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Subject:Ack: Appeal Acknowledgement - ETKODate:Friday, January 22, 2016 2:32:49 PM

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From: RPost

To: <u>Kuhn Meg - AMS</u>

Subject: Ack: Executed Settlement Agreement, ETKO - APL-008-16

**Date:** Wednesday, April 13, 2016 4:25:41 PM

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From: RPost

To: <u>Kuhn Meg - AMS</u>

Subject: Ack: Proposed Settlement Agreement - ETKO, APL-008-16

**Date:** Friday, March 25, 2016 1:23:47 AM

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January 15, 2016

# VIA REGISTERED EMAIL

Administrator, Agricultural Marketing Service United States Department of Agriculture c/o NOP Appeals Team Room 2648 –S, STOP 0268 1400 Independence Avenue S.W. Washington, DC 20250-0268

Re: National Organic Program
Appellant: ETKO, Ecological Farming Control Organization
Appeal of Notice of Proposed Suspension of Accreditation
Issued by National Organic Program, December 18, 2015

Dear Mr. /Ms. Administrator:

I am counsel to ETKO, Ecological Farming Control Organization (hereafter "ETKO"), in Izmir, Turkey. ETKO is an Accredited Certifying Agent of the USDA National Organic Program (NOP), accredited to certify crop, wild crop and handling operations. The NOP first granted accreditation to ETKO nearly 13 years ago, on January 22, 2003, and renewed ETKO's accreditation on January 22, 2008. ETKO's current certificate of accreditation is attached as Attachment A. According to the latest available data on the NOP Organic Integrity Database, ETKO certifies 50 operations under the NOP.

ETKO, founded in 1996, certifies 526 operations worldwide under several different standards, including organic standards (NOP, EU and Turkish standards), GlobalGap, GOTS and other textile standards, and COSMOS cosmetics standards. It was first accredited by International Organic Accreditation Services (IOAS) in 2005.

ETKO applied to the NOP for renewal of its NOP accreditation in June 2012. As part of the NOP's renewal assessment, the NOP conducted an on-site audit of ETKO on May 12-16, 2014. One year later the NOP issued a Notice of Noncompliance, dated May 13, 2015, based on that audit, charging ETKO with seven noncompliances. The Notice of

Noncompliance and the 16-page report of the May 12-16, 2014, audit are attached as Attachment B.

While ETKO was fully responsive and prompt in proposing corrective actions, the NOP determined that the noncompliances were not resolved, and on December 18, 2015, the NOP issued a Notice of Proposed Suspension against ETKO The Notice of Proposed Suspension, in a two-page letter signed by Deputy Administrator Miles V. McEvoy, was accompanied by the report of the May 12-16, 2014, audit and a six-page Corrective Action Report dated November 3, 2015. The Notice and the two accompanying reports are attached as Attachment C.

ETKO hereby submits this timely appeal of the NOP's Notice of Proposed Suspension. By filing this appeal, ETKO seeks to have the NOP (a) rescind this notice, and (b) take the further steps to renew ETKO's accreditation.

# NOP Gave Three Grounds for ETKO's Suspension and ETKO's Response

Deputy Administrator McEvoy's letter gave three grounds for proposing that ETKO's accreditation be suspended. The first ground was "the number, and severity of the noncompliances issued during the NOP Renewal Assessment." The second ground was "the multiple inadequate submissions of corrective actions from ETKO." The third ground was "the suspensions of organic program accreditations by IOAS, EU and CFIA." This refers to the fact that in the period of March 30 – April 23, 2015, International Organic Accreditation Services (IOAS), the EU's European Commission (EC) and the Canadian Food Inspection Agency (CFIA), which had all granted accreditation to ETKO as an organic certifier outside the United States, suspended their respective accreditations of ETKO.

In this appeal letter, ETKO will challenge all three of the NOP's grounds as not being a valid basis for the NOP to suspend ETKO.

Regarding the NOP's first charge, *i.e.* that suspension is justified by the "number, and severity of the (seven) noncompliances issued during the NOP renewal assessment," this is merely a vague, subjective statement. It cannot therefore provide any basis for suspending ETKO.

This is a vague, subjective statement because the NOP does not have any specific, objective standard to indicate how many noncompliances need to exist in order to justify suspension of an accredited certifying agent. Nor does the NOP have a specific, objective standard to measure the "severity" of a noncompliance. Whether a noncompliance is "severe" or not is not relevant, until it is determined whether or not the so-called "severe"

noncompliance has been or can be remedied with appropriate corrective action. The NOP's penalty matrix, NOP 4002, effective January 20, 2015, attempts to measure the weight of noncompliances to enable "consistent responses to noncompliance...across certifiers and certified operations." (NOP 4002, Background, page 1.) However, NOP 4002 is not applicable in this case because it applies only to noncompliances against certified operators, not to noncompliances brought by the NOP against accredited certifying agents.

The specific facts in this case bear out that the NOP does not have a consistent standard for either the "number" or the "severity" of noncompliances lodged against certifying agents. The NOP had knowledge of these seven noncompliances as soon as it completed its on-site audit of ETKO on May 12-16, 2014. (See Attachment B, Noncompliance Report from on-site audit of May 12-16, 2014.) Nevertheless, it took a full year for the NOP to issue the Notice of Noncompliance to ETKO. (See Attachment B, Notice of Noncompliance dated May 13, 2015.) While the NOP now contends that the seven noncompliances were of such a "number, and severity" to call for ETKO's suspension, if the NOP had truly considered these seven noncompliances so numerous and so severe, it would not have waited so long — a full year — before it sent the Notice of Noncompliance. By not receiving notice of these noncompliances in a timely fashion, ETKO therefore lost a full year in which it could have taken the necessary corrective action.

Turning to the NOP's second charge, *i.e.* that there were "multiple inadequate submissions of corrective actions from ETKO," this is a broad, subjective statement that is not verified when the record itself is examined. For this appeal ETKO has reviewed the NOP's evaluation of the submissions it received from ETKO as corrective action. As this appeal letter will show later in specific detail, the charge of "multiple inadequate submissions" cannot be supported. Four of the noncompliances – NC 21, NC 4, NC5 and NC6 – had only one submission or no submission after ETKO's original submission. NC2 had two submissions, NC3 had three, and NC1 had four.

Turning to the noncompliances that had the most "multiple" submissions of corrective action, NC3 with three and NC1 with four, even these do not support the NOP's charge that the submissions were both "multiple" and "inadequate."

ETKO made three separate submissions to the NOP to follow up on NC3. This was because the NOP itself was working patiently with ETKO until ETKO's corrective action was accepted. NC3 required ETKO to have a rather full knowledge of the regulations for bringing adverse actions against operators. ETKO, coming from Turkey, was not familiar with the U.S. legal formalities and this is why it had to make three submissions before it satisfied the NOP.

NC1 did require four submissions. Of the seven noncompliances, NC1 was the most difficult one to resolve through corrective actions. NC1 involves a practice used only by farm operators in Ukraine in which the operators have uncertified subcontractors under their ownership. ETKO, which has several Ukraine farm clients, has been allowing them to continue following this local practice. When it received the NOP's Notice of Noncompliance on May 13, 2015, ETKO saw that NOP required ETKO to arrange to bring these subcontractors in Ukraine under certification for the first time. The complexities of the corrective action under NC1 caused the NOP to request four separate submissions from ETKO between July 21 and November 19, 2015, but even in this protracted case, in the end the response submitted by ETKO was apparently adequate.

Therefore, it is a gross exaggeration for the NOP to charge ETKO in general with "multiple inadequate submissions of corrective actions." The email correspondence between the NOP and ETKO shows that in the period from May 13 through November 19, 2015, there was a good faith effort on both ETKO's part and the NOP's part to resolve the few remaining points promptly. ETKO rightly assumed it would eventually receive renewal of its NOP accreditation. Therefore, it came as a complete surprise to ETKO when it received the Notice of Proposed Suspension on December 18, 2015.

Finally, the NOP's third charge is that ETKO should be suspended by the NOP because of the "suspensions of organic program accreditations by IOAS, EU, and CFIA." The NOP's position appears to be that because ETKO has been suspended during the past year by these other accreditation authorities, the NOP should respect those decisions and simply follow suit.

Instead of automatically following the accreditation decisions taken against ETKO by these other authorities, the NOP has the responsibility to take an independent look at ETKO's situation. The NOP should, first, determine whether ETKO has failed to comply with the NOP's own standards for certifying agents. Second, the NOP needs to consider both the motivation behind the suspensions of ETKO by the other authorities and the current status of ETKO vis-à-vis those authorities.

Prior to March 30, 2015, ETKO was on the list of countries authorized by the European Commission to issue organic certificates in non-EU member countries, such as Turkey, that are not recognized by the EU as "third countries." On March 30, 2015, the European Commission withdrew ETKO from that "list of recognized control bodies and control authorities for the purpose of equivalence." On April 23, 2015, IOAS "suspended" ETKO's accreditation under ISO 17065 and also ETKO's accreditation under CFIA, because IOAS operates CFIA's accreditation program. While ETKO was on notice that it was no longer being accredited under CFIA as of April 23, the CFIA did not issue a public

announcement of ETKO's suspension until July 31, 2015. It must be noted that these two latter two "suspensions" restrict ETKO's activities but are only provisional suspensions of its accreditation. The IOAS and CFIA "suspensions" can still be lifted if certain requirements are met. By comparison, the "suspension" that the NOP is proposing pursuant to 7 CFR § 205.665(f) would be a total cessation of ETKO's NOP certification activities, calling for the transfer of ETKO's NOP certification records to the NOP.

This appeal letter will explain below how these actions against ETKO stemmed from a unique certification situation in Ukraine that was not reflective of ETKO's overall performance as a certifying agent in Turkey and other countries. Finally, this appeal letter will describe how in the several months that have elapsed since ETKO received these suspensions, ETKO has used this time to put itself on a path to become reinstated by IOAS in the near future. This will secure ETKO's reinstatement with CFIA as well, and will set the stage for ETKO to reapply to the European Commission. If the NOP is scrutinizing its own accreditation of ETKO because of the suspensions made last year by the other authorities, then as ETKO regains its accreditation with the other authorities, this should no longer be an issue affecting the NOP's accreditation of ETKO.

In the remainder of this appeal letter, ETKO will show in more detail:

- that by reviewing the record of all seven noncompliances, the NOP's charge that there were "multiple inadequate submissions of corrective action," its second ground for suspension, is without basis, and
- that the previous suspensions of ETKO by IOAS, the EC and CFIA, the NOP's second ground, should not cause the NOP to take similar action against ETKO.

# ETKO Did Not Submit "Multiple Inadequate Submissions of Corrective Action"

In the May 12-16, 2014, audit of ETKO, the NOP started out with 26 prior noncompliances, for which it needed to verify the corrective action. The corrective action for these noncompliances was last verified in 2010. The NOP withdrew one of the noncompliances, leaving a set of 25 prior noncompliances. The NOP verified that in 24 of the prior 25 noncompliances the prior corrective action from 2010 remained valid.

As for the one remaining noncompliance from the set of 25, NP9222ZZA.NC21 (hereafter "NC21"), the auditor raised a number of concerns so that he could not verify the previously approved corrective action for NC21. Consequently NC21 was reclassified as an outstanding noncompliance again. In addition, the May 12-16, 2014, audit found six new

noncompliances: NP4132LCA.NC1 through NC6. (See Attachment B, Noncompliance Report, pages 14-16.)

Therefore, the seven noncompliances that remained outstanding were NC21 plus the six that were newly found in the May 12-16, 2014, audit. After ETKO received the Notice of Noncompliance on May 13, 2015, it formulated a corrective action plan that fully addressed all of these noncompliances and presented the plan to the NOP. (Attachment D.)

This appeal letter will now review the seven current noncompliances in their numerical order, starting with NC21 and continuing with NC1, 2, 3, 4, 5 and 6. This review will show that NC1 required three submissions, NC, two, and NC3, four. All the rest required one or no submission. This shows that the "multiple" submissions were confined to a few noncompliances. In any event, none of the corrective action submissions ended up as "inadequate" responses.

# NC21: The NOP Never Indicated Corrective Action was "Inadequate"

On page 14 of the NOP Noncompliance Report (Attachment C), the NOP set forth the text of NC21 with its original corrective action in 2009-10 and the auditor's attempt to verify that corrective action in the audit of May 12 -16, 2014:

NP9222ZZA.NC21 – Outstanding. 7 CFR §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part." Interviews conducted, records reviewed, and witness inspections observed, verified a general lack of understanding of the NOP standards. While personnel had sufficient experience and education in organic agricultural production and handling practices, there was insufficient understanding on the application of the NOP standards as evidenced by inadequate information in the approved organic compliance (system) plans with no issues of concern or non-compliances being identified over multiple years of certification. The primary Certification Committee (CC) member with expertise in crops was not familiar with basic requirements such as the 90/120 day rule for raw manure application, did not know where to reference in the NOP Rule to determine if an input is permitted, and did not know when commercially available seeds and planting stock could be used. Additionally, while it was stated that the Certification Committee (CC) had received training there were no training records for any of the CC members prior to 2009.

Corrective Action: ETKO conducted training of inspectors, reviewers, and Certification Committee members on November 21, 2009 and March 12-14, 2010 which covered NOP standards, review, inspection, and certification procedures. ETKO has designed a 2010 training plan to ensure periodic training on the NOP is completed. ETKO submitted records of training for all inspectors, reviewers, and Certification Committee members.

**2014 Verification of Corrective Action:** The NOP auditor found the following issues of concern that demonstrated an insufficient understanding of the USDA organic regulations and NOP policies:

- 1. Label review the label review checklist did not include USDA organic regulation label requirements to be verified.
- 2. Inspectors during the witness audits used incorrect regulation citations during exit interviews to identify findings.
- 3. OCP templates state the incorrect USDA organic regulations.
- 4. Inspectors are using outdated USDA organic regulations (2010).
- 5. Inspectors and reviewers not readily able to look up regulations.
- 6. ETKO personnel have an incomplete understanding of the noncompliance and adverse action notification procedures.
- 7. Several crop operation OCPs reviewed by the NOP auditor indicated "Not Applicable" for Crop Rotation practice standard (205.205).
- 8. ETKO personnel did not understand and document buffer zone requirements (205.202(c)).

Because the auditor found these issues of concern and thus was not able to verify the earlier corrective action, the auditor reopened NC21 as an outstanding noncompliance in the Notice of Noncompliance issued to ETKO on May 13, 2015 (Attachment B). In response, ETKO submitted corrective action, which the NOP recorded in its Corrective Action Report of November 3, 2015 (See Attachment C, Corrective Action Report, page 4.) The NOP described ETKO's corrective action as follows:

**2015** Corrective Action: ETKO submitted PowerPoint presentations, updated forms, training agenda, and training log of the training that was conducted for inspectors, staff, and advisory committee members. The documentation submitted also included copies of completed OCPs with documented buffer zones, and crop rotation practices.

ETKO has designated a responsible person to follow up on NOP updates to the Program Handbook and regulations. This person will translate all updates and provide them to staff members and inspectors by email and/or hardcopy. When necessary, related staff members will be trained for specific updates. The training

will be recorded in the training register (new document) and the register will be provided to USDA with ETKO's annual reporting. A copy of the training register form was submitted to NOP.

Even though the auditor had raised eight specific issues of concern under NC21, the NOP, in its correspondence with ETKO between May 13, 2015, and December 18, 2015, appeared to be generally satisfied with ETKO's corrective action on NC21. The corrective action plan ETKO submitted (Attachment D) contained a response to each of the eight points. The NOP raised only one question, concerning issue #4. In an email to ETKO on October 15, 2015, Penny Zuck of the NOP asked, "I understand an updated version of the NOP regulations was provided to all staff. Who will be in charge of making sure ETKO monitors the NOP's updates to the NOP regulations? And how will staff and inspectors be informed of the updates?" (Attachment F.) ETKO replied in an email on November 1, 2015, as follows:

Mustafa Akyüz is responsible person to follow up NOP updates and will inform ETKO staff and inspectors by translating the updates. Translated original document will be transferred by email and/or as printed form. When necessary related staff members will be trained for specific updates. Training will be recorded for Training register and this register will be provided to USDA with annual reporting. (Attachment F.)

Having received this answer from ETKO, the NOP included it in its description of ETKO's corrective action (above). The single question and answer meant that there were no "multiple" corrective action submissions for NC21. ETKO adequately responded to NC21.

NC1: While the NOP Questioned ETKO Four Times About Corrective Action, ETKO's Answers Were, in the End, Adequate

NCI, as noted earlier, identified the need for ETKO to bring all subcontractors, which are processors for certified producers, into certification as well. ETKO notes that the practice of having uncertified processors as subcontractors is prevalent in Ukraine, but not in other countries where ETKO certifies. Even though Ms. Zuck, in her email to ETKO on November 12, 2015 (See Attachment E) told ETKO the NOP was accepting ETKO's corrective action on NC1, she continued to press ETKO to provide more specific information. In all, the NOP posed questions to ETKO about NC1 on four dates: July 21, July 29, November 12 and November 19, 2015. NC1 proved to be the most difficult noncompliance of the seven that ETKO and NOP were dealing with, but ultimately ETKO was able to provide specific answers. Therefore, if in the eyes of the NOP ETKO had not provided "adequate" responses, this was not a conclusion that can be justified.

This noncompliance was first noted in the NOP audit of May 12-16, 2014, and first revealed to ETKO in the Notice of Noncompliance on May 13, 2015. The following is the text of NC1 and the NOP's description of the corrective action ETKO submitted following the Notice of Noncompliance:

NP4132LCA.NC1 -7 CFR §205.501(a) (3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670." Furthermore, NOP 4009, Instruction – Who Needs to be Certified?, states "The OFPA requires that agricultural products sold or labeled as organically produced must be produced only on certified farms and handled only through certified handling operations (see 7 USC § 6506(a)(1)). The USDA organic regulations reiterate these requirements (see 7 CFR 205.100)."

**Comments:** ETKO certifies projects that contain uncertified operations (i.e. contractors) that produce or handle organic products that are not certified entities.

Corrective Action: ETKO stated it will certify each subcontracted processing facility during the 2015 production period. ETKO sent a letter to all clients in August 2015 informing them of this requirement. ETKO issued a new instruction for staff, NOP Certification of Subcontracted Operators (Tl 48), which describes the basic rules of subcontracted facilities under NOP certification requiring separate certification. ETKO updated the NOP procedure section 7.2.2.3 Processing and Handling Facilities, which requires subcontractors to be certified separately and refers to the instruction (Tl 48) for details. ETKO staff was trained during the annual training in July 2015.

There is no indication that the NOP had evaluated ETKO's corrective action on NC1 and found it inadequate. There were instances in which the NOP requested further information from ETKO on how it would deal with the question of bringing uncertified contractors into certification. ETKO fully responded to these requests.

On July 21, 2015, Ms. Zuck, in an email to ETKO, noted that ETKO's Corrective Action Plan "indicates you will certify each subcontracted facility during the 2015 production period." She asked, "Can you please submit documented evidence of how this is being handled, such as notification letters to clients, etc." On July 23, 2015, ETKO replied in an email, attaching the draft letter that ETKO would be sending to its certified clients regarding the requirement to certify their processing subcontractors. ETKO asked for advice on whether storage, transport and forwarding facilities needed to be certified. (See Attachment E).

On July 29, 2015, Ms. Zuck replied to answer ETKO's question, to point out that the draft letter was not complete and to request a timeline by which ETKO intended to certify each subcontracted processor during the 2015 production period. On August 12, 2015, ETKO responded with a new draft of the letter which was much more detailed. (See Attachment E.)

From that date on, until November 12, ETKO received no further emails from Ms. Zuck concerning NC1. From August 14 to October 15, 2015, ETKO received no further correspondence from NOP on any of the seven noncompliances. NOP resumed its emails to ETKO on October 15 but did not bring up NC1 until November 12, when Ms. Zuck wrote that the NOP was accepting ETKO's corrective action, but asked ETKO to indicate "how you prevent this from occurring in the future. Did you change any procedures, train the staff so they know how to handle new applicants with uncertified contractors?" Pointing out that she wanted to "get these noncompliances corrected and accepted" as soon as possible, she reminded ETKO that ETKO's application for renewal would have to be reviewed by the NOP Accreditation Committee. She asked for ETKO to respond by November 18. The following day, on November 13, ETKO responded to provide Ms. Zuck with an updated ETKO procedure on the certification of subcontracted operators. (Attachment E).

This still failed to satisfy Ms. Zuck. On November 19, 2015, Ms. Zuck sent ETKO a further question on NCI:

ETKO mailed a letter to clients informing and instructing them about all contracted operations required to be certified separately by December 31, 2015. How many contracted operations did this affect? Have they all obtained their own certification yet? If not, what is the status report on this and detailed plans to carry out your corrective action?

Ms. Zuck requested an answer to this and other questions by November 27. On December 1, 2015, ETKO provided its answer: "We contracted so far 26 handling/processing facilities and 24 already inspected, certification process going on. There will be few other will be inspected within December. No subcontractor certification was accepted this year we comply this rule 100% this year." (Attachment E.) There was no further correspondence on NC1 between the NOP and ETKO prior to December 18, 2015, when the Notice of Proposed Suspension was issued.

In summary, while the NOP in retrospect might claim that ETKO's responses on NCI were "multiple" and "inadequate," ETKO tried to answer every question to the best of its ability. ETKO said in its original corrective action that it would be making its best efforts to have all the subcontractors certified during the 2015 production period. The NOP appeared to be pressing ETKO for a firmer guarantee that this would happen, and for a guarantee that the problem would not arise again. ETKO's final response, on December 1, 2015, was a specific answer as to the status of this corrective action. Under the circumstances, ETKO's responses may have fallen

short of what Ms. Zuck was requesting, but can hardly be considered as so "inadequate" as to call for ETKO's suspension.

