

Submitting Corrective Actions to the NOP

Graham Davis
January 31, 2017
USDA Agricultural Marketing Service
National Organic Program



Training Overview



- Review the process for developing and submitting corrective actions
- Review the components of a corrective action submission
- Examples of insufficient and sufficient submissions

Background



During the accreditation process, the NOP occasionally encounters certifying agents not complying with USDA organic regulations and NOP policies. When this occurs, the NOP issues a notice of noncompliance to the certifying agents.

"Certifying agents are required to submit corrective actions that **adequately address** noncompliances identified by the NOP in a **timely manner**."

See NOP 2608 Instruction Responding to Noncompliances in the NOP Program Handbook

Example - Noncompliance



NC1 –7 CFR §205.402(a)(2) states that "Upon acceptance of an application for certification, a certifying agent must:.. Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part..."

Comments: De Best Certified Organic (DBCO) approved a "Made with Organic ***" label that displayed the word "organic" on the front panel with no "Made with Organic" phrase.

Reading a noncompliance



 The noncompliance cites the specific USDA organic regulation that the certifying agent is not in compliance.

 The comments section explains how the certifying agent is not in compliance.

Reading a noncompliance



If You Need Clarification What Should You Do?

Contact your Accreditation Manager

Developing a Corrective Action



- First, identify the underlying cause(s) of the noncompliance.
- Second, determine which appropriate actions should be taken to
 - ✓ Bring the certifier into compliance.
 - ✓ Prevent reoccurrence of the noncompliance.
- Third, control noncompliant product, when applicable
 ✓ Ex: Correct a product label



Step 1

- Identify the cause(s) of the noncompliance
 - ✓ Provide a brief explanation of the cause.
 - ✓ The root cause of the noncompliance will dictate the necessary corrective actions.
 - ✓ Corrective actions cannot be accepted unless the NOP understands the cause of the noncompliance.

Example - Noncompliance



NC1 –7 CFR §205.402(a)(2) states that "Upon acceptance of an application for certification, a certifying agent must:.. Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part..."

Comments: De Best Certified Organic (DBCO) approved a "Made with Organic ***" label that displayed the word "organic" on the front panel with no "Made with Organic" phrase.



Step 1

- Identify the cause of the noncompliance
 - ➤ Possible causes of the noncompliance
 - ✓ DBCO staff member approved a label but didn't understand label regulations.
 - ✓ DBCO doesn't have documentation that verifies the approval of this label.

The corrective actions submitted for this noncompliance are dependent upon which of these is the root cause of the noncompliance.



Step 1

- Identify the cause of the noncompliance
 - ✓ DBCO staff member approved a label but didn't understand label regulations.

The root cause of the noncompliance has been identified and will dictate the necessary corrective actions

Example – Correcting the Noncompliance



Step 2

- Correct the noncompliance
 - Describe the verifiable action that will bring the certifying agent into compliance.
 - ✓ A notice of noncompliance was issued to the operation for the noncompliant label.
 - Provide objective evidence (i.e. documentary evidence) supporting how the noncompliance was corrected.
 - ✓ A copy of the Notice of Noncompliance to the operation (Attachment A) was submitted.



Step 2 (Cont.)

- Prevent the reoccurrence of the noncompliance
 - Describe the verifiable action that prevents a reoccurrence of the event.
 - ✓ Refresher training on label review is needed for certification staff, focused on "Made with Organic" labels. Training on label review is planned for June 9, 2016.
 - ✓ The Review Procedures Manual was updated to include checklist that ensures organic claims, and the USDA seal aren't used on product labels certified to the "Made with Organic ***" labeling category.
 - Provide documented evidence indicating how the implemented actions will be effective in preventing a reoccurrence.
 - ✓ Label review training materials (Attachment B) was submitted
 - ✓ The Review Procedures Manual (Attachment C) was submitted



Step 3

- Controlling noncompliant product, when applicable
 - ✓ A corrected a product label (Attachment D) was submitted.



- Organize the corrective action submission so that it can be easily reviewed and understood
 - ✓ Include the regulation cited for the noncompliance
 - ✓ Include the comments
- Recommended formats for corrective action submissions
 - ✓ Table
 - ✓ Bullet points
 - ✓ Narrative

For corrective actions that will be implemented at a later date, include the implementation date and timeframe for completion.

Examples of Objective Evidence

- <u>Training</u>: A copy of the training agenda, training materials, an attendance list or sign in sheet, policy memos and/or quality manual updates covered in the training.
- Organic System Plan (OSP) Updates: A copy of the updated OSP template and any related policy memo and/or quality manual updates made as a result to OSP modifications, along with details and documents supporting any training.
- Procedural Changes: A copy of the updated policy memo and/or quality manual update, standard operating procedure (SOP) update resulting from the corrective action, along with details and documents supporting any training provided.

Clearly identify what was revised in the objective evidence that is submitted (please highlight the revised section(s) of a document). For procedural changes please indicate how your staff was made aware of the changes.

