

Annex III: Nonconformity grading

1 Introduction

In accordance with the definitions in the Scheme and as defined below, the CB is required to establish and maintain criteria as a reference against which to determine the level of nonconformities resulting in three grading levels:

- a) Minor nonconformity,
- b) Major nonconformity,
- c) Critical nonconformity.

2 Opportunity for improvement

The use of opportunities for improvement during a FSSC 22000 audit is not allowed by the Scheme.

3 Minor nonconformity

A minor nonconformity shall be issued when the finding does not affect the capability of the management system to achieve the intended results:

- 1) When a minor nonconformity is issued during an audit, the organization must provide the CB with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP). This shall be provided to the auditor within three (3) months after the audit.
- 2) Corrective action (CA) shall be implemented by the organization within 12 months after the audit.
- 3) The CB shall review the design of the corrective action plan, challenge it and approve it when acceptable.
- 4) Implementation of the corrective action plan shall be reviewed, at the latest, at the next scheduled on-site audit. The CB shall review the corrective action plan and determine its effectiveness of implementation through recording auditor name and date of review on the CAP.
- 5) A major nonconformity is raised (on management responsibility and resource allocation) in the event of non-completion of the approved action plan at the next scheduled on-site audit.

4 Major nonconformity

A major nonconformity shall be issued when the finding affects the capability of the management system to achieve the intended results:

- 1) When a major nonconformity is issued during an audit, the organization must provide the CB with objective evidence of an investigation into causative factors, exposed risks and the proposed CAP. This shall be provided to the CB within 14 days after the audit.
- 2) Corrective action shall be implemented by the organization within 14 days after the audit.

- 3) The major nonconformity shall be closed by the CB within a further 14 days after implementation of the corrective action by the organization. The organization shall submit objective evidence of implementation to the CB.
- 4) The CB shall review the corrective action plan and related objective evidence of implementation, challenge it if necessary and determine its effectiveness and approve the CAP and CA through recording his/her name and date of review on the CAP.
- 5) The CB shall conduct a follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, the CB may decide to perform a desk review.
- 6) The completion of corrective actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causative factors. In such cases the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented. A follow-up audit shall be conducted to verify the permanent corrective action and to close the major nonconformity.
- 7) A critical nonconformity is raised in the event of non-completion of the approved corrective action.

5 Critical nonconformity

A critical nonconformity is issued when a direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/or certification integrity are at stake:

- 1) When a critical nonconformity is issued at a certified site the certificate shall be immediately suspended for a maximum period of six (6) months.
- 2) When a critical nonconformity is issued during an audit, the organization must provide the CB with objective evidence of an investigation into causative factors, exposed risks and the proposed CAP. This shall be provided to the CB within 14 days after the audit.
- 3) A follow-up audit shall be conducted by the CB within the six (6) month timeframe to verify the closure of the critical nonconformity.
- 4) The certificate shall be withdrawn when the critical nonconformity is not effectively solved within the six (6) month timeframe.
- 5) In case of a certification audit, the full certification audit shall be repeated.