# NC2: The NOP Never Indicated that Corrective Action was "Inadequate"

Noncompliance NC2 was first noted in the NOP audit of May 12-16, 2014, and first revealed to ETKO in the Notice of Noncompliance on May 13, 2015. The following is the text of NC2 and the NOP's description of the corrective action ETKO submitted following the Notice of Noncompliance:

NP4132LCA.NC2 -7 CFR §205.404(b) (3) states, "The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation."

**Comments:** Certificates do not adequately indicate the certification scopes of Crop, Wild Crop, and Handling/Processing.

Corrective Action: ETKO submitted copies of corrected certificates identifying the scopes of certification. To prevent this from recurring, ETKO has updated the certificate template and the corrected form will now be used. ETKO submitted a copy of the revised template document with the correct NOP scopes of certification.

On July 21, 2015, after ETKO had sent numerous emails to the NOP attaching documents, Ms. Zuck wrote to ETKO stating that she still needed two items, including the following item on NC2: "The Corrective Action plan indicates corrected certificates including scopes of certification were attached, but I did not receive the certificate examples as an attachment to any of the emails." (Attachment F.)

ETKO provided these certificate examples. Then, on October 15, 2015, Ms. Zuck wrote to ETKO again regarding NC2, this time requesting evidence of ETKO taking a preventative measure: "Copy of a corrected certificate was submitted to NOP, but a description and documented evidence of how you will prevent a reoccurrence of this noncompliance was not submitted. What is ETKO's preventative action that will prevent this from occurring in the future?" On November 1, 2015, ETKO responded, "NOP Certificate format was updated, this form will be used from now on to avoid problems. See NOP Certificate." (Attachment F.)

The NOP's description of ETKO's corrective action incorporated the information ETKO provided. There is no indication that the NOP considered ETKO's response to NC2 as "inadequate."

# NC3: The NOP Never Indicated that Corrective Action was "Inadequate"

Noncompliance NC3 relates to ETKO's procedures and templates for adverse actions. The NOP regulations for adverse actions stem from the Due Process clause of the U.S. Constitution, and embody formalities and legal nuances that can be difficult for some certifiers to master, especially certifiers in countries such as Turkey which do not have a legal system modeled after the U.S. or British systems.

NC3 was first noted in the NOP audit of May 12-16, 2014, and first revealed to ETKO in the Notice of Noncompliance on May 13, 2015. The following is the text of NC3 and the NOP's description of the corrective action ETKO submitted following the Notice of Noncompliance:

NP4132LCA.NC3 -7 CFR §205.662(c) states, "When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent... shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance....The notification of proposed suspension or revocation of certification shall state: (1) The reasons for the proposed suspension or revocation; (2) The proposed effective date of such suspension or revocation; (3) The impact of a suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681."

Comments: ETKO suspended an operation without issuing a Notice of Proposed Suspension. The same operation after receiving the Notice of Suspension effective for 30 days was issued a Notice of Proposed Revocation and subsequently a Notice of Revocation. The sequence of issued notices and contents of the notifications demonstrate that ETKO does not fully comprehend the process of issuing notifications for noncompliances and adverse actions.

Corrective Action: ETKO has updated their procedures and trained staff and inspectors on the following: NOP 4002 Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix, NOP Penalty Matrix 2612 and NOP 4011 Adverse Action Appeal Process for the NOP. These documents were translated into Turkish in order to provide better understanding of the procedures by NOP involved ETKO staff members. The translated documents, training documents and agenda were submitted to NOP. Further, ETKO will check the NOP Handbook regularly and pertinent documents will be translated immediately. Translated documents will be studied with related staff and inspectors.

ETKO submitted NOP Handbook documents to NOP as they were being translated.

On July 29, 2015, Penny Zuck informed ETKO that the updated procedures and adverse action templates ETKO had submitted were not in compliance with the NOP regulations. She painstakingly explained that after a Notice of Proposed Suspension or Notice of Suspension of an operator, it was no longer possible for the operator to submit corrective action in response to the underlying noncompliance. Similarly she explained the difference between a Notice of Suspension and a Notice of Revocation; she explained what a Notice of Revocation means and explained that after a Notice of Revocation it is not possible for the operator to submit corrective action, with the operator's remedies being only to file an appeal or to request mediation. She directed ETKO to consult the regulations on noncompliance procedure at 7 CFR § 205.662 and the NOP Training Modules for appeals and settlements.

On August 13, 2015, Ms. Zuck wrote again to ETKO to state that despite ETKO's revisions to its adverse action templates and procedures, they were still incorrect and stated the reasons. Ms. Zuck acknowledged, "I know these procedures can be very confusing, so please let me know if you have any further questions or need to discuss in further detail." She asked for a response by August 21.

On October 15, 2015, Ms. Zuck wrote to ETKO to acknowledge that ETKO had satisfactorily corrected NC3: "ETKO translated the following documents into Turkish and conducted training of staff: NOP 4002 Instruction Enforcement of the USDA Organic Regulations; Penalty Matrix, NOP Penalty Matrix 2612, and NOP 4011 Adverse Action Appeal Process for the NOP." This statement was reflected in the NOP's description of ETKO's corrective action, quoted above. Ms. Zuck then asked ETKO a further question:

How does ETKO ensure that its staff is well informed and knowledgeable of the NOP Regulations, including the remainder of the NOP Handbook? How will you address this concern and prevent this from occurring in the future?

On November 1, 2015, ETKO provided the following answer:

NOP Handbook will be checked regularly and related documents will be translated as an immediate effect. Translated documents will be studied with related staff and inspectors. We already ordered for translations of the yellow indicated documents in NOP Handbook See attached. Part of the documents was already translated. See Translated NOP Handbook

The NOP incorporated this answer as well in its description of ETKO's corrective action on NC3. There was no further exchange between the NOP and ETKO regarding NC3. Although it took some time for ETKO to master the complexities of this legal topic and have the proper documents translated into Turkish, Ms. Zuck showed patience and understanding toward ETKO throughout the process. In the end there was no indication that the NOP considered ETKO's response to NC3 as "inadequate."

# NC4: The NOP Never Indicated that Corrective Action was "Inadequate"

NC4 was first noted in the NOP audit of May 12-16, 2014, and first revealed to ETKO in the Notice of Noncompliance on May 13, 2015. The following is the text of NC4 and the NOP's description of the corrective action ETKO submitted following the Notice of Noncompliance:

NP4132LCA.NC4 -7 CFR §205.403(c) states, "The on-site inspection of an operation must verify: (1) The operation's compliance or capability to comply with the Act and the regulations of this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples."

**Comments**: The following issues were identified by the NOP auditor during a review of the operation files and witness audits:

- 1. Inspectors did not completely verify the information stated in the Organic Compliance Plans. If observations and interviews at the onsite inspection did not align with the Organic Compliance Plan, the inspector failed to state this finding as an issue of concern.
- 2. ETKO inspectors are responsible for collecting large amounts of information about the operations when the Organic Compliance Plan (OCP) is incomplete or in error. The inspector did not note the finding as an issue of concern, failing to indicate that the OCP is incomplete. The inspector did not record these findings in the inspection report. Minor updates or adjustments

to the OCP during the onsite inspection is acceptable and can be noted in the inspector's report.

3. The inspection reports did not include a description and the outcome of the reconciliation activities (e.g. mass balance and audit trail audit) conducted by inspectors.

Corrective Action: ETKO submitted documentation from the training it conducted with inspectors on the following topics: "1) Using and evaluation of OCP during onsite inspection; 2) Review of organic compliance plans and identifying noncompliances before inspections, in order to avoid losing time to collect large amount of information and documents; and 3) How to make input-output balance and report it." ETKO also submitted examples of completed inspection reports from inspectors showing input-output balance and updates to the inspection forms.

In its review of the corrective action submitted by ETKO on NC4, the NOP did not raise any questions about NC4 until November 19, 2015. On that date the NOP noted that ETKO had held training for its inspectors, but it asked how ETKO and its inspectors were following up with the specific operators whose OCPs were not accurate or incomplete, by informing them of this and possibly issuing noncompliances. On December 1, 2015, ETKO supplied answers to the questions. Following are the questions the NOP posed on November 19, followed by the answers to the respective questions that ETKO supplied on December 1:

**NP4132LCA.NC4** – ETKO conducted training for inspectors on these issues, however, how did ETKO follow up with the operations to be sure they are in compliance?

a. 1) Inspectors did not completely verify the information stated in the Organic Compliance Plans. If observations and interviews at the onsite inspection did not align with the Organic Compliance Plan, the inspector failed to state this finding as an issue of concern. Did ETKO follow up with the operation and inform them of the issues observed? Issue a Non-compliance?

Yes, inspectors verified OCPs during the inspection and identified NCs and minor issues. See examples of NONC + Minor issues from different inspectors.

b. 2) ETKO inspectors are responsible for collecting large amounts of information about the operations when the Organic Compliance Plan (OCP) is incomplete or in error. The inspector did not note the finding as an issue of concern, failing to indicate that the OCP is incomplete. The inspector did not record these findings in the inspection report. Was the operation informed of these issues/noncompliances? And how did they correct them?

Yes, inspectors checked carefully OCPs and identified several issues and informed operators, corrections were assessed during onsite inspections. See examples of Application Package review forms of operators. Note: First date is the review date and second date is inspection date.

This appears to be the only exchange that the NOP had with ETKO on ETKO's execution of its corrective action on NC4. There was no indication that the NOP considered ETKO's response to NC4 as "inadequate."

# NC5: The NOP Never Indicated that Corrective Action was "Inadequate"

NC5 was first noted in the NOP audit of May 12-16, 2014, and first revealed to ETKO in the Notice of Noncompliance on May 13, 2015. The following is the text of NC5 and the NOP's description of the corrective action ETKO submitted following the Notice of Noncompliance:

NP4132LCA.NC5 –7 CFR § 205.501(a) (2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: During a crop witness audit observation, the NOP auditor noted that the inspector was not equipped and possibly not adequately trained to conduct sampling for pesticide residues. Product samples were collected during the crop inspection; however, the inspector collected the samples with bare hands potential exposing the samples to contamination and jeopardizing sample integrity.

Corrective Action: ETKO submitted training slides and updated forms used to conduct training for NOP inspectors, staff, and advisory committee members on the following topics: OP 03 Testing, TI 05 Sampling Method, TI 40 NOP Guide Testing & Enforcement Action. Training took place July 6-9, 2015.

ETKO cannot find any correspondence between the NOP and ETKO on the subject of noncompliance NC5. Therefore it appears that the corrective action submitted by ETKO on NC5 was acceptable to the NOP. There is no indication that the NOP considered ETKO's response to NC5 as "inadequate."

# NC6: The NOP Never Indicated that Corrective Action was "Inadequate"

NC6 relates to the grower groups certified by ETKO under the NOP and whether they have documented and functioning Internal Control Systems, as required by NOP Policy Memo 11-10 and the related policy recommendations of the National Organic Standards Board (NOSB) of October 20, 2002, and November 19, 2008.

NC6 was first noted in the NOP audit of May 12-16, 2014, and first revealed to ETKO in the Notice of Noncompliance on May 13, 2015. The following is the text of NC6 and the NOP's description of the corrective action ETKO submitted following the Notice of Noncompliance:

NP4132LCA.NC6 -7 CFR § 205.501(a) (21) states "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms or conditions determined by the Administrator to be necessary." NOP Policy Memo (PM) 11-10 (dated 01/21/11) states, "Grower group certification...accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies."

**Comments:** Grower Groups certified by ETKO do not have documented and functioning Internal Control Systems.

Corrective Action: ETKO created a form to be used for inspection of Internal Control Systems for grower groups and revised the OCP to include the grower group Internal Control System requirement. ETKO updated its NOP Certification Procedure Manual with the requirements to document and verify Internal Control Systems. These forms and procedures will be implemented this year for all grower groups. The forms and revised NOP Certification Procedure Manual were submitted to NOP. ETKO conducted training on this topic July 7, 2015. The training materials and an agenda were submitted to NOP.

In its review of the corrective action submitted by ETKO on NC6, the NOP did not raise any questions about NC6 until November 19, 2015. On that date the NOP noted that ETKO had "created forms and updated certification procedures for grower groups to require

and verify Internal Control Systems." The NOP raised the following questions: "Have all grower groups come into compliance with this? If not, provide a status report and detailed plans on how and when you will carry out this corrective action. How many grower groups does this affect?" (Attachment H.)

On December 1, ETKO inserted the following answer in Ms. Zuck's email of November 19 (See Attachment H):

There are 5 grower groups inspected this year. Projects finalized their internal control for producers and ETKO to finish follow up inspections until end of December. The main issue is setting up the Quality Management System, one operator completed so far and the other 4 still under progress. We expect all to be ready until the end of December.

This answer is inserted in response to appears to be the only exchange that the NOP had with ETKO on ETKO's execution of its corrective action on NC6. While ETKO gave the NOP the number of grower groups affected and a status report on its efforts to have the grower groups adopt the new procedures, it appears that ETKO did not give the NOP "detailed plans on how and when (ETKO) will carry out this corrective action." Nevertheless, there is no indication that the NOP considered ETKO's overall response to NC6 as "inadequate."

This concludes the review of corrective action submissions in NC21, and NC1 through NC6. The next, and final, section of the appeal will address the NOP's third ground for proposing suspension of ETKO, the fact that IOAS, the EC and CFIA took action against ETKO's accreditation in the spring of last year.

# ETKO's Suspensions by Other Accrediting Authorities

As noted above in the introductory section of this letter, prior to March 30, 2015, ETKO was on the list of countries authorized by the European Commission (EC) to issue organic certificates in non-EU member countries, such as Turkey, that are not recognized by the EU as "third countries." On March 30, 2015, the European Commission withdrew ETKO from that "list of recognized control bodies and control authorities for the purpose of equivalence." At the same time ETKO was under investigation by IOAS, which had conducted an audit of ETKO on March 10-13, 2015. On April 23, 2015, IOAS "suspended" ETKO's accreditation under ISO 17065, the "EU Equivalence Programme," and also ETKO's accreditation under CFIA, because IOAS operates CFIA's accreditation program.

While ETKO was on notice that it was no longer being accredited under CFIA as of April 23, the CFIA did not issue a public announcement of ETKO's suspension until July 31, 2015.

These actions have had grave consequences for ETKO, especially the action taken by the EC. The EU allows certified organic products to be imported into the entire EU only under specific conditions. One way for organic goods to enter the EU is if they are imported from "third countries" with which the EU has equivalency agreements. The US is one of those "third countries," as is Canada, Argentina, Australia, Japan, Switzerland and just seven other countries. However, as long as ETKO was on the EC list as a "recognized control body," this let ETKO certify organic shipments from Turkey and other countries into the EU, even though Turkey is neither in the EU nor on the select list of EU "third countries."

The IOAS and CFIA "suspensions" have also affected ETKO's activities. While the suspensions are pending, ETKO may not take on new applicants for certification and may not renew or extend the certification scope of its existing clients. It must be noted that while the IOAS and CFIA actions are called "suspensions," they are only provisional suspensions of its accreditation. The IOAS and CFIA "suspensions" can be lifted within a year if certain requirements are met. Thus, neither the ISO 17065 "suspension" nor the CFIA "suspension" is comparable to the total suspension that the NOP is proposing pursuant to 7 CFR § 205.665(f).

Before discussing the reasons contributing to these actions by the EC, IOAS and CFIA, ETKO wishes to point out that these actions by these other accrediting authorities are not binding in any way, by law or policy, on the NOP. First, it is expressly not NOP's policy to defer to an accreditation decision by IOAS. In 2000, in the Preamble to the Final Rule, the NOP stated that it would not recognize nongovernmental accrediting bodies. Therefore, accreditation decisions of IOAS, a nongovernmental organization, cannot be binding on the NOP.

In accrediting ETKO, IOAS has been "wearing two hats" – as a private organization accrediting ETKO under ISO 17065 and as a private organization acting as the CFIA's accrediting body for the Canadian Organic Regime (COR). This does not alter the fact that IOAS itself is still not a government accrediting body and does not have any recognition agreement with the NOP. Therefore, IOAS accreditation decisions with regard to ETKO should not determine what action the NOP takes with regard to ETKO's NOP accreditation.

The European Commission is a governmental organization and a party to the US-EU Organic Equivalency Arrangement. The EC has suspended ETKO from its list of certifying

<sup>&</sup>lt;sup>1</sup> NOP Final Rule, Preamble, "Accreditation by Private-Sector Accreditation Bodies," 65 Fed.Reg. 80605-6 (Dec. 21, 2000).

bodies. However, this does not affect ETKO's accreditation status under the NOP. The US-EU Organic Equivalency Arrangement, under which the NOP recognizes certification by certifiers in EU member states, does not apply to ETKO because Turkey is not an EU member state.

We will now turn to the past events in which ETKO was caught up, and then report on what ETKO has been doing over the past nine months to have its previous accreditations restored.

Because ETKO Certified in Ukraine, It Was Caught Up In Western Europe's Organic Feed Scandal

In early 2015 the EC and IOAS both moved against ETKO with amazing speed. The reason was a major scandal in Western Europe. The Ukrainian agribusiness industry has been a major supplier of organic sunflower expeller, or sunflower seed cake, a low-cost byproduct of the sunflower crushing and oil extraction process that is in high demand as an ingredient in organic livestock feed formulations. Ukraine is the second largest source of this product in the world. Beginning in the fall of 2014, as members of the organic feed trade in Western Europe tested this product in shipments from Ukraine, they discovered pesticide residues in the certified organic sunflower expeller. By this time much of the product had already moved out through the supply chain to a wide range of customers, and time was of the essence. The problem was quickly traced to certain organic operations in Ukraine, some of which were certified by ETKO and the rest by SGS Austria. The EC called for prompt action and this led to the IOAS audit of ETKO.

As an organic certifier based in Turkey, a non-EU country, ETKO stood as a ready target for such an investigation driven by market worries in Western Europe. SGS Austria, identified with 26 percent of the contaminated products, promptly chose to give up its certification in all "third countries." As a certifier based in the EU, SGS Austria already has access to the EU market, whereas ETKO, from a country not in the EU, depends on accreditation by the EC and IOAS to certify shipments bound for the EU market. Meanwhile, according to an EC report, an assessment of SGS Austria's part in the sunflower expeller scandal is in progress. (See Attachment I, European Commission, Note to the Regulatory Committee for Organic Production Delegates, June 29, 2015, at page 4.)

As ETKO faces the Proposed Notice of Suspension from the NOP, ETKO notes that SGS Austria, unlike ETKO, is not subject to having its NOP accreditation suspended over this matter, because SGS Austria, which was formerly NOP accredited, surrendered its accreditation in 2013 after adoption of the U.S.-EU Equivalency Arrangement.

The IOAS audit March 10-13, 2015, was made by experienced auditors but was also prepared at breakneck speed. Even though ETKO certified 346 clients under the EU standards, of which only 20 were in Ukraine, the primary focus of the audit became ETKO's work in Ukraine, because that was where the scandal was that was upsetting Western Europe. The IOAS found a number of indications that ETKO's organization in Ukraine was not equal to the challenges that Ukraine presented. These findings triggered the EU and IOAS itself to take their actions.

Because of the war and political unrest throughout Ukraine, ETKO, and any other organic certifier, faces unusual difficulties on top of the normal challenges. These include language barriers, corruption at customs offices, poor roads, outdated technology, and a lack of government support for organic farming. Poor roads mean that most shipments move by boat, which makes it more difficult to obtain samples of products for testing.

However, ETKO's problems in Ukraine were not the sole cause of the scandal. In a response to the IOAS audit, ETKO explained that while ETKO as a control body needed to make changes in its staffing and documentation in Ukraine, a "major issue" there in the scandal was "falsification of documents for the raw material and final product exported by the exporting companies." As a result, "product flow and traceability are not supported by reliable documents." ETKO contrasted this with conditions in Turkey. (Attachment J, ETKO, Explanation of the Issues Raised by IOAS for Ukraine and Situation of Turkey for Mentioned Issues.)

# ETKO's Efforts to Regain its IOAS and Other Accreditations

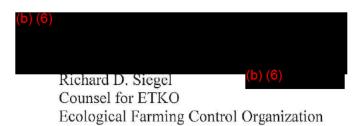
In spite of these obstacles, since last spring ETKO has been preparing either to have its IOAS suspension lifted by this spring or else to make a new application for accreditation from IOAS. Because ETKO still sees a future for itself in Ukraine, where 32 of its 50 current NOP clients are located, ETKO has been working with determination to improve its inspection and enforcement with its organic clients in Ukraine. It is taking more samples at the farms and at shipment points to test for contamination. It is putting more emphasis on checking product flows. It knows what it needs to do to strengthen its hold on operators in Ukraine, and it is doing so.

Nine months have now elapsed since ETKO received the blow of being removed from the EC list and suspended by IOAS and CFIA. But ETKO has not stood still. ETKO has used this time effectively both to strengthen its organization in Ukraine and to put itself on a path to become reinstated by IOAS, CFIA and the EC in the near future. ETKO has already satisfied 63 percent of the requirements that IOAS imposed as a condition to have the suspension lifted. ETKO will continue to keep the NOP informed on its progress.

Therefore, if the NOP is scrutinizing its own accreditation of ETKO because of the suspensions made last year by the other authorities, then as ETKO regains its accreditation with the other authorities, this should no longer be an issue to cloud the NOP's decision to renew ETKO's accreditation.