ORGANIC



Objective evidence supporting the action taken to correct the noncompliance:

Please clearly label all attachments

Ex: DBCORPMVerB4.5.pdf



Objective evidence supporting the action taken to correct the noncompliance:

Please clearly label all attachments

DBCORPMVerB4.5.pdf Bad

Annex1_DBCO_Review_Proc_VerB4.pdf Better



Objective evidence supporting the action taken to correct the noncompliance:

Please clearly label all attachments

DBCORPMVerB4.5.pdf Bad
Annex1_DBCO_Review_Proc_VerB4.pdf Better
NC1_DBCO_Proc_Man_VerB4.pdf Best



Documents library example 2	Arrange by: Folder ▼
Name	Date modified
2016NC9	11/25/2016 7:38 PM
2016NC8	11/25/2016 7:38 PM
2016NC7	11/25/2016 7:37 PM
2016NC6	11/25/2016 7:37 PM
2016NC5	11/25/2016 7:37 PM
2016NC4	11/25/2016 7:37 PM
2016NC3	11/25/2016 7:37 PM
2016NC2	11/25/2016 7:36 PM
7 2016NC1	11/25/2016 7:36 PM

This corrective actions submission lacks a document that contains the narrative, bullets points, or table that explains the root cause of the noncompliance, the immediate corrective action, and the prevention of reoccurrence. It only contains the objective evidence.



Documents library example	Arrange by: Folder ▼
Name	▼ Date modified
ANNEX 7 - notice of denial ANNEX 6 - combined notice of noncompliance and pro ANNEX 4 - notice of suspension ANNEX 3 - notice of proposed suspension ANNEX 2 - notice of noncompliance ANNEX 1 - Mod CONP r 4 2016_10_31 CONTRACT USDA A Findings and Proposed CA	9/30/2016 8:24 AM 9/30/2016 8:25 AM 9/30/2016 8:22 AM

This corrective actions submission contains all of the required documents (i.e., the narrative and objective evidence).

USDA ORGANIC

USDA National Organic Program

Accreditation and International Activities Division Room 2646--S, Stop 0268

Washington, DC 20250--0268

To Whom It May Concern:

On November 30, 2016, we received a letter reporting a noncompliance recorded from our Mid--term Audit on the DBCO's organic certification program. This letter is to address the noncompliances issued.

The following actions have been taken to address the noncompliance:

NPXXXXXX.NC1: All certificates issued from the date of the mid--term audit have the anniversary date listed as "April 1st" which is when renewals are due each year. "Grower" has been changed to "Crops" (Attachment A). These two changes are in the certificate code managed by in--house DBCO IT Support and will automatically be changed for all certificates as they are generated.

This corrective actions does not include the specific USDA organic regulation the certifying agent is not complying with and the comments section that explains how the certifying agent is not in compliance.

USDA National Organic Program

Accreditation and International Activities Division Room 2646--S, Stop 0268

Washington, DC 20250--0268



To Whom It May Concern:

On November 30, 2016, we received a letter reporting a noncompliances recorded from our Mid--term Audit on the DBCO's organic certification program. This letter is to address the noncompliance issued.

The following actions have been taken to address the noncompliance:

NPXXXXXX.NC1: 7 CFR §205.402(a)(2) states that "Upon acceptance of an application for certification, a certifying agent must:.. Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part..."

Comments: De Best Certified Organic (DBCO) approved a "Made with Organic ***" label that displayed the word "organic" on the front panel with no "Made with Organic" phrase.

Cause of NC1: DBCO staff member approved a label but didn't understand label regulations.



Corrective Action: A notice of noncompliance was issued to the operation for the noncompliant label. Copy of the Notice of Noncompliance to the operation (Attachment A).

Prevention of Reoccurrence: Refresher training on label review is needed for certification staff, focused on "Made with Organic" labels. Training on label review is planned for June 9, 2016 (*Label Review Training materials – Attachment B*). The Review Procedures Manual (*Attachment C*) was updated to include checklist that ensures organic claims, and the USDA seal aren't used on product labels certified to the "Made with Organic ***" labeling category.

Controlling noncompliant product: Corrected product label (*Attachment D*)

This corrective action submission has all of the required elements.



Documents library

example 3

Name



NPXXXXXX.NC1 and Proposed CA



Attachment D - Corrected Label



Attachment C - Label Review Procedures



Attachment A - Notice of Noncompliance



Attachement B - Label Review Training Materials

This documents library contains all of the required documents (i.e., the narrative and objective evidence).

Arrange by: Folder ▼

Rebuttals

Certifiers choosing to rebut a noncompliance must:

• Clearly identify which noncompliance is being rebutted and submit objective evidence that supports your argument.

Rebuttals will be reviewed, and if accepted by the NOP, the noncompliance is removed from the report with a note that it was withdrawn. If the rebuttals are not accepted by the NOP, corrective actions will need to be submitted.

ORGANIC

Rebuttals



- When would you submit a rebuttal?
 - ✓ When you think the auditor made an error.
- When would you **not** submit a rebuttal?
 - ✓ When you made a correction (based on a finding during the audit) prior to receiving the NC report.