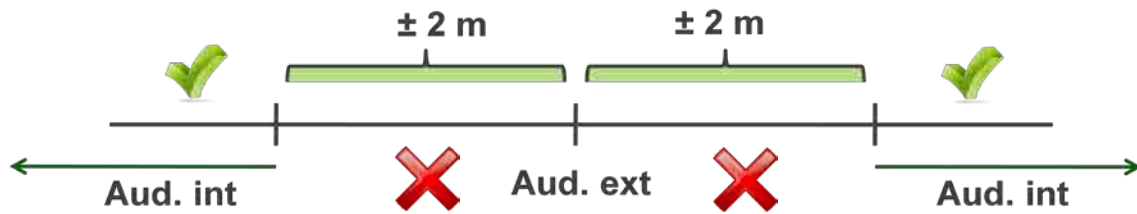


Figure 1 : Planning of internal audit must take place, at least 2 months before or after the external certification audit .

This way, the company has the possibility to examine the quality system as a whole and to determine the areas for improvement.

The internal audit is also a good preparation for the external audit, which usually takes place in better circumstances.

Finally, comparing the results of the internal audit with those of the external audit, provides valuable information for assessing the relevance of the internal auditor's work (see previous point).

If it proved to be impossible, to conduct an internal audit before the external audit (e.g. seasonal activity was delayed due to climatic reasons, or temporary unavailability of staff, the extend of the activities to be audited), the company must record the reasons, and explicitly mention them during the external certification audit.

It is also important that all business units, belonging to the same central quality system, are audited regularly. It is recommended to conduct yearly audits of all the business units.

However, if this seems to be impossible, the following internal audit frequency should be regarded as a minimum, for an organization with multiple business units operating under the same central quality system.

- The minimum number of sites to be audited internally each year (y) is the square root of the number of sites (x) $\rightarrow y = \sqrt{x}$ rounded to a higher unit.

For example in case of a company with 5 units, the internal auditor must audit at least 3 sites a year, including Headquarters.

In function of the complexity of the organization, the multinational aspect of the company, of risks linked to the activities, the history of non-conformities, etc., can the sample size be increased. The sites to be audited are freely determined by the internal auditor.

For the annual determination of sites to be audited, those sites audited the previous year can be taken into consideration; the Headquarters will, in any case be subject to yearly internal audits.

7. Course of an internal audit

Although, some understanding is required as to how an audit should take place, the internal auditor should not necessarily be a professional auditor.

The company must establish a procedure of the way an internal audit is planned and executed, within the company.

In order to verify the adequacy of the company's quality system, as regards the FCA Standard, the internal auditor may rely on various tools, namely:

- A check-list: concerns a questionnaire containing all the requirements included in the FCA Standard to be applied by the company;
- Record of complaints registered during the past year;

- Records of warnings, minutes, etc., prepared by the competent authorities;
- Analysis results;
- Report of previous internal audit reports;
- Report of previous external audit reports;
- Action plan for the for non-conformities and implementation of corrective actions;
- Etc.

If opting for the use of a check-list, this list should be ready before the start of the internal audit. This list will gradually be completed, as the audit progresses.

Use of a checklist is highly recommended, given that:

- The internal audit program, can be outlined by means of these guiding principles;
- All aspects of the FCA Standard will be addressed without forgetting one or the other;
- To repeat the internal audit over the years, even if the internal auditor changes from year to year.

The internal audit must be preceded by an introduction, in order for the auditor to provide clarification of the context in which the audit will take place.

If possible, the internal auditor will question the staff members who are present.

The internal auditor must visit the installations (buildings) as well as the existing material and equipment (e.g. vehicle with a tipping body or cistern trucks, mixing equipment).

At the end of the internal audit, the auditor will hand over his conclusions. Points, which are the object of a non-conformity and in need for improvement, are indicated. In order to highlight the initiatives and progress, it is recommended that the internal auditor mentions the positive points which he might have observed.

Optionally, he may also identify areas for improvement, and suggestions for resolving, any possibly identified, non-conformities.

8. Internal audit report

The internal auditor will draw up a report. The report should minimum contain:

- The date of audit;
- The name of internal auditor (or audit team members);
- The audited persons;
- The visited sites (if the company has more than one business unit);
- The identification of examined buildings and/or vehicles ;
- References to the audited standard (e.g. 'BT-02: Purchase: General Provisions');
- References to documents audited (e.g. internal reference to quality system documents);
- non-conformities recorded and items for improvement;
- Audit conclusions.


The auditor will sign his conclusions. He may also add possible recommendations.

9. Recall simulation

As mentioned in point 3.11 in AC-01, every operator should verify on a yearly basis, the recall procedure. The verification (e.g. verify that the data of the responsible persons are still up to date, and that new staff members are aware of the procedure) should always be registered.

At least every 3 years, or after any changes in responsibilities, or in the procedure regarding registration or production, the company must perform a simulation recall. This recall-exercise should always be recorded. This recall simulation may take place during the internal audit. The lesson learned from this simulation should be recorded and, if necessary, improvements should be proposed where gaps have been identified.

For service providers: If the simulation cannot related to a product (e.g. in the case transport), the exercise will than cover the part 'traceability' as regards the activity and communication with (potential) persons involved (authorities, clients, ordering parties, subcontractors etc.).

 Availability of the information	
Information regarding a possible recall should be available within a reasonable period (target: 4 hours).	
The information should at least include the following:	
<ul style="list-style-type: none">- The batch (or) batches concerned (identification, production date);- The composition of the batch(s);- The list of clients concerned (name, address, herd number (if relevant));- The presumed origin of the hazard, motivating the recall.	
This information shall be made available to the responsible authorities within the same time frame.	

10. Communication of incidents and crises

The application of the requirements contained in document 'BT-17: Incident en crisis management: communication to OVOCOM and the certification body' should be checked annually, e.g. during internal audits, traceability exercise or recall simulation. Such verification (e.g. to check whether data regarding the minimum information to be communicated to OVOCOM for incidents is still correct, or that the new staff has been informed of the procedure), should always be recorded.