# Conclusion

For the reasons stated above, ETKO respectfully requests that the Administrator grant this appeal and therefore rescind the Notice of Proposed Suspension, which the NOP issued on December 18, 2015. ETKO respectfully requests that after the NOP rescinds the Notice of Proposed Suspension, the NOP should take the necessary steps to renew ETKO's accreditation.



### Attachments

cc: Mustafa Akyüz, Ph.D. Miles McEvoy Cheri Courtney From: <u>Kuhn, Meg - AMS</u>
To: <u>Richard Siegel</u>

Cc: <u>Mustafa Akyuz; Courtney, Cheri - AMS</u>

Subject: Appeal Acknowledgement - ETKO (Sent Registered)

**Date:** Friday, January 22, 2016 2:30:29 PM

Attachments: Ack.ETKO.APL-008-16.pdf

Importance: High

Hello Mr. Siegel,

Please find attached an appeal acknowledgement letter for your client's (ETKO) appeal of the National Organic Program's December 22, 2015 Notice of Proposed Suspension of Accreditation. Should you have any questions or concerns, please do not hesitate to contact me.

Thank you, Meg

Meg Kuhn Appeals Specialist USDA-NOP-ODA (202) 205-9644

**From:** Richard Siegel [mailto:rsiegel@rdslaw.net]

**Sent:** Friday, January 15, 2016 6:41 PM

**To:** AMS - NOPAppeals

Cc: Mustafa Akyuz; Kuhn, Meg - AMS; Schurkamp, Lynnea - AMS; Tucker, Jennifer - AMS; McEvoy, Miles

- AMS; Courtney, Cheri - AMS

Subject: Appeal of Notice of Proposed Suspension Issued December 18, 2015, to ETKO

To NOP Appeals Team:

Attached is an appeal on behalf of ETKO, an accredited certifying agent. ETKO is based in Izmir, Turkey. ETKO is a Turkish acronym that stands for "Ecological Farming Control Organization."

ETKO received a Notice of Proposed Suspension of its accreditation dated December 18, 2015. Today is January 15 and this is a timely appeal.

Attached is the appeal letter (22 pages), and two PDFs containing attachments.

The letter says that this appeal is delivered by Registered Email. I intended to send this appeal that way, but I have not been able to open a Registered Email account this evening and send this to you that way because of technical problems installing the necessary software. Please notify me that you have received this email, so that the delivery requirement will be satisfied.

Meanwhile, if I am successful in opening a Registered Email account over the weekend, I will resend the documents that way. I appreciate your cooperation.

Many thanks, and enjoy your weekend.

Richard D. Siegel

Richard D. Siegel Law Offices The Watergate 600 New Hampshire Avenue NW, Suite 500 Washington, DC 20037

Telephone: 202-518-6364 Facsimile: 202-234-3550 Email: rsiegel@rdslaw.net

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TO: Miles McEvoy, Deputy Administrator

Cheri Courtney, AIA Division Director

FROM: Meg Kuhn, NOP Appeals Specialist

202.205.9644

CC: Jennifer Tucker, National Organic Program

DATE: March 2, 2016

SUBJECT: ETKO Appeal, APL-008-16 – Appeal Resolution Options

On January 15, 2016, Ecological Farming Control Organization (ETKO) appealed NOP's December 18, 2015 Notice of Proposed Suspension of Accreditation. After reviewing the appeal, the NOP wishes to resolve the appeal without an Administrator's Decision. Therefore, we present two options:

- 1. Settlement a settlement would accept the corrective actions ETKO submitted in response to the 2014 Renewal Assessment Notice of Noncompliance, focus primarily on ETKO's loss of international accreditations, and require a compliance assessment:
  - a. NOP would agree to withdraw the Notice of Proposed Suspension of Accreditation.
  - b. NOP would agree to accept ETKO's corrective actions, on the condition that ETKO agree to undergo an on-site compliance assessment, at ETKO's expense, within 12 months of signing.
  - c. ETKO would agree to that the compliance assessment would include a review of whether nonconformances issued by IOAS and the EU, which contributed to the loss of ISO 17065 and CFIA accreditations and EU's 3<sup>rd</sup> country recognition as a certifying body, had been resolved. The term would indicate that any outstanding nonconformances would be evaluated based on their impact on NOP accreditation requirements, and that future adverse actions may result from a lack of conformity in these areas.

When the settlement agreement is executed, NOP would close the appeal.

- 2. Withdraw December 18, 2015 Notice of Proposed Suspension of Accreditation In this scenario, NOP would withdraw its notice and issue a renewal of accreditation, accepting the corrective actions submitted in response to 2014 Renewal Assessment and NOP 2000 Procedures, but including a term that requires a compliance audit in the next 12 months.
  - a. The withdrawal notice would indicate that should ETKO accept the accreditation renewal terms, it would include a compliance assessment of ETKO within the next 12 months, at ETKO's expense, specifically to verify that corrective actions submitted have been effectively implemented; as well as to review the nonconformances that IOAS and EU issued. This is authorized under §205.508(b) and §205.640(a), and would be a term in the renewal document accompanying the withdrawal.
  - b. The withdrawal notice would further indicate that noncompliances identified as a result of the compliance assessment may lead to future adverse action.

Once the adverse action notice is withdrawn, the NOP would close the appeal.

Both options, generally, close the appeal with the same results; however, through different methods.

TO: Michael Sheats

AMS Livestock, Poultry and Seed – Agricultural Analytics Division

FROM: Meg Kuhn, NOP Appeals Specialist

202.205.9644

CC: Miles McEvoy, National Organic Program

Jennifer Tucker, National Organic Program

DATE: February 16 – 19, 2016

SUBJECT: Case Summary – Ecological Farming Control Organization, APL-008-16

Please review the following case summary concerning Ecological Farming Control Organization's (ETKO) appeal of a Notice of Proposed Suspension of Accreditation issued by the National Organic Program (NOP). The Notice of Proposed Suspension of Accreditation did not specify a suspension timeframe, allowing ETKO to seek reinstatement of its accreditation at any time after the suspension becomes effective. ETKO, based in Turkey, was initially accredited as a certifying agent under the USDA organic regulations on January 22, 2003.

Because this is an appeal of an adverse action issued by the NOP, we are forwarding this summary to you for your review and recommendation.

# **Summary of Facts:**

On May 12 - 16, 2014, NOP auditors conducted a Renewal Assessment of ETKO's accreditation system.

On May 15, 2015, the NOP issued ETKO a Notice of Noncompliance related to the May 2014 Renewal Assessment. The Notice of Noncompliance and corresponding Noncompliance Report identified one outstanding noncompliance from a previous assessment, as well as six new noncompliances, for a total of seven noncompliances.

In May 2015, the International Organic Accreditation Service (IOAS) suspended ETKO for accreditation of its certification activities to the European Union (EU) equivalent standard for all scopes and all countries. In June 2015, the EU removed ETKO's recognition as a 3<sup>rd</sup> country certification body for all EU scopes in all countries. Additionally in June 2015, the Canadian Food Inspection Agency (CFIA) suspended ETKO for accreditation of its certification activities to the Canadian Organic Regime.

Between September 10 – November 3, 2015, ETKO submitted corrective actions for the seven noncompliances in the May 2015 Noncompliance Report and NOP conducted a corrective action review.

On December 22, 2015, the NOP issued ETKO a Notice of Proposed Suspension of Accreditation for "the number, and severity of the noncompliances issued during the NOP

Renewal Assessment, the multiple inadequate submissions of corrective actions from ETKO, and the suspensions of organic program accreditations by IOAS, EU, and CFIA...." The Notice of Proposed Suspension included a copy of both the original Noncompliance Report and the December 18, 2015 final Corrective Action Report.

On January 15, 2016, ETKO submitted an appeal through its retained counsel, which was accepted as timely.

# **Summary of Positions:**

# **NOP Perspective:**

In the outstanding noncompliance from a previous assessment that was cited as "outstanding" in the 2014 Noncompliance Report following the Renewal Assessment, the auditor made the following observation about ETKO's certification system: "Interviews conducted, records reviewed, and witness inspections observed verified a general lack of understanding of the NOP standards." To correct and prevent reoccurrence of the noncompliance, ETKO conducted training with its staff and inspectors on the NOP standards, review, and certification procedures. Despite this training, at the 2014 Renewal Assessment, the NOP auditor identified that ETKO "demonstrated an insufficient understanding of the USDA organic regulations and NOP policies." From NOP's perspective, the outstanding noncompliance and subsequent additional findings from the NOP auditor in 2014 supported the position that ETKO had a general lack of understanding of the regulations; this demonstrated to the NOP that ETKO was not adequately meeting general accreditation requirements.

When ETKO was notified of the noncompliances from the 2014 Renewal Assessment, it did not provide complete or adequate corrective and preventive actions in a timely manner. Over five months, ETKO submitted multiple corrective actions for multiple noncompliances, demonstrating ETKO was unable to understand requirements to comply with USDA organic accreditation requirements.

In addition to ETKO's demonstrated inability to meet USDA organic accreditation requirements, the NOP considered ETKO's recent loss of accreditations from IOAS for the EU and CFIA organic programs, as well as the EU's removal of ETKO as a recognized 3<sup>rd</sup> country certification body. The NOP considered offering ETKO a settlement agreement with its Notice of Proposed Suspension of Accreditation that would require ETKO to respond to noncomformances issued by IOAS for the EU and CFIA regulations, as well as the EU nonconformances related to the 3<sup>rd</sup> country recognition requirements; however, the NOP later decided a settlement agreement, if issued, would be more appropriate at the appeal stage.

# ETKO's Perspective:

In its appeal, ETKO argued that each of the statements NOP listed in its Notice of Proposed Suspension of Accreditation as reasons for the adverse action were not valid reasons to propose suspension. A summary of appeal points is below; the full appeal is enclosed with this file.

1. "The number, and severity of the noncompliances issued during the NOP Renewal Assessment..." ETKO argued that:

- This statement is vague and subjective;
- The NOP does not have "any specific, objective standard to measure the "severity" of a noncompliance;"
- The NOP does not have a "consistent standard for... the "number"... of noncompliances lodged against certifying agents;"
- The NOP had knowledge of the seven noncompliances identified in the May 2014 Renewal Assessment, yet, "if the NOP had truly considered these seven noncompliances so numerous and severe, it would not have waited so long a full year before it sent a Notice of Noncompliance. By not receiving the notice of these noncompliances in a timely fashion, ETKO therefore lost a full year in which it could have taken the necessary corrective action."
- 2. "The multiple inadequate submissions of corrective actions from ETKO..." ETKO argued that:
  - This statement is also "a broad, subjective statement that is not verified when the record itself is examined" and that the "charge of multiple inadequacies cannot be supported."
  - ETKO submitted between one to two submissions for five noncompliances; three submissions for one; and four submissions for one.
  - Though there was a back-and-forth in communication between NOP and ETKO for two noncompliances between July 21 November 19, 2015, ETKO showed a good faith effort in demonstrating compliance and "in the end the response submitted by ETKO was apparently adequate.... ETKO rightly assumed it would eventually receive renewal of its NOP accreditation. Therefore, it came as a surprise to ETKO when it received the Notice of Proposed Suspension on December 18, 2015."
- 3. "The suspensions of the organic program accreditations by IOAS, EU, and CFIA..." ETKO argued that:
  - "The NOP's position appears to be that because ETKO has been suspended during the past year by these other accreditation authorities, the NOP should respect those decisions and simply follow suit. Instead of automatically following the accreditation decisions taken against ETKO by these other authorities, the NOP has the responsibility to take an independent look at ETKO's situation. The NOP should, first, determine whether ETKO has failed to comply with the NOP's own standards for certifying agents. Second, the NOP needs to consider both the motivation behind the suspensions of ETKO by other authorities and the current status of ETKO vis-à-vis those authorities."
  - ETKO received only a provisional suspension from IOAS and CFIA, restricting ETKO's activities, but which can be "lifted" if certain requirements are met. "By comparison, the "suspension" that the NOP is proposing... would be a total cessation of ETKO's NOP certification activities...."
  - "If the NOP is scrutinizing its own accreditation of ETKO because of the suspension made last year by other authorities, then as ETKO regains its accreditation with the other authorities, this should no longer be an issue affecting the NOP accreditation of ETKO."

# Proposed Action to Resolve the Appeal

The NOP proposes a settlement agreement to resolve the appeal. The proposed settlement would withdraw the NOP's notice; accept the corrective actions ETKO submitted in response to the 2014 Renewal Assessment Notice of Noncompliance; focus on ETKO's loss of international accreditations; and require a compliance assessment (site evaluation). Settlement term examples include:

- 1. NOP would agree to withdraw the Notice of Proposed Suspension of Accreditation.
- 2. NOP would agree to accept ETKO's corrective actions, on the condition that ETKO agree to undergo an on-site compliance assessment, at ETKO's expense, within 12 months of signing.
- 3. ETKO would agree to that the compliance assessment would include a review of whether nonconformances issued by IOAS and the EU, which contributed to the loss of ISO 17065 and CFIA accreditations and EU's 3<sup>rd</sup> country recognition as a certifying body, had been resolved. The term would indicate that any outstanding nonconformances would be evaluated based on their impact on NOP accreditation requirements, and that future adverse actions may result from a lack of conformity in these areas.

# APPEALS CLEARANCE SHEET

# **Case Summary**

Certifying Agent: Appellant:	NOP Adverse Action (Proposed Suspension of Accreditation) Ecological Farming Control Organization, APL-008-16		
Associate Deputy A	dministrator, National Organic Program		
Approved			
Jennifer Tucker	(signature & date)		
Deputy Administra	tor, National Organic Program		
ApprovedMinor EditsSubstantive	Disagreement		
Miles V. McEvoy	(signature & date)		
	Agricultural Analytics Division, ultry and Seed Program		
Recommendation to	Administrator:		
Sustain Ap Settlement	al – Uphold NOP Decision  peal – Support Operator Appeal  Offer  out a Decision		
Brief explanation for	recommendation:		
	(signature & date)		



# National Organic Program (NOP) Appeal APL-008-16

# **Appellant:**

ETKO, c/o
Richard D. Siegel
Suite 500, The Watergate
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037-2403

# NOP ADVERSE ACTION

# → PLEASE RETURN TO NOP: (202) 720-3252

Reviewed by:	Initials and Date	Initials and Date
NOP Deputy Administrator		
Division Director, Agricultural Analytics		
Division, Livestock and Seed Program		
AMS Administrator		

From: Kuhn, Meg - AMS Courtney, Cheri - AMS To:

Cc: Mann, Renee - AMS; Yang, RobertH - AMS Subject: ETKO appeal - settlement executed Date: Wednesday, April 13, 2016 4:41:00 PM

Dear Cheri,

The settlement agreement that resolved the appeal between NOP and ETKO has been executed. In the settlement, the NOP agreed to withdraw the Notice of Proposed Suspension and also accepted the corrective and preventive actions ETKO has submitted to address the May 15, 2015 Notice of Noncompliance. This is a reminder to AIA to follow up on those actions, and any other accreditation actions that may need to occur in order to resolve the 2013 Renewal process.

If you have any questions, please do not hesitate to reach out to me or Jenny. Thanks. Meg

# Meg Kuhn

**Appeals Specialist** Office of the Deputy Administrator National Organic Program U.S. Department of Agriculture Room 2649-So. (Stop 0268) 1400 Independence Ave SW Washington, DC 20250-0268 Main Office: 202.720.3252

Direct: 202.205.9644 Cell: 202.603.5158

meg.kuhn@ams.usda.gov www.ams.usda.gov/nop

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#### LAW OFFICES

# RICHARD D. SIEGEL

SUITE 500 THE WATERGATE 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, D.C. 20037-2403 (202) 518-6364 FACSIMILE (202) 234-3550 rsiegel@rdslaw.net

February 1, 2016

# BY REGISTERED EMAIL

National Organic Program Appeals Team USDA Agricultural Marketing Service Room 2642-S, STOP 0268 Washington, D.C. 20250 Attention: Meg Kuhn, Appeals Specialist

Re: NOP Appeal: APL-008-16

Appellant: ETKO, Ecological Farming Control Organization

Additional Developments Since Appeal Was Filed January 15, 2016

Dear Ms. Kuhn:

In your letter of January 22, 2016, acknowledging the filing of this appeal, you invited ETKO to supply additional information in support of the appeal within ten days of receipt of the letter. On behalf of ETKO, I am pleased to report new developments that have taken place since the filing of the appeal.

The appeal letter of January 15, 2016, at pages 5 and 21-22, explained that since the date ETKO was suspended by IOAS, April 23, 2015, ETKO has been working to satisfy the requirements that IOAS imposed as a condition to have the suspension lifted. The following information is to update these parts of the appeal letter.

First, under the IOAS suspension policy, ETKO was given one year -- until April 23, 2016 -- to satisfy IOAS that the suspension should be lifted. The appeal letter stated that ETKO had already satisfied 63 percent of the requirements that IOAS imposed as a condition to have the suspension lifted. Since the date the appeal was filed, ETKO can report that it has finished nearly all the remaining requirements and has submitted its responses to IOAS.

In addition, before IOAS can lift ETKO's suspension, it must carry out witness audits. When ETKO filed the appeal two weeks ago, IOAS had not yet scheduled the witness audits with ETKO. However, on January 28, 2016, IOAS confirmed to ETKO that it would perform

Letter to NOP Appeals Team February 1, 2016 Page 2

the witness audits in early or mid-March when ETKO inspects MEZO and WBT, two operations in Turkey. Therefore, these two IOAS witness audits will take place more than one month before the deadline of April 23, 2016. Both MEZO and WBT are operations ETKO certifies under the NOP as well.

Attached is the email message dated January 28, 2016, from Gergana Nentcheva of IOAS to Mustafa Akyüz of ETKO, in which IOAS confirms these witness audits in March and discusses other witness audits later in the year.

Thank you for your consideration of this additional information concerning the appeal. Please advise me if you have further questions.

Sincerely yours,

(b) (6)

Richard D. Siegel
Counsel for ETKO
Ecological Farming Control Organization

Attachment

cc: Mustafa Akyüz, Ph.D.

From: nentcheva [mailto:nentcheva@ioas.org]
Sent: Thursday, January 28, 2016 10:09 AM

To: ma@etko.org
Cc: fa@etko.org

Subject: RE: IOAS - site visits for EU-equivalent and COR programmes

Dear Mustafa,

With apologies for the delay in my response I could summarise as follows:

Please check and let me know as soon as you can whether it is possible to arrange the regular inspection to MEZO and WBT for  $8-11^{th}$  of March. I can book evaluator for this period and there is flexibility with the dates in case of emergency – if needed we can use also the next week –  $14-17^{th}$  March.

The focus will be on the cultivated plant production as it seems the time will be more suitable for this type of activity, and on the processing.

In August we will have another trip in Ukraine and I will combine it with site visits to ETKO operators there.

Is the Autumn a suitable period for inspection of Voce Product? For example very early in October?

Best regards, Gergana Nentcheva

The IOAS- cultivating integrity and trust across the organic community.



Gergana Nentcheva Client Manager IOAS Deutschland nentcheva@ioas.org

# ATTACHMENT A

# NOP Certificate of Accreditation

Certifying

Ekolojik Tarim Kontrol Organizasyonu

(Ecological Farming Control Organization – ETKO)

As an Accredited Certifying Agent

Issued January 22, 2008



# **United States Department of Agriculture**

Agricultural Marketing Service National Organic Program

Ekolojik Tarim Kontrol Organizasyonu Bornova—Izmir, Turkey

meets all the requirements prescribed in the National Organic Program Regulations

7 CFR Part 205

As an Accredited Certifying Agent

for the scope of

Crops, Wild Crops and Handling

This certificate is receivable by all officers of all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the U.S. Department of Agriculture.

Annual status of this accreditation may be verified at http://www.ams.usda.gov



Certificate No: NP9222ZZA

Issue Date: January 22, 2008

Renewal Date: January 22, 2013

Rayne Pegg Administrator

Agricultural Marketing Service

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program.

# ATTACHMENT B

NOP Notice of Noncompliance

Issued May 13, 2015, to ETKO:

Letter signed by Cheri Courtney,

Director, NOP Accreditation and International Activities Division

Accompanied by

16-page Noncompliance Report

Of Onsite Audit May 12-16, 2014



# NOTICE OF NONCOMPLIANCE

MAY 1 3 2015

Dr. Mustafa Akyuz Ecological Farming Control Organization 160 Sk. No. 13/7 35040 Bornova – Izmir Turkey

Dear Dr. Akyuz:

On May 12-16, 2014, a representative of the United States Department of Agriculture (USDA), National Organic Program (NOP), completed an onsite audit of the Ecological Farming Controlling Organization's (ETKO) organic certification program as part of its USDA Renewal Accreditation Assessment. On April 29, 2015 the NOP reviewed the results of the onsite audit to determine ETKO's compliance to the USDA organic regulations. A copy of the assessment report, NP4132LCA, is enclosed for your reference.

As the report indicates, 24 corrective actions for prior noncompliances (NP7199OOA.NC3, NC5, NC6; NP8050OOA.NC1, NC2; and NP9222ZZA.NC1-NC5, NC7-NC20) were cleared and determined to be implemented and effective. One noncompliance, NP9222ZZA.NC6, was withdrawn.

One noncompliance, NP9222ZZA.NC21, remains outstanding from your previous audit. Six new noncompliances (NP4132LCA.NC1 – NC6) were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all outstanding and new noncompliances to the <u>AIAInbox@ams.usda.gov</u> within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the ETKO management system will be modified to prevent future noncompliances.

Please refer to <u>NOP 2608</u>, <u>Responding to Noncompliances</u>, for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

# Page 2

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 690-4540 or RobertH. Yang@ams.usda.gov.

Sincerely,

Cheri Courtney

Director, Accreditation and International Activities Division

National Organic Program

Enclosure

cc: AIA Inbox

1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

# NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

## **AUDIT AND REVIEW PROCESS**

The National Organic Program (NOP) received Ecological Farming Control Organization's (ETKO) renewal application to maintain its U.S. Department of Agriculture (USDA) National Organic Program accreditation in June 2012. The NOP has reviewed ETKO's application, conducted an onsite audit, and reviewed the audit report to determine ETKO's capability to operate as a USDA accredited certifier.

#### **GENERAL INFORMATION**

Applicant Name	ETKO – Ecological Farming Control Organization
Physical Address	160 Sk. No. 13/7, 35040, Bornova - Izmir, Turkey
Mailing Address	160 Sk. No. 13/7, 35040, Bornova - Izmir, Turkey
Contact & Title	Dr. Mustafa Akyuz
	General and QMS Manager
E-mail Address	ma@etko.org
Phone Number	+90-232-3397606
Reviewer & Auditor	Penny Zuck, NOP Reviewer; Lars Crail, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: April 29, 2015
	Onsite audit: May 12-16, 2014
Audit Identifier	NP4132LCA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the
	implementation and effectiveness of ETKO's certification program.
Audit & Determination	7 CFR Part 205, National Organic Program as amended
Criteria	
Audit & Review Scope	ETKO's certification services in carrying out the audit criteria for
	Crops, Wild Crops, and Handling.

#### Organizational Structure:

The Ecological Farming Controlling Organization is abbreviated as ETKO from their Turkish name (Ekolojik Tarım Kontrol Organizasyonu). ETKO is a for-profit, limited liability company with two shareholders. The main office for USDA organic certification for ETKO is located in Bornova – Izmir, Turkey. All certification activities for the NOP are conducted at the Izmir office; there are no satellite offices that conduct USDA organic key activities.

ETKO was initially accredited as a certifying agent on January 22, 2003 to the USDA National Organic Program (NOP) for crops, wild crops, and handling. ETKO currently certifies operations

to the USDA organic regulations in the following countries: Turkey, Russia, Serbia, Korea, Kazakhstan, and the Ukraine. As of May 2014, ETKO's NOP client list had 40 certified operations with 22 crops, 3 wild crops, and 39 handling operations. ETKO certifies to the Turkish Organic Standard under the legal authority of the Organic Farming Committee of the Republic of Turkey the Ministry of Agriculture and Rural Affairs Research Planning and Coordination Council (TURKAK). ETKO is also accredited by TURKAK to perform conformity assessments for Turkey's Good Agricultural Practices (GAP). ETKO is accredited to ISO 17065 by the International Organic Accreditation Service (IOAS) in the areas of agricultural production, processing and imports of organic agricultural products according to the EEC, GlobalGap, and the Global Organic Textile Standard (GOTS). ETKO is accredited to conduct Canadian Organic Regime (COR) certification.

ETKO employees staff members that are involved in USDA organic certification. The staff consists of administrative personnel and technical personnel which also conduct inspections.

## Certification Process:

Requests for certification are reviewed by the Managing Director (MD) and an information packet is provided by e-mail or a hard copy with information on the certification process, fee structure, USDA organic regulations, and a standard application document. The initial compliance review for new applicants is always conducted by a reviewer. Once the applicant appears to comply, an inspector is assigned based on region, experience, and availability. When the inspection is completed, a reviewer then evaluates the inspection results and a certification decision is made by the Organic Certifier position.

The continuing certification procedure is similar to that of initial applicants. For continuing certified operations, an annual production or handling update is received by ETKO on or before the anniversary date of the operation. A review is conducted by a reviewer or the assigned inspector. Inspectors are then assigned according to region, experience, and availability. Certification decisions are made by the Organic Certifier position.

The Turkish National Organic Standard does not permit grower group certification; therefore, all production and handling units must receive external inspections. However, there are four operations identified as grower groups in Turkey (mainly fruits, eg. figs, raisins, etc...) and four in foreign countries. ETKO has established certification procedures for grower groups.

## Administrative Records and Processes:

ETKO has an extensive and well-designed, functioning quality system. Procedures and forms are established that cover most certification activities. The quality system documents are in English. Training is conducted annually for all certification staff and appears to be comprehensive and well documented. Key certification staff receive annual external certification training.

# Summary of Witness Inspections Conducted:

Three witness audits were conducted during the course of the onsite renewal assessment. All operation locations were within four hours of Izmir, Turkey, ETKO's main office. All inspections were annual inspections and announced. ETKO was planning to conduct additional

inspections when harvest or processing is occurring. One operation was certified organic wild crop and gathering capers. The other two witness operations were certified for crop and handling/processing scopes. The crop operation was identified as a community of fig producers and the processor operation handled a number of fruit products to include the figs from the grower group.

#### NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether ETKO's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to ETKO.

# **Noncompliances from Prior Assessments**

Any noncompliance labeled as "Cleared," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "Outstanding" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP7199OOA.NC3 – Cleared. 7 CFR §205.501 (a)(1) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part." *Qualifications for the Certification Committee were not submitted for review*.

**Corrective Action:** Qualifications for the Certification Committee were submitted. The submitted material verified that personnel serving on the Certification Committee have adequate qualifications.

2009 Verification of Corrective Action: Personnel records reviewed during the on-site audit verified personnel had sufficient qualifications as they pertained to experience and education in organic agricultural production and handling methods. However, interviews conducted, records reviewed, and witness inspection findings verified that the training provided to personnel did not include sufficient information on the NOP standards for ETKO to fully comply with and implement the organic certification program in accordance with the NOP Final Rule.

**2010 Corrective Action:** ETKO conducted training of inspectors, reviewers, and Certification Committee members on November 21, 2009 and March 12-14, 2010 which covered NOP standards, review, inspection, and certification procedures. ETKO has designed a 2010 training plan to ensure periodic training on the NOP is completed. ETKO submitted records of training for all inspectors, reviewers, and Certification Committee members.

2014 Verification of Corrective Action: The new organizational structure of ETKO does not include a Certification Committee. Certification decisions are now determined by the "Organic Certifier." This position is held by one person. Annual certification training is required by all ETKO certification staff according to their Quality System procedures. ETKO provided evidence (Training summary, lesson plans, presentation materials, and training roster) of training conducted during 2013 through May 2014 for the NOP auditor's review.

The training plan for the remainder of 2014 was also provided and determined to be adequate.

NP7199OOA.NC5 – Cleared. 7 CFR §205.501 (a)(11)(v) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report." Conflict of interest disclosure reports were not submitted for the Certification Committee.

**Corrective Action:** Signed Conflict of Interest Disclosure Reports for 2006 and 2007 were submitted for the Certification Committee.

**2009 Verification of Corrective Action:** The Agreement for Confidentiality and Conflict of Interest Disclosure Reports were reviewed for all eight Certification Committee members. On two of the eight reports, the committee members had signed the document but did not provide any responses to the questions on the form. Additionally, there was no Agreement for Confidentiality and Conflict of Interest Disclosure Report for one of the two responsibly connected parties of ETKO.

**2010 Corrective Action:** ETKO submitted completed Agreement for Confidentiality and Conflict of Interest Disclosure Reports for all Certification Committee members and responsibly connected parties.

**2014 Verification of Corrective Action:** The Agreement for Confidentiality and Conflict of Interest Disclosure reports are signed annually. All reports were signed on January 2, 2014. The NOP auditor reviewed the personnel files of a reviewer, the decision maker, and an inspector. All reports were complete and no issues were noted.

NP7199OOA.NC6 – Cleared. 7 CFR §205.662 (b) states, "When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution." Non-compliance resolutions were not addressed in the policies or procedures submitted.

Corrective Action: ETKO has submitted a template of the non-compliance resolution.

**2009 Verification of Corrective Action:** ETKO has the template letter of non-compliance as part of their quality management documentation; however, they have not implemented its use and the inspector, not ETKO, is documenting corrective actions and resolution of non-compliances using ETKO's Non-Conformity Report.

**2010 Corrective Action:** ETKO revised GP 18, section 5.24 to address the handling of non-compliances. ETKO has implemented the use of the non-compliance letter and submitted example of non-compliance letters.

**2014 Verification of Corrective Action:** Procedures for issuing a Notice of Noncompliance Resolution is listed in GP 18, section 5.25.1. The Notice of Noncompliance Resolution template was revised in 2012 and is compliant. The NOP auditor reviewed records of four noncompliance notifications that were issued. The corrective actions were accepted and ETKO issued a Notice of Resolution to the operations.

NP8050OOA.NC1 - Cleared. 7 CFR §205.201 (a) states, "The producer or handler of a production or handling operation, except as exempt or excluded under §205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include: (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed; (2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable; (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented; (4) A description of the recordkeeping system implemented to comply with the requirements established in §205.103; (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations." The organic system plans for the files submitted do not contain all of the information required in this section. The plans are designed with questions requiring a yes or no answer which does not give any detail as to how the applicant's operation complies with the NOP Final Rule.

Corrective Action: Operators were requested to update the Organic System Plans. Organic System Plans for all NOP certified operations were submitted. They now contain information necessary to determine compliance to the NOP Final Rule.

**2009 Verification of Corrective Action:** In three of four files reviewed there were deficiencies identified with the organic system plans (OSP). Two of the files were the same certified operations for which the original non-compliance was identified and were also the selected witness inspections. The on-site review of files, interviews, and observations during the witness inspections verified the OSPs were not in compliance.

- 1. The wild crop Organic System Plan (OSP) did not adequately address requirements for recordkeeping, designated harvest areas and buffers zone.
- 2. The OSP for the producer witness inspection did not adequately address requirements for the description of recordkeeping, buffer zone requirements, soil fertility and crop nutrient management, and input use.
- 3. The OSP for the processor witness inspection had insufficient information to address the requirements for the monitoring and frequencies to be performed and maintained to verify the plan is implemented. The OSP did not contain documented procedures of the measures for preventing the commingling of organic and nonorganic products. The processor was not maintaining production, cleaning, or shipment records. The OSP did not identify the use of "organic" vegetable oil in the equipment used for processing the organic raisins.
- 4. The OSP for the processor/producer did not identify the use of lime sulfur for pest prevention at the raisin storage depot prior to shipment to the processor.
- 5. Overall, OSP's did not meet the requirements for compliance to this clause.

**2010 Corrective Action:** ETKO issued a notification of non-compliances to the operations and ultimately suspended the operations. ETKO revised their OSP for wild crop, producers, and processors to emphasize the requirement to fully address all requirements. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which addressed the need for fully completed OSPs.

**2014 Verification of Corrective Action:** The revised Organic Compliance Plans (OCPs) for the wild crop and handler witness audits were in use. The NOP auditor reviewed the OCPs and determined that they were compliant.

NP8050OOA.NC2 – Cleared. 7 CFR §205.402 (a) states, "Upon acceptance of an application for certification, a certifying agent must: (2) 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." The organic system plans for the files submitted do not contain all of the information required in NOP §205.201. Due to the lack of the required information it would not be possible to make an accurate determination that the organic system plan complies with the requirements of this section.

Corrective Action: Operators were requested to update the Organic System Plans. Organic System Plans for all NOP certified operations were submitted. They now contain information necessary to determine compliance to the NOP Final Rule.

**2009 Verification of Corrective Action:** The on-site review of files, interviews, and observations during the witness inspections verified that the OSPs had inadequate information to determine compliance to the NOP Final Rule and certified operations were not in compliance with the NOP Final Rule (see NP8050OOA.NC1 above).

**2010 Corrective Action:** ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which addressed the need for fully completed OSPs. ETKO submitted a completed OSP review documenting that the ETKO reviewers were requiring adequate information.

**2014 Verification of Corrective Action:** OCPs reviewed by the auditor showed that there was sufficient detail and where there was not enough detail, the inspectors would ask the operations to provide the additional information by updating the OCP onsite or submitting it to the ETKO office.

NP9222ZZA.NC1 – Cleared. 7 CFR §205.405(a) states, "When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant." 7 CFR §205.406(c) states, "If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662." ETKO as a certifying agent is not making a determination of compliance or issuing a written notification of non-compliance based on a review of the on-site inspection findings. ETKO's inspectors are issuing non-compliances directly to the applicants or certified operations at the time of inspection using their Non-Conformity Report and also reviewing and approving the corrective actions for identified non-

compliances. ETKO's Certification Committee does not review or make a determination of non-compliances and all non-compliances identified by the inspector must be resolved prior to forwarding the file to the committee.

**Corrective Action:** ETKO revised General Procedure 18 (GP 18) in sections 5.7, 5.22, and 5.24 to require that the Certification Committee be responsible for providing notification of non-compliance and for the resolution of non-compliance. The revised procedures specifically state that inspectors are not issuing non-compliances directly to the applicants or certified operations.

**2014 Verification of Corrective Action:** Notifications of minor issues and non-compliances are issued by ETKO. The NOP auditor noted no issues with ETKO's process of issuing notifications.

NP9222ZZA.NC2 – Cleared. 7 CFR §205.406(a)(1-4) states, "To continue certification, a certified operation must annually...submit the following information, as applicable, to the certifying agent:..." 7 CFR §205.662(a) states, "Notification. When an inspection, review, or investigation of a certified operation by a certifying agent...reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation." ETKO is not issuing a notification of noncompliance to certified operations that do not annually submit the information required in §205.406(a)(1-4).

Corrective Action: ETKO revised GP 18 in sections 5.23 and 5.24 to require that a notification of non-compliance be sent to certified operations that do not submit the required annual update. **2014 Verification of Corrective Action:** All files reviewed by the NOP auditor indicated that operations were submitting their annual updates in a timely manner.

NP9222ZZA.NC3 – Cleared. 7 CFR §205.501(11)(vi) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection." ETKO's head inspector or the individual inspectors are conducting the inspections and essentially making the certification decision based on the fact that no files are forwarded to the certification committee until all non-compliances identified by the inspector have been addressed by the clients and corrective actions reviewed and approved by the inspector or head inspector. No files with outstanding non-compliances are sent forward for review by the Certification Committee.

**Corrective Action:** ETKO revised General Procedure 18 (GP 18) in section 5.24 to require that the Certification Committee be responsible for making the certification decision, including review and resolution of non-compliances, and that the head inspector and inspectors not have any responsibility or authority for these activities.

**2014 Verification of Corrective Action:** All decisions are now made by the Organic Certifier and recorded on form: GP 13 F 01, Certification Proposal. No issues noted by the NOP auditor.

NP922ZZA.NC4 – Cleared. 7 CFR §205.662(a-c) states, "When an inspection, review, or investigation of a certified operation by a certifying agent... reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation..." NOP §205.404(c) states, "Once certified, production or handling

operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator." ETKO is not requiring clients to notify them when they want to surrender their certification and is issuing letters of surrender to the clients informing them their NOP certificate was surrendered because they did not re-apply for NOP Certification and they cannot use their NOP certificate and must return it. ETKO has "surrendered" the certification of four of their fifteen currently certified operations during years the clients chose not to re-apply for certification and then re-certified them in subsequent years when they reapplied. ETKO also "surrendered" the certification of sixteen additional clients that did not ever re-apply for certification and are no longer listed as certified operations.

**Corrective Action:** ETKO revised GP 15 in section 5.4 to require clients to inform ETKO of their decision to surrender their certification and to return the original certificate. The revised procedure also requires ETKO to contact clients that have not submitted updates to determine if they want to surrender.

**2014 Verification of Corrective Action:** The NOP auditor reviewed two operation files where certification was surrendered and no issues were noted.

NP9222ZZA.NC5 - Cleared. 7 CFR §205.404(b)(2) states, "The certifying agent must issue a certificate of organic compliance to the certified operation which specifies the: effective date of certification. The effective date of certification was not included on the certificates for 2 of 4 files reviewed.

Corrective Action: ETKO revised their template certificates to include the effective date of certification. ETKO reviewed their files and issued revised certificates with the effective date of certification for five certified operations.

**2014 Verification of Corrective Action:** All certificates reviewed by the NOP auditor displayed an effective date.

NP9222ZZA.NC6 – Withdrawn. ETKO's general procedure GP 18, Section 5.2.2 Review of Application, specifies that the application review is conducted by a competent inspector assigned by ETKO. The Managing Director is conducting all of the initial application reviews and prior to 2009 was also conducting the annual update reviews; however, this responsibility is not identified in ETKO's procedures.

**Corrective Action:** ETKO revised GP 18, Section 5.2.2 Review of Application to specify that the application review is conducted by a competent person assigned by ETKO. The competent person may be the Managing Director or other review staff.

**2014 Verification of Corrective Action:** This noncompliance did not cite the USDA organic regulations and does not appear to be in violation of the regulations. Interviews of ETKO personnel and a review of the operation files indicate that certification reviews are conducted by someone other than the certification decision maker. Therefore, the NOP withdrew this noncompliance.

NP9222ZZA.NC7 – Cleared. 7 CFR §205.501(a)(16) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Charge applicants for certification and certified production and handling operations only those fees and charges for

certification activities that it has filed with the administrator." Fees charged and described on the Cost Estimate and Invoice as "Follow-up, Certification: NOP ETKO Staff" are not included on the submitted fee schedule (TI 14). On all three files reviewed for fees charged to clients all three clients were not charged in accordance with the fee schedule. All three clients were undercharged based on the number of inspectors and days taken for the certification which is the method utilized by ETKO to determine the certification fees to be charged.

**Corrective Action:** ETKO revised their fee schedule (TI 14) to match the fees charged and described in the Cost Estimate and Invoice.

**2014 Verification of Corrective Action:** Interviews with ETKO personnel and certified operators in addition to operation file review indicated that estimated fees are provided to applicants and continuing certified operations and calculated according to the fee schedule.

NP9222ZZA.NC8 – Cleared. 7 CFR §205.642 states, "Fees charged by a certifying agent must be reasonable...The certifying agent shall provide each applicant with an estimate of the total cost of certification and estimate of the annual cost of updating the certification...The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule."

Nonrefundable fees are explained in the procedures but not in the fee schedule.

Corrective Action: ETKO revised their fee schedule (TI 14) to explain nonrefundable fees. 2014 Verification of Corrective Action: ETKO lists nonrefundable fees in the current fee schedule.

NP9222ZZA.NC9 – Cleared. 7 CFR §205.501(a)(7) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measure to correct any non-compliances with the Act and the regulations in this part that are identified in the evaluation." ETKO's annual program review is not addressing all certification activities for the NOP. The 2008 internal audit used for the annual program review only reviewed EU files. The 2009 internal audit included NOP files; however, the 2009 annual program review had not been completed so it was not possible to verify the information to be reviewed.

**Corrective Action:** ETKO revised TI 30 NOP Accreditation Requirements and SP 03 Management Review procedure to ensure the annual program review addresses all certification activities for the NOP.

**2014 Verification of Corrective Action:** Management review report was completed on December 28, 2013 and included in ETKO's annual report acknowledged by the NOP in March 2014.

NP9222ZZA.NC10 – Cleared. 7 CFR §205.207(a) states, "A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area..." NOP §205.202 states, "Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as organic must: (c) Have distinct, defined boundaries and buffer zones..." The wild crop witness inspection operation did not have maps or description designating the harvest area or identifying the buffer zones.

Corrective Action: ETKO issued a notification of non-compliance to the operation and ultimately suspend the operation. ETKO revised their wild collection procedure (TI 20) to more specifically require maps or a description of designated harvest areas and identification of buffer zones. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010.

**2014 Verification of Corrective Action:** During a witness audit of a wild crop inspection, the OCP maps of the three gathering areas indicated defined boundaries.

NP9222ZZA.NC11 – Cleared. 7 CFR §205.307(b) states, "Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the lot number of the product if applicable." The clients organic system plan (Section A16.3 Collection Activities) stated the main wild crop collector stores the product in a barrel labeled as organic. A barrel of capers at the wild crop collection depot did not have any labels or identification; although, the head collector stated it was organic.

Corrective Action: ETKO issued a notification of non-compliance to the operation and ultimately suspend the operation. ETKO revised the GP 18 procedure and the GP 18 F01-02 forms to ensure adequate labels and identification of organic product during inspections. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures.

**2014 Verification of Corrective Action:** All wholesale containers inspected and observed during the witness audits had lot numbers on labels.

NP9222ZZA.NC12 – Cleared. 7 CFR §205.103(b)(2)(4) states, "(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are... (b) Such records must: (2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited; (4) Be sufficient to demonstrate compliance with the Act and the regulations in this part." The operators for the wild crop, crop, and processing witness inspections did not maintain sufficient records to comply with the requirements.

Corrective Action: ETKO issued a notification of non-compliance to the operations and ultimately suspended the operations. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures, including the necessity of maintaining sufficient records.

**2014 Verification of Corrective Action:** All the operations observed during witness audits had sufficient records for the inspections to be fully conducted.

NP9222ZZA.NC13 – Cleared. 7 CFR §205.403(c)(1) – (3) states, "The on-site inspection of an operation must verify: (1) the operation's compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan... accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which..."

1. During the inspection of the wild crop operation, the inspector did not reference the organic system plan during the inspection, did not physically verify all buffer

- areas or inquire about potential areas of contamination, and did not identify a non-labeled barrel (containing organic product) as a non-compliance.
- 2. During the producer witness inspection, the inspector did not inspect the storage unit where raisins are stored prior to shipment to the processor because there was nothing currently in storage. The inspector did not inquire about the use of (b) (4) for pest prevention at the storage depot; although, the product had recently been used by the certified operation and a bag was available for review.
- 3. During the producer witness inspection, the inspector did not fully inspect the chemical storage area of the producer and did not inquire about the (b) (4)

  (b) (4)

  product in the storage area which were being used for conventional crops.

Corrective Action: ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures. ETKO increased monitoring activities of inspectors in 2009 and identified that during the 2010 inspection cycle all inspectors will be observed conducting NOP inspections to ensure compliance. ETKO submitted Inspector Monitoring Reports from the end of 2009.

**2014 Verification of Corrective Action:** ETKO continues to conduct annual training and field monitoring of inspectors. During the witness audits, inspectors were conducting thorough inspections with only minor issues observed and noted by the NOP auditor.

NP9222ZZA.NC14 – Cleared. 7 CFR §205.202(c) states, "Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as 'organic' must: (c) Have distinct, defined boundaries and buffer zones..." The crop witness inspection locations did not have maps or written descriptions to identify the boundaries and the buffer zones.

Corrective Action: ETKO issued a notification of non-compliance to the operation and ultimately suspended the operations. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures. ETKO revised GP 18 to specify that NOP applicants and clients must submit maps with defined boundaries and buffer zones, as applicable.

**2014 Verification of Corrective Action:** During the witness inspections all OCPs were complete with land or facility maps.

NP9222ZZA.NC15 - Cleared. 7 CFR §205.203(a) states, "The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological conditions of soil..." The OSP for the producer witness inspection stated they did practice cultivation methods to maintain or improve; however, five of the seven producers visited were leaving the fields unattended with little or no tillage or cultivation practices and only the application of inputs for pest or disease prevention and treatment.

Corrective Action: ETKO issued a notification of non-compliance to the operation and ultimately suspended the operations. ETKO revised GP 18 and GP 18 F 02 Agriculture Plan to address the issue of unattended fields. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures.

2014 Verification of Corrective Action (May 2014): Witness audits of several crop operations

revealed that producers were actively farming the sites and improving soil health.

NP9222ZZA.NC16 – Cleared. 7 CFR §205.501(a)(8) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part." The wild crop, crop, and processor witness inspection clients and their subcontracted units did not have adequate knowledge of the NOP requirements to enable them to comply with the Act. The wild crop witness inspection client purchasing representative and person responsible for training the head collectors stated he had not seen the NOP Rule and did not have any knowledge of the NOP Rule.

Corrective Action: ETKO issued a notification of non-compliance to the operations and ultimately suspended the operations. ETKO revised GP 18 to emphasize the necessity of adequate knowledge of the NOP requirements. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures.

**2014 Verification of Corrective Action:** ETKO is requiring certified operations to train and monitor individuals involved in organic production and handling activities. All operations observed and operation files reviewed indicated that training was occurring and recorded.

NP9222ZA.NC17 – Cleared. 7 CFR §205.403 (a)(1) states, "A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each..." and ETKO Technical Instruction TI 20 Certification of Wild Collection, Rev Nr. 2, 20.10.2008, section 5.4 states "ETKO inspectors will visit a certain number of collecting sites, according to the risk factors of the collection system; minimum site visit must be 5 and according to inspector's decision: This number can be increased up to 10 collection sites." The ETKO instructions and procedures allow for a sampling of certified operations to be inspected as opposed to all certified sites being inspected annually and thereafter as required. These operations are not certified as grower groups and would not qualify as grower groups (don't have to sell all organic harvest through the group). The wild crop and producer witness inspections along with interviews conducted, and records reviewed verified that not all sites are inspected as required.

**Corrective Action:** ETKO revised TI 20 Certification of Wild Collection, section 5.4 to distinguish between group certification with an internal control system and individual collection operations without an internal control system. The individual collection operations have multiple collectors; however, they are not considered grower groups and according to the revised procedure the on-site inspection will include all collectors and all locations.

**2014 Verification of Corrective Action:** All certified and applicant locations require annual on-site inspections according to Turkish organic standards. During the witness audits, all fields were inspected by the inspectors. No issues noted by the NOP auditor.

NP9222ZZA.NC18 – Cleared. 7 CFR §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary" and

the 2002 NOSB Recommendation states, "The certifying agent shall have policies and procedures for determining how many growers must receive an annual inspection by the certifying agent." ETKO Procedure OP 02 Certification of Grower Groups is just a copy of the requirements for grower groups from the NOSB Recommendation. The procedure does not provide any actual information on how many growers will receive an annual inspection from the ETKO inspector.

**Corrective Action:** ETKO revised procedure OP 02 Certification of Grower Groups to define the risk categories of normal, medium, and high, and specify the number of members to be evaluated for each category. The total number for each category is based on increasing multiplication factors (1, 1.2, 1.4) of the square root of the total number of farmers with a mandatory minimum number of members that must be evaluated.

**2014 Verification of Corrective Action:** ETKO has a method (EU guidance) to calculate the number of external inspections of grower groups. All grower group files reviewed indicate that ETKO has properly implemented this procedure.

NP9222ZZA.NC19 – Cleared. 7 CFR §205.403(b)(2) states, "All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present..." Five of seven farms inspected did not have the farmer that manages the operation present for the inspection. The company representative responsible for purchasing the product from the farmers was present and he is also a farmer of a certified operation; however, he was only aware of the general production practices and not the specific practices of each operation. An interview with one of the farmers was conducted off-site; however, he was not present during the review at his field.

Corrective Action: ETKO revised GP 18, section 5.7 to specify that the NOP inspection cannot be carried out without the presence of an authorized and knowledgeable representative. ETKO informed NOP clients to provide NOP training to their responsible staff and producers. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures.

**2014 Verification of Corrective Action:** All producers and operators were present during the witness audits. No issues noted by the NOP auditor.

NP9222ZZA.NC20 – Cleared. 7 CFR §205.301(a) states, "A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients." The crop and processing witness inspection client's organic certificate and organic system plan identifies the processed product (raisins) as 100 percent organic, but a potassium bicarbonate solution is being added to the grapes prior to on-farm drying to speed up the drying process and facilitate color development. One additional file reviewed identified the use of enzymes and non-certified pectin in a product identified as 100 percent organic.

**Corrective Action:** ETKO reviewed the files and revised the categories on the certificates to organic. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards and labeling requirements.

**2014 Verification of Corrective Action:** During the review of operation files and certificates, the NOP auditor did not note any issues of concern with ETKO's classification

of organic products.

NP9222ZZA.NC21 - Outstanding. 7 CFR §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part." Interviews conducted, records reviewed, and witness inspections observed, verified a general lack of understanding of the NOP standards. While personnel had sufficient experience and education in organic agricultural production and handling practices, there was insufficient understanding on the application of the NOP standards as evidenced by inadequate information in the approved organic compliance (system) plans with no issues of concern or non-compliances being identified over multiple years of certification. The primary Certification Committee (CC) member with expertise in crops was not familiar with basic requirements such as the 90/120 day rule for raw manure application, did not know where to reference in the NOP Rule to determine if an input is permitted, and did not know when commercially available seeds and planting stock could be used. Additionally, while it was stated that the Certification Committee (CC) had received training there were no training records for any of the CC members prior to 2009.

Corrective Action: ETKO conducted training of inspectors, reviewers, and Certification Committee members on November 21, 2009 and March 12-14, 2010 which covered NOP standards, review, inspection, and certification procedures. ETKO has designed a 2010 training plan to ensure periodic training on the NOP is completed. ETKO submitted records of training for all inspectors, reviewers, and Certification Committee members.

**2014 Verification of Corrective Action:** The NOP auditor found the following issues of concern that demonstrated an insufficient understanding of the USDA organic regulations and NOP policies:

- 1. Label review the label review checklist did not include USDA organic regulation label requirements to be verified.
- 2. Inspectors during the witness audits used incorrect regulation citations during exit interviews to identify findings.
- 3. OCP templates state the incorrect USDA organic regulations.
- 4. Inspectors are using outdated USDA organic regulations (2010).
- 5. Inspectors and reviewers not readily able to look up regulations.
- 6. EKTO personnel have an incomplete understanding of the noncompliance and adverse action notification procedures.
- 7. Several crop operation OCPs reviewed by the NOP auditor indicated "Not Applicable" for Crop Rotation practice standard (205.205).
- 8. ETKO personnel did not understand and document buffer zone requirements (205.202(c)).

# Noncompliances Identified during the Current Assessment

NP4132LCA.NC1 – 7 CFR §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670." Furthermore, NOP 4009, Instruction – Who Needs to be Certified?, states "The OFPA requires

that agricultural products sold or labeled as organically produced must be produced only on certified farms and handled only through certified handling operations (see 7 USC § 6506(a)(1)). The USDA organic regulations reiterate these requirements (see 7 CFR 205.100.)"

**Comments:** ETKO certifies projects that contain uncertified operations (i.e. contractors) that produce or handle organic products that are not certified entities.

NP4132LCA.NC2 – 7 CFR §205.404(b)(3) states, "The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation."

Comments: Certificates do not adequately indicate the certification scopes of Crop, Wild Crop,

NP4132LCA.NC3 – 7 CFR §205.662(c) states, "When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent... shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance....The notification of proposed suspension or revocation of certification shall state: (1) The reasons for the proposed suspension or revocation; (2) The proposed effective date of such suspension or revocation; (3) The impact of a suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681."

**Comments:** ETKO suspended an operation without issuing a Notice of Proposed Suspension. The same operation after receiving the Notice of Suspension effective for 30 days was issued a Notice of Proposed Revocation and subsequently a Notice of Revocation. The sequence of issued notices and contents of the notifications demonstrate that ETKO does not fully comprehend the process of issuing notifications for noncompliances and adverse actions.

NP4132LCA.NC4 – 7 CFR §205.403(c) states, "The on-site inspection of an operation must verify: (1) The operation's compliance or capability to comply with the Act and the regulations of this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples."

**Comments**: The following issues were identified by the NOP auditor during a review of the operation files and witness audits:

- 1. Inspectors did not completely verify the information stated in the Organic Compliance Plans. If observations and interviews at the onsite inspection did not align with the Organic Compliance Plan, the inspector failed to state this finding as an issue of concern.
- 2. ETKO inspectors are responsible for collecting large amounts of information about the operations when the Organic Compliance Plan (OCP) is incomplete or in error. The inspector did not note the finding as an issue of concern, failing to indicate that the OCP is incomplete. The inspector did not record these findings in the inspection report.

and Handling/Processing.

Minor updates or adjustments to the OCP during the onsite inspection is acceptable and can be noted in the inspector's report.

3. The inspection reports did not include a description and the outcome of the reconciliation activities (e.g. mass balance and audit trail audit) conducted by inspectors.

NP4132LCA.NC5 - 7 CFR § 205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

**Comments:** During a crop witness audit observation, the NOP auditor noted that the inspector was not equipped and possibly not adequately trained to conduct sampling for pesticide residues. Product samples were collected during the crop inspection; however, the inspector collected the samples with bare hands potential exposing the samples to contamination and jeopardizing sample integrity.

NP4132LCA.NC6 - 7 CFR § 205.501(a)(21) states "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms or conditions determined by the Administrator to be necessary." NOP Policy Memo (PM) 11-10 (dated 01/21/11) states, "Grower group certification...accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies."

**Comments:** Grower Groups certified by ETKO do not have documented and functioning Internal Control Systems.

# ATTACHMENT C

NOP Notice of Proposed Suspension

Issued December 18, 2015, to ETKO:

Letter signed by Miles V. McEvoy,

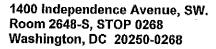
Deputy Administrator, USDA Agricultural Marketing Service, for the National Organic Program

Accompanied by

16-page Noncompliance Report Of Onsite Audit May 12-16, 2014

And

6-page Corrective Action Report Dated November 3, 2015





# NOTICE OF PROPOSED SUSPENSION OF ACCREDITATION

# DEC 1 8 2015

Mustafa Akyuz, PhD Ecological Farming Control Organization 160 Sk. No. 13/7 35040 Bornova – Izmir Turkey

Dear Dr. Akyuz:

As an accredited certifying agent for the USDA National Organic Program (NOP), Ecological Farming Control Organization (ETKO) is required to demonstrate its ability to fully comply with, and implement, its organic certification program. On May 13, 2015, the NOP issued ETKO a Notice of Noncompliance regarding the May 12-16, 2014, Renewal of Accreditation Audit Report. The Noncompliance Report included one outstanding noncompliance from a previous assessment and six new noncompliances.

In May, 2015, International Organic Accreditation Service (IOAS) suspended ETKO's ISO Guide 65 accreditation with the scope of a European Union equivalent standard for all scopes and all countries. In June, 2015, The European Commission removed ETKO's recognition as a 3<sup>rd</sup> country certification body for all European Union scopes and in all countries. In June, 2015, The Canadian Food Inspection Agency suspended ETKO's accreditation under the Canadian Organic Regime subject to subsection 2 of the Organic Products Regulations 2009.

Due to the number, and severity of the noncompliances issued during the NOP Renewal Assessment, the multiple inadequate submissions of corrective actions from ETKO, and the suspensions of organic program accreditations by IOAS, EU, and CFIA, I am proposing to suspend your accreditation as a certifying agent under 7 CFR §205.665(c) of the USDA Organic Regulations, Proposed suspension or revocation, and under §6515(i)(1) of the Organic Foods Production Act of 1990, which states "If the Secretary or the governing State official (if applicable) determines that a certifying agent is not properly adhering to the provisions of this chapter, the Secretary or such governing State official may suspend such certifying agent's accreditation."

Copies of the NOP Noncompliance Report, and NOP Corrective Action Report are enclosed for your reference.

The NOP proposes to suspend ETKO's accreditation as a NOP certifying agent effective 30 days from receipt of this letter. If the NOP suspends ETKO's accreditation, you will be directed to cease all certification activities and make all client files available to the NOP pursuant to § 205.665(f) of the USDA organic regulations.

Pursuant to § 205.681 of the USDA organic regulations, ETKO has the right to file an appeal of this proposed action within 30 days of receipt of this letter. Appeals must be filed in writing to:



1400 Independence Avenue, SW. Room 2648-S, STOP 0268 Washington, DC 20250-0268

Administrator, USDA, AMS c/o NOP Appeals Staff 1400 Independence Avenue, SW Room 2095-S, STOP 0203 Washington, DC 20250

If the NOP suspends ETKO's accreditation you may, at any time, submit a request to the Secretary for reinstatement of your accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Organic Foods Production Act and the USDA organic regulations.

If you have questions regarding this proposed action, please contact your Accreditation Manager, Robert Yang, at Roberth. Yang@ams.usda.gov or (202) 690-4540.

Sincerely

Deputy Administrator

National Organic Program

Enclosures:

NOP Noncompliance Report

NOP Corrective Action Report

cc:

NOP Appeals

1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

#### NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

#### AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Ecological Farming Control Organization's (ETKO) renewal application to maintain its U.S. Department of Agriculture (USDA) National Organic Program accreditation in June 2012. The NOP has reviewed ETKO's application, conducted an onsite audit, and reviewed the audit report to determine ETKO's capability to operate as a USDA accredited certifier.

# **GENERAL INFORMATION**

Applicant Name	ETKO – Ecological Farming Control Organization
Physical Address	160 Sk. No. 13/7, 35040, Bornova - Izmir, Turkey
Mailing Address	160 Sk. No. 13/7, 35040, Bornova - Izmir, Turkey
Contact & Title	Dr. Mustafa Akyuz
	General and QMS Manager
E-mail Address	ma@etko.org
Phone Number	+90-232-3397606
Reviewer & Auditor	Penny Zuck, NOP Reviewer; Lars Crail, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: April 29, 2015
	Onsite audit: May 12-16, 2014
Audit Identifier	NP4132LCA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the
	implementation and effectiveness of ETKO's certification program.
Audit & Determination	7 CFR Part 205, National Organic Program as amended
Criteria	
Audit & Review Scope	ETKO's certification services in carrying out the audit criteria for
	Crops, Wild Crops, and Handling.

## Organizational Structure:

The Ecological Farming Controlling Organization is abbreviated as ETKO from their Turkish name (Ekolojik Tarım Kontrol Organizasyonu). ETKO is a for-profit, limited liability company with two shareholders. The main office for USDA organic certification for ETKO is located in Bornova – Izmir, Turkey. All certification activities for the NOP are conducted at the Izmir office; there are no satellite offices that conduct USDA organic key activities.

ETKO was initially accredited as a certifying agent on January 22, 2003 to the USDA National Organic Program (NOP) for crops, wild crops, and handling. ETKO currently certifies operations

to the USDA organic regulations in the following countries: Turkey, Russia, Serbia, Korea, Kazakhstan, and the Ukraine. As of May 2014, ETKO's NOP client list had 40 certified operations with 22 crops, 3 wild crops, and 39 handling operations. ETKO certifies to the Turkish Organic Standard under the legal authority of the Organic Farming Committee of the Republic of Turkey the Ministry of Agriculture and Rural Affairs Research Planning and Coordination Council (TURKAK). ETKO is also accredited by TURKAK to perform conformity assessments for Turkey's Good Agricultural Practices (GAP). ETKO is accredited to ISO 17065 by the International Organic Accreditation Service (IOAS) in the areas of agricultural production, processing and imports of organic agricultural products according to the EEC, GlobalGap, and the Global Organic Textile Standard (GOTS). ETKO is accredited to conduct Canadian Organic Regime (COR) certification.

ETKO employees staff members that are involved in USDA organic certification. The staff consists of administrative personnel and technical personnel which also conduct inspections. Contract inspectors are used.

# Certification Process:

Requests for certification are reviewed by the Managing Director (MD) and an information packet is provided by e-mail or a hard copy with information on the certification process, fee structure, USDA organic regulations, and a standard application document. The initial compliance review for new applicants is always conducted by a reviewer. Once the applicant appears to comply, an inspector is assigned based on region, experience, and availability. When the inspection is completed, a reviewer then evaluates the inspection results and a certification decision is made by the Organic Certifier position.

The continuing certification procedure is similar to that of initial applicants. For continuing certified operations, an annual production or handling update is received by ETKO on or before the anniversary date of the operation. A review is conducted by a reviewer or the assigned inspector. Inspectors are then assigned according to region, experience, and availability. Certification decisions are made by the Organic Certifier position.

The Turkish National Organic Standard does not permit grower group certification; therefore, all production and handling units must receive external inspections. However, there are four operations identified as grower groups in Turkey (mainly fruits, eg. figs, raisins, etc...) and four in foreign countries. ETKO has established certification procedures for grower groups.

#### Administrative Records and Processes:

ETKO has an extensive and well-designed, functioning quality system. Procedures and forms are established that cover most certification activities. The quality system documents are in English. Training is conducted annually for all certification staff and appears to be comprehensive and well documented. Key certification staff receive annual external certification training.

## Summary of Witness Inspections Conducted:

Three witness audits were conducted during the course of the onsite renewal assessment. All operation locations were within four hours of Izmir, Turkey, ETKO's main office. All inspections were annual inspections and announced. ETKO was planning to conduct additional

inspections when harvest or processing is occurring. One operation was certified organic wild crop and gathering capers. The other two witness operations were certified for crop and handling/processing scopes. The crop operation was identified as a community of fig producers and the processor operation handled a number of fruit products to include the figs from the grower group.

#### NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether ETKO's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to ETKO.

#### **Noncompliances from Prior Assessments**

Any noncompliance labeled as "Cleared," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "Outstanding" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP7199OOA.NC3 – Cleared. 7 CFR §205.501 (a)(1) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part." Qualifications for the Certification Committee were not submitted for review.

Corrective Action: Qualifications for the Certification Committee were submitted. The submitted material verified that personnel serving on the Certification Committee have adequate qualifications.

**2009 Verification of Corrective Action:** Personnel records reviewed during the on-site audit verified personnel had sufficient qualifications as they pertained to experience and education in organic agricultural production and handling methods. However, interviews conducted, records reviewed, and witness inspection findings verified that the training provided to personnel did not include sufficient information on the NOP standards for ETKO to fully comply with and implement the organic certification program in accordance with the NOP Final Rule.

**2010 Corrective Action:** ETKO conducted training of inspectors, reviewers, and Certification Committee members on November 21, 2009 and March 12-14, 2010 which covered NOP standards, review, inspection, and certification procedures. ETKO has designed a 2010 training plan to ensure periodic training on the NOP is completed. ETKO submitted records of training for all inspectors, reviewers, and Certification Committee members.

2014 Verification of Corrective Action: The new organizational structure of ETKO does not include a Certification Committee. Certification decisions are now determined by the "Organic Certifier." This position is held by one person. Annual certification training is required by all ETKO certification staff according to their Quality System procedures. ETKO provided evidence (Training summary, lesson plans, presentation materials, and training roster) of training conducted during 2013 through May 2014 for the NOP auditor's review.

The training plan for the remainder of 2014 was also provided and determined to be adequate.

NP7199OOA.NC5 – Cleared. 7 CFR §205.501 (a)(11)(v) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report." Conflict of interest disclosure reports were not submitted for the Certification Committee.

Corrective Action: Signed Conflict of Interest Disclosure Reports for 2006 and 2007 were submitted for the Certification Committee.

**2009 Verification of Corrective Action:** The Agreement for Confidentiality and Conflict of Interest Disclosure Reports were reviewed for all eight Certification Committee members. On two of the eight reports, the committee members had signed the document but did not provide any responses to the questions on the form. Additionally, there was no Agreement for Confidentiality and Conflict of Interest Disclosure Report for one of the two responsibly connected parties of ETKO.

**2010 Corrective Action:** ETKO submitted completed Agreement for Confidentiality and Conflict of Interest Disclosure Reports for all Certification Committee members and responsibly connected parties.

**2014 Verification of Corrective Action:** The Agreement for Confidentiality and Conflict of Interest Disclosure reports are signed annually. All reports were signed on January 2, 2014. The NOP auditor reviewed the personnel files of a reviewer, the decision maker, and an inspector. All reports were complete and no issues were noted.

NP7199OOA.NC6 – Cleared. 7 CFR §205.662 (b) states, "When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution." Non-compliance resolutions were not addressed in the policies or procedures submitted.

Corrective Action: ETKO has submitted a template of the non-compliance resolution.

**2009 Verification of Corrective Action:** ETKO has the template letter of non-compliance as part of their quality management documentation; however, they have not implemented its use and the inspector, not ETKO, is documenting corrective actions and resolution of non-compliances using ETKO's Non-Conformity Report.

**2010 Corrective Action:** ETKO revised GP 18, section 5.24 to address the handling of non-compliances. ETKO has implemented the use of the non-compliance letter and submitted example of non-compliance letters.

**2014 Verification of Corrective Action:** Procedures for issuing a Notice of Noncompliance Resolution is listed in GP 18, section 5.25.1. The Notice of Noncompliance Resolution template was revised in 2012 and is compliant. The NOP auditor reviewed records of four noncompliance notifications that were issued. The corrective actions were accepted and ETKO issued a Notice of Resolution to the operations.

NP805000A.NC1 - Cleared. 7 CFR §205.201 (a) states, "The producer or handler of a production or handling operation, except as exempt or excluded under §205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include: (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed; (2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable; (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented; (4) A description of the recordkeeping system implemented to comply with the requirements established in §205.103; (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations." The organic system plans for the files submitted do not contain all of the information required in this section. The plans are designed with questions requiring a yes or no answer which does not give any detail as to how the applicant's operation complies with the NOP Final Rule.

Corrective Action: Operators were requested to update the Organic System Plans. Organic System Plans for all NOP certified operations were submitted. They now contain information necessary to determine compliance to the NOP Final Rule.

**2009 Verification of Corrective Action:** In three of four files reviewed there were deficiencies identified with the organic system plans (OSP). Two of the files were the same certified operations for which the original non-compliance was identified and were also the selected witness inspections. The on-site review of files, interviews, and observations during the witness inspections verified the OSPs were not in compliance.

- 1. The wild crop Organic System Plan (OSP) did not adequately address requirements for recordkeeping, designated harvest areas and buffers zone.
- 2. The OSP for the producer witness inspection did not adequately address requirements for the description of recordkeeping, buffer zone requirements, soil fertility and crop nutrient management, and input use.
- 3. The OSP for the processor witness inspection had insufficient information to address the requirements for the monitoring and frequencies to be performed and maintained to verify the plan is implemented. The OSP did not contain documented procedures of the measures for preventing the commingling of organic and nonorganic products. The processor was not maintaining production, cleaning, or shipment records. The OSP did not identify the use of "organic" vegetable oil in the equipment used for processing the organic raisins.
- 4. The OSP for the processor/producer did not identify the use of lime sulfur for pest prevention at the raisin storage depot prior to shipment to the processor.
- 5. Overall, OSP's did not meet the requirements for compliance to this clause.

**2010 Corrective Action:** ETKO issued a notification of non-compliances to the operations and ultimately suspended the operations. ETKO revised their OSP for wild crop, producers, and processors to emphasize the requirement to fully address all requirements. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which addressed the need for fully completed OSPs.

**2014 Verification of Corrective Action:** The revised Organic Compliance Plans (OCPs) for the wild crop and handler witness audits were in use. The NOP auditor reviewed the OCPs and determined that they were compliant.

NP8050OOA.NC2 - Cleared. 7 CFR §205.402 (a) states, "Upon acceptance of an application for certification, a certifying agent must: (2) 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." The organic system plans for the files submitted do not contain all of the information required in NOP §205.201. Due to the lack of the required information it would not be possible to make an accurate determination that the organic system plan complies with the requirements of this section.

Corrective Action: Operators were requested to update the Organic System Plans. Organic System Plans for all NOP certified operations were submitted. They now contain information necessary to determine compliance to the NOP Final Rule.

**2009 Verification of Corrective Action:** The on-site review of files, interviews, and observations during the witness inspections verified that the OSPs had inadequate information to determine compliance to the NOP Final Rule and certified operations were not in compliance with the NOP Final Rule (see NP8050OOA.NC1 above).

**2010 Corrective Action:** ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which addressed the need for fully completed OSPs. ETKO submitted a completed OSP review documenting that the ETKO reviewers were requiring adequate information.

**2014 Verification of Corrective Action:** OCPs reviewed by the auditor showed that there was sufficient detail and where there was not enough detail, the inspectors would ask the operations to provide the additional information by updating the OCP onsite or submitting it to the ETKO office.

NP9222ZZA.NC1 – Cleared. 7 CFR §205.405(a) states, "When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant." 7 CFR §205.406(c) states, "If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662." ETKO as a certifying agent is not making a determination of compliance or issuing a written notification of non-compliance based on a review of the on-site inspection findings. ETKO's inspectors are issuing non-compliances directly to the applicants or certified operations at the time of inspection using their Non-Conformity Report and also reviewing and approving the corrective actions for identified non-

compliances. ETKO's Certification Committee does not review or make a determination of non-compliances and all non-compliances identified by the inspector must be resolved prior to forwarding the file to the committee.

Corrective Action: ETKO revised General Procedure 18 (GP 18) in sections 5.7, 5.22, and 5.24 to require that the Certification Committee be responsible for providing notification of non-compliance and for the resolution of non-compliance. The revised procedures specifically state that inspectors are not issuing non-compliances directly to the applicants or certified operations.

**2014 Verification of Corrective Action:** Notifications of minor issues and non-compliances are issued by ETKO. The NOP auditor noted no issues with ETKO's process of issuing notifications.

NP9222ZZA.NC2 – Cleared. 7 CFR §205.406(a)(1-4) states, "To continue certification, a certified operation must annually...submit the following information, as applicable, to the certifying agent:..." 7 CFR §205.662(a) states, "Notification. When an inspection, review, or investigation of a certified operation by a certifying agent...reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation." ETKO is not issuing a notification of noncompliance to certified operations that do not annually submit the information required in §205.406(a)(1-4).

Corrective Action: ETKO revised GP 18 in sections 5.23 and 5.24 to require that a notification of non-compliance be sent to certified operations that do not submit the required annual update.

2014 Verification of Corrective Action: All files reviewed by the NOP auditor indicated that operations were submitting their annual updates in a timely manner.

NP9222ZZA.NC3 – Cleared. 7 CFR §205.501(11)(vi) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection." ETKO's head inspector or the individual inspectors are conducting the inspections and essentially making the certification decision based on the fact that no files are forwarded to the certification committee until all non-compliances identified by the inspector have been addressed by the clients and corrective actions reviewed and approved by the inspector or head inspector. No files with outstanding non-compliances are sent forward for review by the Certification Committee.

**Corrective Action:** ETKO revised General Procedure 18 (GP 18) in section 5.24 to require that the Certification Committee be responsible for making the certification decision, including review and resolution of non-compliances, and that the head inspector and inspectors not have any responsibility or authority for these activities.

**2014 Verification of Corrective Action:** All decisions are now made by the Organic Certifier and recorded on form: GP 13 F 01, Certification Proposal. No issues noted by the NOP auditor.

NP9222ZZA.NC4 – Cleared. 7 CFR §205.662(a-c) states, "When an inspection, review, or investigation of a certified operation by a certifying agent... reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation..." NOP §205.404(c) states, "Once certified, production or handling

operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator." ETKO is not requiring clients to notify them when they want to surrender their certification and is issuing letters of surrender to the clients informing them their NOP certificate was surrendered because they did not re-apply for NOP Certification and they cannot use their NOP certificate and must return it. ETKO has "surrendered" the certification of four of their fifteen currently certified operations during years the clients chose not to re-apply for certification and then re-certified them in subsequent years when they reapplied. ETKO also "surrendered" the certification of sixteen additional clients that did not ever re-apply for certification and are no longer listed as certified operations.

**Corrective Action:** ETKO revised GP 15 in section 5.4 to require clients to inform ETKO of their decision to surrender their certification and to return the original certificate. The revised procedure also requires ETKO to contact clients that have not submitted updates to determine if they want to surrender.

**2014 Verification of Corrective Action:** The NOP auditor reviewed two operation files where certification was surrendered and no issues were noted.

NP9222ZZA.NC5 – Cleared. 7 CFR §205.404(b)(2) states, "The certifying agent must issue a certificate of organic compliance to the certified operation which specifies the: effective date of certification. The effective date of certification was not included on the certificates for 2 of 4 files reviewed.

Corrective Action: ETKO revised their template certificates to include the effective date of certification. ETKO reviewed their files and issued revised certificates with the effective date of certification for five certified operations.

**2014 Verification of Corrective Action:** All certificates reviewed by the NOP auditor displayed an effective date.

NP9222ZZA.NC6 – Withdrawn. ETKO's general procedure GP 18, Section 5.2.2 Review of Application, specifies that the application review is conducted by a competent inspector assigned by ETKO. The Managing Director is conducting all of the initial application reviews and prior to 2009 was also conducting the annual update reviews; however, this responsibility is not identified in ETKO's procedures.

Corrective Action: ETKO revised GP 18, Section 5.2.2 Review of Application to specify that the application review is conducted by a competent person assigned by ETKO. The competent person may be the Managing Director or other review staff.

**2014 Verification of Corrective Action:** This noncompliance did not cite the USDA organic regulations and does not appear to be in violation of the regulations. Interviews of ETKO personnel and a review of the operation files indicate that certification reviews are conducted by someone other than the certification decision maker. Therefore, the NOP withdrew this noncompliance.

NP9222ZZA.NC7 – Cleared. 7 CFR §205.501(a)(16) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Charge applicants for certification and certified production and handling operations only those fees and charges for

certification activities that it has filed with the administrator." Fees charged and described on the Cost Estimate and Invoice as "Follow-up, Certification: NOP ETKO Staff" are not included on the submitted fee schedule (TI 14). On all three files reviewed for fees charged to clients all three clients were not charged in accordance with the fee schedule. All three clients were undercharged based on the number of inspectors and days taken for the certification which is the method utilized by ETKO to determine the certification fees to be charged.

Corrective Action: ETKO revised their fee schedule (TI 14) to match the fees charged and described in the Cost Estimate and Invoice.

**2014 Verification of Corrective Action:** Interviews with ETKO personnel and certified operators in addition to operation file review indicated that estimated fees are provided to applicants and continuing certified operations and calculated according to the fee schedule.

NP9222ZZA.NC8 – Cleared. 7 CFR §205.642 states, "Fees charged by a certifying agent must be reasonable...The certifying agent shall provide each applicant with an estimate of the total cost of certification and estimate of the annual cost of updating the certification...The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule."

Nonrefundable fees are explained in the procedures but not in the fee schedule.

Corrective Action: ETKO revised their fee schedule (TI 14) to explain nonrefundable fees. **2014 Verification of Corrective Action:** ETKO lists nonrefundable fees in the current fee schedule.

NP9222ZZA.NC9 – Cleared. 7 CFR §205.501(a)(7) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measure to correct any non-compliances with the Act and the regulations in this part that are identified in the evaluation." ETKO's annual program review is not addressing all certification activities for the NOP. The 2008 internal audit used for the annual program review only reviewed EU files. The 2009 internal audit included NOP files; however, the 2009 annual program review had not been completed so it was not possible to verify the information to be reviewed.

Corrective Action: ETKO revised TI 30 NOP Accreditation Requirements and SP 03 Management Review procedure to ensure the annual program review addresses all certification activities for the NOP.

**2014 Verification of Corrective Action:** Management review report was completed on December 28, 2013 and included in ETKO's annual report acknowledged by the NOP in March 2014.

NP922ZZA.NC10 - Cleared. 7 CFR §205.207(a) states, "A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area..." NOP §205.202 states, "Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as organic must: (c) Have distinct, defined boundaries and buffer zones..." The wild crop witness inspection operation did not have maps or description designating the harvest area or identifying the buffer zones.

Corrective Action: ETKO issued a notification of non-compliance to the operation and ultimately suspend the operation. ETKO revised their wild collection procedure (TI 20) to more specifically require maps or a description of designated harvest areas and identification of buffer zones. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010.

**2014 Verification of Corrective Action:** During a witness audit of a wild crop inspection, the OCP maps of the three gathering areas indicated defined boundaries.

NP9222ZZA.NC11 – Cleared. 7 CFR §205.307(b) states, "Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the lot number of the product if applicable." The clients organic system plan (Section A16.3 Collection Activities) stated the main wild crop collector stores the product in a barrel labeled as organic. A barrel of capers at the wild crop collection depot did not have any labels or identification; although, the head collector stated it was organic.

Corrective Action: ETKO issued a notification of non-compliance to the operation and ultimately suspend the operation. ETKO revised the GP 18 procedure and the GP 18 F01-02 forms to ensure adequate labels and identification of organic product during inspections. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures.

2014 Verification of Corrective Action: All wholesale containers inspected and observed during the witness audits had lot numbers on labels.

NP9222ZZA.NC12 – Cleared. 7 CFR §205.103(b)(2)(4) states, "(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are... (b) Such records must: (2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited; (4) Be sufficient to demonstrate compliance with the Act and the regulations in this part." The operators for the wild crop, crop, and processing witness inspections did not maintain sufficient records to comply with the requirements.

Corrective Action: ETKO issued a notification of non-compliance to the operations and ultimately suspended the operations. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures, including the necessity of maintaining sufficient records.

**2014 Verification of Corrective Action:** All the operations observed during witness audits had sufficient records for the inspections to be fully conducted.

NP9222ZZA.NC13 – Cleared. 7 CFR  $\S205.403(c)(1) - (3)$  states, "The on-site inspection of an operation must verify: (1) the operation's compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan... accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which..."

1. During the inspection of the wild crop operation, the inspector did not reference the organic system plan during the inspection, did not physically verify all buffer

- areas or inquire about potential areas of contamination, and did not identify a non-labeled barrel (containing organic product) as a non-compliance.
- 2. During the producer witness inspection, the inspector did not inspect the storage unit where raisins are stored prior to shipment to the processor because there was nothing currently in storage. The inspector did not inquire about the use of (b) (4) for pest prevention at the storage depot; although, the product had recently been used by the certified operation and a bag was available for review.
- 3. During the producer witness inspection, the inspector did not fully inspect the chemical storage area of the producer and did not inquire about the (b) (4)

product in the storage area which were being used for conventional crops.

Corrective Action: ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures. ETKO increased monitoring activities of inspectors in 2009 and identified that during the 2010 inspection cycle all inspectors will be observed conducting NOP inspections to ensure compliance. ETKO submitted Inspector Monitoring Reports from the end of 2009.

**2014 Verification of Corrective Action:** ETKO continues to conduct annual training and field monitoring of inspectors. During the witness audits, inspectors were conducting thorough inspections with only minor issues observed and noted by the NOP auditor.

NP9222ZZA.NC14 - Cleared. 7 CFR §205.202(c) states, "Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as 'organic' must: (c) Have distinct, defined boundaries and buffer zones..." The crop witness inspection locations did not have maps or written descriptions to identify the boundaries and the buffer zones.

Corrective Action: ETKO issued a notification of non-compliance to the operation and ultimately suspended the operations. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures. ETKO revised GP 18 to specify that NOP applicants and clients must submit maps with defined boundaries and buffer zones, as applicable.

**2014 Verification of Corrective Action**: During the witness inspections all OCPs were complete with land or facility maps.

NP9222ZZA.NC15 – Cleared. 7 CFR §205.203(a) states, "The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological conditions of soil..." The OSP for the producer witness inspection stated they did practice cultivation methods to maintain or improve; however, five of the seven producers visited were leaving the fields unattended with little or no tillage or cultivation practices and only the application of inputs for pest or disease prevention and treatment.

Corrective Action: ETKO issued a notification of non-compliance to the operation and ultimately suspended the operations. ETKO revised GP 18 and GP 18 F 02 Agriculture Plan to address the issue of unattended fields. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures.

2014 Verification of Corrective Action (May 2014): Witness audits of several crop operations

revealed that producers were actively farming the sites and improving soil health.

NP9222ZZA.NC16 – Cleared. 7 CFR §205.501(a)(8) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part." The wild crop, crop, and processor witness inspection clients and their subcontracted units did not have adequate knowledge of the NOP requirements to enable them to comply with the Act. The wild crop witness inspection client purchasing representative and person responsible for training the head collectors stated he had not seen the NOP Rule and did not have any knowledge of the NOP Rule.

Corrective Action: ETKO issued a notification of non-compliance to the operations and ultimately suspended the operations. ETKO revised GP 18 to emphasize the necessity of adequate knowledge of the NOP requirements. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures.

**2014 Verification of Corrective Action:** ETKO is requiring certified operations to train and monitor individuals involved in organic production and handling activities. All operations observed and operation files reviewed indicated that training was occurring and recorded.

NP9222ZA.NC17 – Cleared. 7 CFR §205.403 (a)(1) states, "A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each..." and ETKO Technical Instruction TI 20 Certification of Wild Collection, Rev Nr. 2, 20.10.2008, section 5.4 states "ETKO inspectors will visit a certain number of collecting sites, according to the risk factors of the collection system; minimum site visit must be 5 and according to inspector's decision: This number can be increased up to 10 collection sites." The ETKO instructions and procedures allow for a sampling of certified operations to be inspected as opposed to all certified sites being inspected annually and thereafter as required. These operations are not certified as grower groups and would not qualify as grower groups (don't have to sell all organic harvest through the group). The wild crop and producer witness inspections along with interviews conducted, and records reviewed verified that not all sites are inspected as required.

Corrective Action: ETKO revised TI 20 Certification of Wild Collection, section 5.4 to distinguish between group certification with an internal control system and individual collection operations without an internal control system. The individual collection operations have multiple collectors; however, they are not considered grower groups and according to the revised procedure the on-site inspection will include all collectors and all locations.

**2014 Verification of Corrective Action:** All certified and applicant locations require annual on-site inspections according to Turkish organic standards. During the witness audits, all fields were inspected by the inspectors. No issues noted by the NOP auditor.

NP922ZZA.NC18 – Cleared. 7 CFR §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary" and

the 2002 NOSB Recommendation states, "The certifying agent shall have policies and procedures for determining how many growers must receive an annual inspection by the certifying agent." ETKO Procedure OP 02 Certification of Grower Groups is just a copy of the requirements for grower groups from the NOSB Recommendation. The procedure does not provide any actual information on how many growers will receive an annual inspection from the ETKO inspector.

Corrective Action: ETKO revised procedure OP 02 Certification of Grower Groups to define the risk categories of normal, medium, and high, and specify the number of members to be evaluated for each category. The total number for each category is based on increasing multiplication factors (1, 1.2, 1.4) of the square root of the total number of farmers with a mandatory minimum number of members that must be evaluated.

**2014 Verification of Corrective Action:** ETKO has a method (EU guidance) to calculate the number of external inspections of grower groups. All grower group files reviewed indicate that ETKO has properly implemented this procedure.

NP9222ZZA.NC19 – Cleared. 7 CFR §205.403(b)(2) states, "All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present..." Five of seven farms inspected did not have the farmer that manages the operation present for the inspection. The company representative responsible for purchasing the product from the farmers was present and he is also a farmer of a certified operation; however, he was only aware of the general production practices and not the specific practices of each operation. An interview with one of the farmers was conducted off-site; however, he was not present during the review at his field.

Corrective Action: ETKO revised GP 18, section 5.7 to specify that the NOP inspection cannot be carried out without the presence of an authorized and knowledgeable representative. ETKO informed NOP clients to provide NOP training to their responsible staff and producers. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards, review, inspection, and certification procedures.

**2014 Verification of Corrective Action:** All producers and operators were present during the witness audits. No issues noted by the NOP auditor.

NP9222ZZA.NC20 – Cleared. 7 CFR §205.301(a) states, "A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients." The crop and processing witness inspection client's organic certificate and organic system plan identifies the processed product (raisins) as 100 percent organic, but a potassium bicarbonate solution is being added to the grapes prior to on-farm drying to speed up the drying process and facilitate color development. One additional file reviewed identified the use of enzymes and non-certified pectin in a product identified as 100 percent organic.

Corrective Action: ETKO reviewed the files and revised the categories on the certificates to organic. ETKO conducted training of inspectors and reviewers on November 21, 2009 and March 12-14, 2010 which covered the NOP standards and labeling requirements.

2014 Verification of Corrective Action: During the review of operation files and certificates, the NOP auditor did not note any issues of concern with ETKO's classification

of organic products.

NP9222ZZA.NC21 - Outstanding. 7 CFR §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part." Interviews conducted, records reviewed, and witness inspections observed, verified a general lack of understanding of the NOP standards. While personnel had sufficient experience and education in organic agricultural production and handling practices, there was insufficient understanding on the application of the NOP standards as evidenced by inadequate information in the approved organic compliance (system) plans with no issues of concern or non-compliances being identified over multiple years of certification. The primary Certification Committee (CC) member with expertise in crops was not familiar with basic requirements such as the 90/120 day rule for raw manure application, did not know where to reference in the NOP Rule to determine if an input is permitted, and did not know when commercially available seeds and planting stock could be used. Additionally, while it was stated that the Certification Committee (CC) had received training there were no training records for any of the ČC members prior to 2009.

Corrective Action: ETKO conducted training of inspectors, reviewers, and Certification Committee members on November 21, 2009 and March 12-14, 2010 which covered NOP standards, review, inspection, and certification procedures. ETKO has designed a 2010 training plan to ensure periodic training on the NOP is completed. ETKO submitted records of training for all inspectors, reviewers, and Certification Committee members.

**2014 Verification of Corrective Action:** The NOP auditor found the following issues of concern that demonstrated an insufficient understanding of the USDA organic regulations and NOP policies:

1. Label review – the label review checklist did not include USDA organic regulation label requirements to be verified.

2. Inspectors during the witness audits used incorrect regulation citations during exit interviews to identify findings.

3. OCP templates state the incorrect USDA organic regulations.

4. Inspectors are using outdated USDA organic regulations (2010).

5. Inspectors and reviewers not readily able to look up regulations.

6. EKTO personnel have an incomplete understanding of the noncompliance and adverse action notification procedures.

7. Several crop operation OCPs reviewed by the NOP auditor indicated "Not Applicable" for Crop Rotation practice standard (205.205).

8. ETKO personnel did not understand and document buffer zone requirements (205.202(c)).

# Noncompliances Identified during the Current Assessment

NP4132LCA.NC1 – 7 CFR §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670." Furthermore, NOP 4009, Instruction – Who Needs to be Certified?, states "The OFPA requires

that agricultural products sold or labeled as organically produced must be produced only on certified farms and handled only through certified handling operations (see 7 USC § 6506(a)(1)). The USDA organic regulations reiterate these requirements (see 7 CFR 205.100.)"

**Comments:** ETKO certifies projects that contain uncertified operations (i.e. contractors) that produce or handle organic products that are not certified entities.

NP4132LCA.NC2 – 7 CFR §205.404(b)(3) states, "The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation."

Comments: Certificates do not adequately indicate the certification scopes of Crop, Wild Crop,

NP4132LCA.NC3 – 7 CFR §205.662(c) states, "When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent... shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance....The notification of proposed suspension or revocation of certification shall state: (1) The reasons for the proposed suspension or revocation; (2) The proposed effective date of such suspension or revocation; (3) The impact of a suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681."

**Comments:** ETKO suspended an operation without issuing a Notice of Proposed Suspension. The same operation after receiving the Notice of Suspension effective for 30 days was issued a Notice of Proposed Revocation and subsequently a Notice of Revocation. The sequence of issued notices and contents of the notifications demonstrate that ETKO does not fully comprehend the process of issuing notifications for noncompliances and adverse actions.

NP4132LCA.NC4 – 7 CFR §205.403(c) states, "The on-site inspection of an operation must verify: (1) The operation's compliance or capability to comply with the Act and the regulations of this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §\$205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples."

**Comments**: The following issues were identified by the NOP auditor during a review of the operation files and witness audits:

- 1. Inspectors did not completely verify the information stated in the Organic Compliance Plans. If observations and interviews at the onsite inspection did not align with the Organic Compliance Plan, the inspector failed to state this finding as an issue of concern.
- 2. ETKO inspectors are responsible for collecting large amounts of information about the operations when the Organic Compliance Plan (OCP) is incomplete or in error. The inspector did not note the finding as an issue of concern, failing to indicate that the OCP is incomplete. The inspector did not record these findings in the inspection report.

and Handling/Processing.

Minor updates or adjustments to the OCP during the onsite inspection is acceptable and can be noted in the inspector's report.

3. The inspection reports did not include a description and the outcome of the reconciliation activities (e.g. mass balance and audit trail audit) conducted by inspectors.

NP4132LCA.NC5 - 7 CFR § 205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

**Comments:** During a crop witness audit observation, the NOP auditor noted that the inspector was not equipped and possibly not adequately trained to conduct sampling for pesticide residues. Product samples were collected during the crop inspection; however, the inspector collected the samples with bare hands potential exposing the samples to contamination and jeopardizing sample integrity.

NP4132LCA.NC6 - 7 CFR § 205.501(a)(21) states "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms or conditions determined by the Administrator to be necessary." NOP Policy Memo (PM) 11-10 (dated 01/21/11) states, "Grower group certification...accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies."

**Comments:** Grower Groups certified by ETKO do not have documented and functioning Internal Control Systems.

1400 Independence Avenue, SW. Room 2646-S, STOP 0268 Washington, DC 20250-0201

## NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

# **AUDIT AND REVIEW PROCESS**

The National Organic Program (NOP) received Ecological Farming Control Organization's (ETKO) renewal application to maintain its U.S. Department of Agriculture (USDA) National Organic Program accreditation in June 2012. The NOP has reviewed ETKO's application, conducted an onsite audit, and reviewed the audit report to determine ETKO's capability to operate as a USDA accredited certifier.

#### **GENERAL INFORMATION**

Applicant Name	Name ETKO – Ecological Farming Control Organization	
Physical Address	160 Sk. No. 13/7, 35040, Bornova - Izmir, Turkey	
Mailing Address	160 Sk. No. 13/7, 35040, Bornova - Izmir, Turkey	
Contact & Title	Dr. Mustafa Akyuz	
Contact & Title	General and QMS Manager	
E-mail Address	ma@etko.org	
Phone Number	+90-232-3397606	
Reviewer(s) &	Penny Zuck, NOP Reviewer	
Auditor(s)	Lars Crail, Onsite Auditor	
Program	USDA National Organic Program (NOP)	
	Corrective Action review: September 10 – November 3, 2015	
Review & Audit Date(s)	NOP assessment review: April 29, 2015	
	Onsite Audit: May 12-16, 2014	
Audit Identifier	NP4132LCA	
Action Required	Required   See Notice of Proposed Suspension	
Audit & Review Type Renewal Assessment		
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the	
Audit Objective	implementation and effectiveness of ETKO's certification system.	
Audit & Determination	7 CFR Part 205, National Organic Program as amended	
Criteria		
Audit & Review Scope	ETKO's certification services in carrying out the audit criteria for Crops,	
Audit & Keview Scope	Wild Crops, and Handling	

### Organizational Structure:

The Ecological Farming Control Organization is abbreviated as ETKO from their Turkish name (Ekolojik Tarım Kontrol Organizasyonu). ETKO is a for-profit, limited liability company with two shareholders. The main office for USDA organic certification for ETKO is located in Bornova – Izmir, Turkey. All certification activities for the NOP are conducted at the Izmir office; there are no satellite offices that conduct USDA organic key activities.

ETKO was initially accredited as a certifying agent on January 22, 2003 to the USDA National Organic Program (NOP) for crops, wild crops, and handling. ETKO currently certifies operations to the USDA organic regulations in the following countries: Turkey, Russia, Serbia, Korea, Kazakhstan, and the Ukraine. As of May 2014, ETKO's NOP client list had 40 certified operations with 22 crops, 3 wild crops, and 39 handling operations. ETKO certifies to the Turkish Organic Standard under the legal authority of the Organic Farming Committee of the Republic of Turkey the Ministry of Agriculture and Rural Affairs Research Planning and Coordination Council (TURKAK). ETKO is also accredited by TURKAK to perform conformity assessments for Turkey's Good Agricultural Practices (GAP). At the time of the renewal audit, ETKO was accredited to ISO 17065 by the International Organic Accreditation Service (IOAS) in the areas of agricultural production, processing and imports of organic agricultural products according to the EEC, GlobalGap, and the Global Organic Textile Standard (GOTS).

ETKO employees staff members that are involved in USDA organic certification. The staff consists of administrative personnel and technical personnel which also conduct inspections.

#### NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether ETKO's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

# Non-compliances from Prior Assessments

Any noncompliance labeled as "Cleared," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "Outstanding" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP7199OOA.NC3 - Cleared

NP7199OOA.NC5 - Cleared

NP7199OOA.NC6 - Cleared

NP8050OOA.NC1 - Cleared

NP8050OOA.NC2 - Cleared

NP9222ZZA.NC1 - Cleared

NP9222ZZA.NC2 - Cleared

NP9222ZZA.NC3 - Cleared

NP9222ZZA.NC4 - Cleared

NP9222ZZA.NC5 - Cleared

NP9222ZZA.NC6 - Withdrawn

NP9222ZZA.NC7 - Cleared

NP9222ZZA.NC8 – Cleared

NP9222ZZA.NC9 - Cleared

NP9222ZZA.NC10 - Cleared

NP9222ZZA.NC11 – Cleared NP9222ZZA.NC12 – Cleared NP9222ZZA.NC13 – Cleared NP9222ZZA.NC14 – Cleared NP9222ZZA.NC15 – Cleared NP9222ZZA.NC16 – Cleared NP9222ZZA.NC17 – Cleared NP9222ZZA.NC18 – Cleared NP9222ZZA.NC19 – Cleared NP9222ZZA.NC20 – Cleared

NP9222ZZA.NC21 - 7 CFR §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part." Interviews conducted, records reviewed, and witness inspections observed, verified a general lack of understanding of the NOP standards. While personnel had sufficient experience and education in organic agricultural production and handling practices, there was insufficient understanding on the application of the NOP standards as evidenced by inadequate information in the approved organic compliance (system) plans with no issues of concern or non-compliances being identified over multiple years of certification. The primary Certification Committee (CC) member with expertise in crops was not familiar with basic requirements such as the 90/120 day rule for raw manure application, did not know where to reference in the NOP Rule to determine if an input is permitted, and did not know when commercially available seeds and planting stock could be used. Additionally, while it was stated that the Certification Committee (CC) had received training there were no training records for any of the CC members prior to 2009.

Corrective Action: ETKO conducted training of inspectors, reviewers, and Certification Committee members on November 21, 2009 and March 12-14, 2010 which covered NOP standards, review, inspection, and certification procedures. ETKO has designed a 2010 training plan to ensure periodic training on the NOP is completed. ETKO submitted records of training for all inspectors, reviewers, and Certification Committee members.

**2014 Verification of Corrective Action:** The NOP auditor found the following issues of concern that demonstrated an insufficient understanding of the USDA organic regulations and NOP policies:

- 1. Label review the label review checklist did not include USDA organic regulation label requirements to be verified.
- 2. Inspectors during the witness audits used incorrect regulation citations during exit interviews to identify findings.
- 3. OCP templates state the incorrect USDA organic regulations.
- 4. Inspectors are using outdated USDA organic regulations (2010).
- 5. Inspectors and reviewers not readily able to look up regulations.
- 6. ETKO personnel have an incomplete understanding of the noncompliance and adverse action notification procedures.
- 7. Several crop operation OCPs reviewed by the NOP auditor indicated "Not Applicable" for Crop Rotation practice standard (205.205).

8. ETKO personnel did not understand and document buffer zone requirements (205.202(c)).

**2015** Corrective Action: ETKO submitted PowerPoint presentations, updated forms, training agenda, and training log of the training that was conducted for inspectors, staff, and advisory committee members. The documentation submitted also included copies of completed OCPs with documented buffer zones, and crop rotation practices.

ETKO has designated a responsible person to follow up on NOP updates to the Program Handbook and regulations. This person will translate all updates and provide them to staff members and inspectors by email and/or hardcopy. When necessary, related staff members will be trained for specific updates. The training will be recorded in the training register (new document) and the register will be provided to USDA with ETKO's annual reporting. A copy of the training register form was submitted to NOP.

# Non-compliances Identified during the Current Assessment

NP4132LCA.NC1 –7 CFR §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670." Furthermore, NOP 4009, Instruction – Who Needs to be Certified?, states "The OFPA requires that agricultural products sold or labeled as organically produced must be produced only on certified farms and handled only through certified handling operations (see 7 USC § 6506(a)(1)). The USDA organic regulations reiterate these requirements (see 7 CFR 205.100)."

**Comments:** ETKO certifies projects that contain uncertified operations (i.e. contractors) that produce or handle organic products that are not certified entities.

Corrective Action: ETKO stated it will certify each subcontracted processing facility during the 2015 production period. ETKO sent a letter to all clients in August 2015 informing them of this requirement. ETKO issued a new instruction for staff, NOP Certification of Subcontracted Operators (TI 48), which describes the basic rules of subcontracted facilities under NOP certification requiring separate certification. ETKO updated the NOP procedure section 7.2.2.3 Processing and Handling Facilities, which requires subcontractors to be certified separately and refers to the instruction (TI 48) for details. ETKO staff was trained during the annual training in July 2015.

NP4132LCA.NC2 –7 CFR §205.404(b)(3) states, "The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation."

**Comments:** Certificates do not adequately indicate the certification scopes of Crop, Wild Crop, and Handling/Processing.

Corrective Action: ETKO submitted copies of corrected certificates identifying the scopes of certification. To prevent this from recurring, ETKO has updated the certificate template and the corrected form will now be used. ETKO submitted a copy of the revised template document with the correct NOP scopes of certification.

NP4132LCA.NC3 –7 CFR §205.662(c) states, "When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent... shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance....The notification of proposed suspension or revocation of certification shall state: (1) The reasons for the proposed suspension or revocation; (2) The proposed effective date of such suspension or revocation; (3) The impact of a suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681."

**Comments:** ETKO suspended an operation without issuing a Notice of Proposed Suspension. The same operation after receiving the Notice of Suspension effective for 30 days was issued a Notice of Proposed Revocation and subsequently a Notice of Revocation. The sequence of issued notices and contents of the notifications demonstrate that ETKO does not fully comprehend the process of issuing notifications for noncompliances and adverse actions.

Corrective Action: ETKO has updated their procedures and trained staff and inspectors on the following: NOP 4002 Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix, NOP Penalty Matrix 2612 and NOP 4011 Adverse Action Appeal Process for the NOP. These documents were translated into Turkish in order to provide better understanding of the procedures by NOP involved ETKO staff members. The translated documents, training documents and agenda were submitted to NOP. Further, ETKO will check the NOP Handbook regularly and pertinent documents will be translated immediately. Translated documents will be studied with related staff and inspectors. ETKO submitted NOP Handbook documents to NOP as they were being translated.

NP4132LCA.NC4 –7 CFR §205.403(c) states, "The on-site inspection of an operation must verify: (1) The operation's compliance or capability to comply with the Act and the regulations of this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples."

**Comments**: The following issues were identified by the NOP auditor during a review of the operation files and witness audits:

- Inspectors did not completely verify the information stated in the Organic Compliance Plans. If observations and interviews at the onsite inspection did not align with the Organic Compliance Plan, the inspector failed to state this finding as an issue of concern.
- 2. ETKO inspectors are responsible for collecting large amounts of information about the operations when the Organic Compliance Plan (OCP) is incomplete or in error. The inspector did not note the finding as an issue of concern, failing to indicate that the OCP is incomplete. The inspector did not record these findings in the inspection report. Minor updates or adjustments to the OCP during the onsite inspection is acceptable and can be noted in the inspector's report.

3. The inspection reports did not include a description and the outcome of the reconciliation activities (e.g. mass balance and audit trail audit) conducted by inspectors.

Corrective Action: ETKO submitted documentation from the training it conducted with inspectors on the following topics: "1) Using and evaluation of OCP during onsite inspection; 2) Review of organic compliance plans and identifying noncompliances before inspections, in order to avoid losing time to collect large amount of information and documents; and 3) How to make input-output balance and report it." ETKO also submitted examples of completed inspection reports from inspectors showing input-output balance and updates to the inspection forms.

NP4132LCA.NC5 –7 CFR § 205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

**Comments:** During a crop witness audit observation, the NOP auditor noted that the inspector was not equipped and possibly not adequately trained to conduct sampling for pesticide residues. Product samples were collected during the crop inspection; however, the inspector collected the samples with bare hands potential exposing the samples to contamination and jeopardizing sample integrity.

Corrective Action: ETKO submitted training slides and updated forms used to conduct training for NOP inspectors, staff, and advisory committee members on the following topics: OP 03 Testing, TI 05 Sampling Method, TI 40 NOP Guide Testing & Enforcement Action. Training took place July 6-9, 2015.

NP4132LCA.NC6 –7 CFR § 205.501(a)(21) states "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms or conditions determined by the Administrator to be necessary." NOP Policy Memo (PM) 11-10 (dated 01/21/11) states, "Grower group certification...accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies."

**Comments:** Grower Groups certified by ETKO do not have documented and functioning Internal Control Systems.

Corrective Action: ETKO created a form to be used for inspection of Internal Control Systems for grower groups and revised the OCP to include the grower group Internal Control System requirement. ETKO updated its NOP Certification Procedure Manual with the requirements to document and verify Internal Control Systems. These forms and procedures will be implemented this year for all grower groups. The forms and revised NOP Certification Procedure Manual were submitted to NOP. ETKO conducted training on this topic July 7, 2015. The training materials and an agenda were submitted to NOP.

# ATTACHMENT D

ETKO Email Message June 13, 2015 To Penelope Zuck and Robert H. Yang of NOP

# Attaching:

ETKO Letter dated June 12, 2015, To Cheri Courtney Director, Accreditation and International Activities Division

# And

ETKO's 5-page Corrective Action Plan In Response to the Seven Noncompliances Identified in the Notice of Noncompliance Dated May 13, 2015 From: ma@etko.org [mailto:ma@etko.org] Sent: Saturday, June 13, 2015 12:50 AM

To: 'Zuck Penelope - AMS'; 'Yang, RobertH - AMS

Cc: 'AlAlnbox@usda.gov'; 'Fatih AKSOY'

Subject: RE: Registered: Notice of Non-compliance - Onsite Assessment

Mrs Zuck

You can find attached ETKO Letter and Corrective Action Plan. For any remaining questions I am at your disposal.

Sincerely

Mustafa Akyuz

ETKO Turkey 160 Sokak No: 13/3 35100 Bornova Izmir – Turkey. www.etko.org



Ekolojik Tarım Kontrol Organizasyonu Ltd Şti 160 sk No: 13/3 35040 Bornova – İzmir Tel: +90-232-3397606 Fax:+90-232-3397607 Email: info@etko.org www.etko.org

Ref No: 2015061201 Date: June 12, 2015

Subject: Proposed Corrective Action Plan related to Renewal Accreditation

Assessment Audit NCs

Dear Mrs Courtney

According to your letter May 13, 2015 and Noncompliance Report we prepared a Corrective Action Plan as attached to this letter.

We will start corrective actions as an immediate effect in line with NOP 2608 Responding to Noncompliance's Instruction.

I hope the Corrective Action Plan is enough for the moment, otherwise please let us know for further explanations.

Sincerely Dr. Mustafa AKYÜZ

## Documents send:

1-Corrective Action Plan



Tel: 0232-3397606	Fax: 0232-3397607	Email: info@etko.org	http; www	w.etko.org
Tax office: Bornova Tax No: 381 023 6931	Chamber of commerce No: 92592.1	Bank Türkiye İşbankası Bornova Şubesi	Accaunt Euro; T.lira;	3403 0535 690 3403 1122 346

	Penny Zuck, NOP Reviewer; Lars Crail, On-site Auditor 12-16 May 2014:		
	Meysan Crop and Processing, Susitas wild collection		
NP4132LCA.NC1 –	NOP REQUIREMENT  7 CFR \$205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of \$\$205.402 through 205.406 and \$205.670." Furthermore, NOP 4009, Instruction — Who Needs to be Certified?, states "The OFPA requires that agricultural products sold or labeled as organically produced must be produced only on certified farms and handled only through certified handling operations (see 7 USC § 6506(a)(1)). The USDA organic regulations reiterate these requirements (see 7 CFR 205.100.)"	NON COMPLIANCES  Comments: ETKO certifies projects that contain uncertified operations (i.e. contractors) that produce or handle organic products that are not certified entities	CORRECTIVE ACTION PLAN During 2015 production period processing facilities will be certified separately in case they are subcontracted to any NOP certified operators.
NP4132LCA.NC2	7 CFR §205.404(b)(3) states, "The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation."	Comments: Certificates do not adequately indicate the certification scopes of Crop, Wild Crop, and Handling/Processing	2014 certificates will be updated accordingly and scopes will be clearly indicated.
NP4132LCA.NC3	CFR §205.662(c) states, "When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncomplianceThe notification of proposed suspension or revocation of certification shall state: (1) The reasons for the proposed suspension or revocation; (2) The proposed effective date of such suspension or revocation; (3) The impact of a suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.	Comments: ETKO suspended an operation without issuing a Notice of Proposed Suspension. The same operation after receiving the Notice of Suspension effective for 30 days was issued a Notice of Proposed Revocation and subsequently a Notice of Revocation. The sequence of issued notices and contents of the notifications demonstrate that ETKO does not fully comprehend the process of issuing notifications for noncompliance's and adverse actions	ETKO NOP Procedure will be updated according to following procedures. These procedures will be studied carefully with ETKO stuff members involved with NOP certification. 1-Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix. January 20, 2015, 2-NOP Penalty Matrix 2612 and 3-NOP 4011 Adverse Action Appeal Process for the National Organic Program. These

	ON SITE AUDIT CORRECTIVE ACT	ION I LENN	
			documents will be
			translated in Turkish in
			order to provide better
			understanding of the
			procedures by NOP
			involved ETKO stuff
			members.
NP4132LCA.NC4	CFR §205.403(c) states, "The on-site inspection of an operation must	Comments: The following	Training will be done for
1	verify: (1) The operation's compliance or capability to comply with the	issues were identified by the	inspectors assigned as
	Act and the regulations of this part; (2) That the information, including	NOP auditor during a review	NOP inspectors for the
ĺ	the organic production or handling system plan, provided in accordance	of the operation files and	following topics:
	with §§205.401, 205.406, and 205.200, accurately reflects the practices	witness audits	
	used or to be used by the applicant for certification or by the certified	1. Inspectors did not	1-Using and Evaluation of
	operation; (3) The prohibited substances have not been and are not	completely verify the	OCP during onsite
	being applied to the operation through means which, at the discretion of	information stated in the	inspection
	the certifying agent, may include the collection and testing of soil; water;	Organic Compliance Plans. If	
	waste; seeds; plant tissue; and plant, animal, and processed products	observations and interviews at	
	samples	the onsite inspection did not	
		align with the Organic	
		Compliance Plan, the	
		inspector failed to state this	
		finding as an issue of concern.	
		2. ETKO inspectors are	
		responsible for collecting large	2-Review of Organic
		amounts of information about	Compliance plans before
		the operations when the	inspections, in order to
		Organic Compliance Plan	avoid losing time to collect
		(OCP) is incomplete or in	large amount of
		error. The inspector did not	information and
		note the finding as an issue of	documents.
		concern, failing to indicate	(dentify noncompliance's
		that the OCP is incomplete.	during the review process
		The inspector did not record	of OCP before inspections.
		these findings in the	
		inspection report. Minor	

	ON SITE AUDIT CORRECTIVE ACT		
		updates or adjustments to the	
		OCP during the onsite	
		inspection is acceptable and	
		can be noted in the inspector's	
		report.	Ī
		3. The inspection reports did	3. How to make Input-
		not include a description and	output balance and report
		the outcome of the	it.
		reconciliation activities (e.g.	Inspection forms will be
		mass balance and audit trail	updated accordingly.
		audit) conducted by	More
		inspectors.	
NP4132LCA.NC5	CFR § 205.501(a)(2) states, "A private or governmental entity accredited	Comments: During a crop	Training will be done for
	as a certifying agent under this subpart must: Demonstrate the ability to	witness audit observation, the	inspectors assigned as
	fully comply with the requirements for accreditation set forth in this	NOP auditor noted that the	NOP inspectors for the
	subpart	inspector was not equipped	following topics: OP 03
		and possibly not adequately	Testing, TI 05 Sampling
		trained to conduct sampling	Method, TI 40 NOP Guide
		for pesticide residues. Product	Testing & Enforcement
		samples were collected during	Action
		the crop inspection; however,	Action
		the inspector collected the	
		samples with bare hands	
		potential exposing the	
		, -	
		samples to contamination and	
NP4132LCA.NC6	7 CFR § 205.501(a)(21) states "A private or governmental entity	jeopardizing sample integrity	ETKO D 1 OD OZ
WF413ZLCA.NCU	· · · · · · · · · · · · · · · · · · ·	Comments: Grower Groups	ETKO Procedure OP 02
	accredited as a certifying agent under this subpart must: Comply with,	certified by ETKO do not have	Grower group certification
	implement, and carry out any other terms or conditions determined by	documented and functioning	will be implemented this
	the Administrator to be necessary." NOP Policy Memo (PM) 11-10	Internal Control Systems	year for all groups.
	(dated 01/21/11) states, "Grower group certificationaccredited		
	certifying agents should use the National Organic Standards Board		
	(NOSB) recommendations of October 2002 and November 2008 as the		
	current policies."		

NP9222ZZA.NC21 -Outstanding

CFR §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part." Interviews conducted, records reviewed, and witness inspections observed, verified a general lack of understanding of the NOP standards. While personnel had sufficient experience and education in organic agricultural production and handling practices, there was insufficient understanding on the application of the NOP standards as evidenced by inadequate information in the approved organic compliance (system) plans with no issues of concern or non-compliances being identified over multiple years of certification. The primary Certification Committee (CC) member with expertise in crops was not familiar with basic requirements such as the 90/120 day rule for raw manure application, did not know where to reference in the NOP Rule to determine if an input is permitted, and did not know when commercially available seeds and planting stock could be used. Additionally, while it was stated that the Certification Committee (CC) had received training there were no training records for any of the CC members prior to 2009.

Corrective Action: ETKO conducted training of inspectors, reviewers, and Certification Committee members on November 21, 2009 and March 12-14, 2010 which covered NOP standards, review, inspection, and certification procedures. ETKO has designed a 2010 training plan to ensure periodic training on the NOP is completed. ETKO submitted records of training for all inspectors, reviewers, and Certification Committee members. 2014 Verification of Corrective Action: The NOP auditor found the following issues of concern that demonstrated an insufficient understanding of the USDA organic regulations and NOP policies: 1. Label review - the label review

- organic regulation label requirements to be verified.

  Inspectors during the witness audits used incorrect regulation citations during exit interviews to identify findings.
- 3. OCP templates state the incorrect USDA organic regulations.
- Inspectors are using outdated USDA organic regulations (2010).
   Inspectors and reviewers not readily able to look up regulations.
- 6. EKTO personnel have an incomplete understanding of the

Training will be intensified for inspectors and necessary updates will be done for the following issues:

1-Label assessment form will be updated and NOP labelling requirements will be added to the assessment form.

2-NOP Regulation will be provided to inspectors assigned for NOP inspections. Inspectors will be trained for "How to identify regulation citations related to findings" 3-OCP templates will be reevaluated and regulation numbers will be corrected.
4-Inspectors will be provided actual regulation.
5-Case study will be prepared for ETKO Stuff (inspectors,

to use the regulation during inspection.
6-NOP Procedure will be updated according to NOP Noncompliance and Adverse Action Notification procedures. ETKO Stuff members will be trained for the updated procedure.

reviewers, and certifier) how

7-Crop rotation standard 205.205 will be studied carefully and NOP operator's compliance will be verified through OCP review and

	 noncompliance and adverse	evaluation on site.
	action notification procedures.	8-Buffer zone practice will be
ł	7. Several crop operation OCPs	studied and buffer zone
	reviewed by the NOP auditor	evaluations will be made
	indicated "Not Applicable" for	onsite. Inspectors will be
	Crop Rotation practice standard	monitored for this practice.
	(205.205).	
ļ	8. ETKO personnel did not	
	understand and document buffer	
-	zone requirements (205,202(c)).	
ļ.		

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Noncompliance NC1

Email correspondence between

Penelope Zuck of NOP

And ETKO

July 21 and July 23, 2015

July 29 and August 12, 2015

November 12 and November 13, 2015

November 19 and December 1, 2015

From: Zuck, Penelope - AMS [mailto:Penelope.Zuck@ams.usda.gov]

Sent: Tuesday, July 21, 2015 4:53 PM

To: ma@etko.org

Cc: 'Fatih AKSOY'; 'Mustafa Akyuz'

Subject: RE: Corrective Actions Email 16 FINISHED

# Hello Mustafa,

Thank you so much for the documentation you submitted. I received all 16 emails. There are 2 items I still need:

- 1. NP4132LCA.NC2 The Corrective Action plan indicates corrected certificates including scopes of certification were attached, but I did not receive the certificate examples as an attachment to any of the emails.
- 2. NP4132LCA.NC1 The Corrective Action plan indicates you will certify each subcontracted facility during the 2015 production period. Can you please submit documented evidence of how this is being handled, such as notification letters to clients, etc.

Hopefully, that is all! Best Regards, Penny

From: ma@etko.org [mailto:ma@etko.org]
Sent: Thursday, July 23, 2015 11:10 AM

To: 'Zuck, Penelope - AMS'

Cc: 'Fatih AKSOY'

Subject: RE: Corrective Actions Email 16 FINISHED

Dear Penny

I prepared the notification as attached. As far as I know subcontracted handling / processing Operations covers only the ones as explained in definition processing. There are other subcontracted handling facilities such as storage, transport, forwarding etc which do not have any processing activities. These kind of subcontractors are not subject for separate certification. If I am mistaken here please inform me so I can renew the letter to clients.

Thank you in advance

Have a nice day

Mustafa

From: Zuck, Penelope - AMS [mailto:Penelope.Zuck@ams.usda.gov]

Sent: Wednesday, July 29, 2015 3:53 PM

To: ma@etko.org
Cc: 'Fatih AKSOY'

Subject: RE: Corrective Actions

Dear Mustafa,

Thank you for sending the certificates and copy of the notification you plan to send to your clients.

Additional information is needed for the following noncompliances:

#### NP4132LCA.NC1

Facilities that are used for storage and transportation will still need to be included in an approved Organic System Plan and ETKO can determine if individual certification will be required based on the activities at the facilities. The draft letter you provided does not instruct your clients how to go about obtaining individual organic certification or a deadline/timeframe by which they must complete the certification. I will also need to know when you expect to send the notification. Your corrective action plan indicated you will certify each subcontracted processing facility during the 2015 production period. I need a timeline explaining how this will be accomplished along with the revised notification.

#### NP4132LCA.NC3

The updated procedures and adverse action templates you submitted are not in compliance with the regulations. Some of the issues are as follows:

- 1. ETKO's Notice of Proposed Suspension template and 7.5.9.1. Resolving the Non-compliances section of NOP Certification Procedure indicates corrective actions can be submitted to address the noncompliance(s). Only appeal or mediation can take place at this stage of compliance.
- 2. ETKO's Notice of Proposed Revocation indicates the operation has received a Notice of Proposed Suspension and Notice of Suspension. 7.5.9.1. Resolving the Non-compliances section of NOP Certification Procedure states: "Once the certification is suspended, if during the suspension period the certified operation fails to make a request to ETKO for the reinstatement of its certification, the Notification of Proposed Revocation (NOPR) (GP 18 F 15) is issued to the certified operator." A Notice of Suspension does not turn into a Notice of Revocation. An operation is either suspended OR revoked. The Notice of Proposed Revocation also indicates the operator can still submit corrective actions. Only appeal or mediation can take place at this stage of compliance.
- 3. Notice of Revocation indicates the operator can still submit corrective actions. A revocation cannot be corrected. A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, Except, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

These are just some of the noncompliant items contained in your adverse action templates and procedures. You will need to revise the procedures and templates to be sure they are following the NOP regulations. Please refer to the following resources:

- 7CFR §205.662 Noncompliance procedure for certified operations.
- Training module (2015) titled "Appeals and Settlement Agreement Updates" and training module (2014) titled "Appeals Update", which can be obtained from the following link to the NOP website: <a href="http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&topNav=NationalOrganicProgram&page=NOPTraining&description=NOP%20Training&acct=nopgeninfo">http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&topNav=NationalOrganicProgram&page=NOPTraining&description=NOP%20Training&acct=nopgeninfo</a>

Please submit the above information/documentation to me by August 12, 2015. Let me know if you have any questions or need any further clarification on these pending noncompliances.

Thank you, Penny



From: ma@etko.org [mailto:ma@etko.org] Sent: Wednesday, August 12, 2015 6:54 PM

To: 'Zuck, Penelope - AMS'

Cc: 'Fatih AKSOY'

Subject: RE: Corrective Actions

Dear Penny

Pleae find attached draft of the info letter for the certified operators, which I am planning to send.

You can also have a look at the forms and the procedure as updated. I hope they are in line now.

I was not sure only about the Notification of Suspension and Notification of Revocation forms if we need to add the Noncompliances as we do with the Notification of Noncompliances and Notification of Proposed Suspension and Revocation templates.

Please inform if any deviations remained in these parts.

Best regards,

Mustafa



Ekolojik Yarım Kontrol Organizasyonu Ltd. Şti. 160 Sok. No:13/3 35040 Bornova İzmir Tel: +90-232-339 76 06 Fax: +90-232-339 76 07 E-mail:info@etko.org www.etko.org

Ref. Nr: 2015081401 Date: 14.08.2015

Subject: Certification of Subcontracted Processing Facilities, Storage and Transport

#### To whom it may concern

#### Dear all

According to USDA National Organic Program "NOP certification" procedures ETKO will make separate certification for the subcontracted handling / processing facilities. You must accomplish to certify these operations until the date December 31st, 2015.

#### Definition of processing is following:

*Processing.* Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

#### Related to transport and storage activities.

Storage and transportation is still integrated in to the handling operations and covered by the Organic System Plan. The difference between processing units and these operations (storage/transport) we will not make separate certification like we do for processing facilities. Storage and transport will be evaluated under the responsibility of the licensee which we make contract and certification.

#### Following scenarios are possible:

A-Storage belongs to the farm and transport is done by the farmer. Farm receives certification either individually or belongs to a certified operator such as group certification. So transport and storage activities are covered by Organic System Plans and inspected by ETKO.

B-Storage belongs to the processor and transport is done by the processor. Processor receives certification independently. So transport and storage activities are covered by Organic System Plans and inspected by ETKO.

C-An independent subcontracted transport company deals with the transport. Transport Company is not inspected and certified but transport activities of organic products are checked from the farms and processing facilities especially documentary evidences. Independent transporting companies are

	Bornova Tax Office: 3810236931	Bank: Türkiye İş Bankası Bornova Branch/Şubesi
İ	Izmlr Chamber of Commerce:	Bank Adress :Mustafa Kemal Cad. No 95/A 35040 Bornova-IZMIR-TURKEY
	92592.1	SWIFT:ISBKTRISAccountNo:EURO: 3403 0535 690 - USD: 3403 0594 407 - T.LIRA: 3403 1122 346
- 1	IBAN	EURO: TR9000 0640 0000 2340 3053 5690 TL: TR3100 0640 0000 1340 3112 2346
-		USD : TR0200 0640 0000 2340 3059 4407



not eligible for OSP and certification. There are some cases operator subcontracts transport companies or individuals having trucks for only one time transport or a few times.

D-An independent storage is rented for organic products by the certified operator. Storage facility is inspected for storage conditions and documents related to organic products. This storage is eligible for OSP. Storage is not certified individually, listed as subcontractor under the certified operators.

#### To have a better overview:

You can find below different scenarios which may apply to your operation. Timeframe you apply this procedure starting the date of this notification letter. You must complete all your operation certifications before December 31<sup>st</sup>, 2015. Please update your Organic Compliance Plans and provide ETKO urgently.

Scenario	Storage	Transport	Eligible for OSP	Independent certification	Subcontracted	Result
А	belongs to the farm	belongs to the farm	Yes	Yes	No	Farm receives certification either individually or belongs to a certified operator such as group certification covers the storage and transport.
В	belongs to processor	belongs to processor	Yes	Yes	No	Processor receives certification independently for activities including transport and storage activities
С		Independent	No	No	Yes	Transport Company is not inspected and certified but transport activities of organic products are inspected from the farms, stores and processing facilities. Especially documentary evidences for transporting activities.
Đ	Independent		Yes	No	Yes	Storage facility is inspected for storage conditions and documents related to organic products. Storage is not certified individually, listed as subcontractor under the certified operators.

For any remaining questions	, do not hesitate to contact to
-----------------------------	---------------------------------

fa@etko.org, info@etko.org .

Fatih AKSOY

Sincerely

Bornova Tax Office: 3810236931	Bank: Türkiye İş Bankası Bornoya Branch/Şubesi	
Izmir Chamber of Commerce:	Bank Adress :Mustafa Kemal Cad, No 95/A 35040 Bornova-IZMIR-TURKEY	
92592.1	SWIFT:ISBKTRISAccountNo:EURO : 3403 0535 690 ~ USD : 3403 0594 407 ~ T.LIRA : 3403 1122 346	
IBAN	EURO: TR9000 0640 0000 2340 3053 5690 TL: TR3100 0640 0000 1340 3112 2346	
	USD : TR0200 0640 0000 2340 3059 4407	

From: Zuck, Penelope - AMS [mailto:Penelope.Zuck@ams.usda.gov]

Sent: Thursday, November 12, 2015 11:20 PM

To: ma@etko.org
Cc: 'Fatih Aksoy'

Subject: RE: Noncompliance Report follow-up

Hello Mustafa,

It has come to my attention that a preventative measure was not submitted along with the corrective action for NP4132LCA.NC1:

7 CFR §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670." Furthermore, NOP 4009, Instruction – Who Needs to be Certified?, states "The OFPA requires that agricultural products sold or labeled as organically produced must be produced only on certified farms and handled only through certified handling operations (see 7 USC § 6506(a)(1)). The USDA organic regulations reiterate these requirements (see 7 CFR 205.100)."

**Comments:** ETKO certifies projects that contain uncertified operations (i.e. contractors) that produce or handle organic products that are not certified entities.

**Corrective Action:** ETKO stated it will certify each subcontracted processing facility during the 2015 production period and submitted the draft letter that will be sent to all clients informing them of this requirement.

The corrective action above is accepted, however, you must indicate how you prevent this from occurring in the future. Did you change any procedures, train the staff so they know how to handle new applicants with uncertified contractors?

I'm really hoping to get all of these noncompliances corrected and accepted by NOP as soon as possible, since this is your renewal of accreditation, it will need to be approved by the NOP Accreditation Committee and takes additional time, so please respond to this request by November 18, 2015.

Let me know if you have any questions or if you have already submitted documentation that addresses this concern, I apologize, but have not located anything in the documentation I've already received that specifically addresses this concern.

Regards, Penny



From: ma@etko.org [mailto:ma@etko.org] Sent: Friday, November 13, 2015 5:51 PM

To: 'Zuck, Penelope - AMS'

Cc: 'Fatih Aksoy'

Subject: RE: Noncompliance Report follow-up

## **Dear Penny**

You can find attached Instruction TI 48 and updated NOP procedure section 7.2.2.3 Processing and Handling Facilities: As I informed you earlier we send out the letter to all etko operators and followed the rule this year accordingly. See attached letter.

For training purpose this subject was discussed with ETKO stuff during annual training in July on Monday 10.00-12.30 explained by Fatih Aksoy and myself. Also the letter was provided to ETKO staff dealing with NOP.

I hope this information is enough to safeguard subcontractor rule.

Have a nice weekend,

Mustafa



# **NOP Certification of Subcontracted Operators**

DOC. NR	TI 48
DATE	13.11.2015
REV. NR	00
SAYFA	1/2

#### 1. PURPOSE

This instruction describes the basic rules of subcontracted facilities under NOP certification.

#### 2. RESPONSIBILITIES

Application, Inspection and certification department.

#### 3. REFERENCES

**NOP Regulation** 

### 4. APPLICATION

According to USDA National Organic Program "NOP certification" procedures separate certification for the subcontracted handling / processing facilities is required.

#### 4.1 Definition of processing is following:

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

#### 4.2 Related to transport and storage activities.

Storage and transportation is still integrated in to the handling operations and covered by the Organic System Plan. The difference between processing units and these operations (storage/transport) we will not make separate certification like we do for processing facilities. Storage and transport will be evaluated under the responsibility of the licensee which we make contract and certification.

#### 4.3 Following scenarios are possible:

A-Storage belongs to the farm and transport is done by the farmer. Farm receives certification either individually or belongs to a certified operator such as group certification. So transport and storage activities are covered by Organic System Plans and inspected by ETKO.

B-Storage belongs to the processor and transport is done by the processor. Processor receives certification independently. So transport and storage activities are covered by Organic System Plans and inspected by ETKO.

PREPARED	APPROVED
QUALITY MANAGEMENT RESPONSIBLE	MANAGING DIRECTOR



# **NOP Certification of Subcontracted Operators**

DOC. NR	TI 48
DATE	13.11.2015
REV. NR	00
SAYFA	2/2

C-An independent subcontracted transport company deals with the transport. Transport Company is not inspected and certified but transport activities of organic products are checked from the farms and processing facilities especially documentary evidences. Independent transporting companies are not eligible for OSP and certification. There are some cases operator subcontracts transport companies or individuals having trucks for only one time transport or a few times.

D-An independent storage is rented for organic products by the certified operator. Storage facility is inspected for storage conditions and documents related to organic products. This storage is eligible for OSP. Storage is not certified individually, listed as subcontractor under the certified operators.

# To have a better overview:

4.4 Different scenarios which may apply to the applicants operation.

Scenario	Storage	Transport	Eligible for OSP	Independent certification	Subcontracted	Result
Α	belongs to the farm	belongs to the farm	Yes	Yes	No	Farm receives certification either individually or belongs to a certified operator such as group certification covers the storage and transport.
В	belongs to processor	belongs to processor	Yes	Yes	No	Processor receives certification independently for activities including transport and storage activities
С		Independent	No	No	Yes	Transport Company is not inspected and certified but transport activities of organic products are inspected from the farms, stores and processing facilities. Especially documentary evidences for transporting activities.
D	Independent		Yes	No	Yes	Storage facility is inspected for storage conditions and documents related to organic products. Storage is not certified individually, listed as subcontractor under the certified operators.

PREPARED	APPROVED						
QUALITY MANAGEMENT RESPONSIBLE	MANAGING DIRECTOR						

From: Zuck, Penelope - AMS [mailto:Penelope.Zuck@ams.usda.gov]

Sent: Thursday, November 19, 2015 9:59 PM

To: ma@etko.org

**Subject:** Additional questions on Corrective Actions

Hello Mustafa,

After further review of the Corrective Action submitted by ETKO in response to the Audit Assessment NP4132LCA, I have some additional questions:

1. NP4132LCA.NC1 – ETKO mailed a letter to clients informing and instructing them about all contracted operations required to be certified separately by December 31, 2015. How many contracted operations did this affect? Have they all obtained their own certification yet? If not, what is the status report on this and detailed plans to carry out your corrective action?

We contracted so far 26 handling/processing facilities and 24 already inspected, certification process going on. There will be few other will be inspected within December.

No subcontractor certification was accepted this year we comply this rule 100% this year.

- 2. NP4132LCA.NC4 ETKO conducted training for inspectors on these issues, however, how did ETKO follow up with the operations to be sure they are in compliance?
  - a. 1) Inspectors did not completely verify the information stated in the Organic Compliance Plans. If observations and interviews at the onsite inspection did not align with the Organic Compliance Plan, the inspector failed to state this finding as an issue of concern. Did ETKO follow up with the operation and inform them of the issues observed? Issue a Non-compliance?

Yes, inspectors verified OCPs during the inspection and identified NCs and minor issues. See examples of NONC+ Minor issues from different inspectors.

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To: 'Zuck, Penelope - AMS'

Cc: 'Fatih Aksoy'

Subject: RE: Additional questions on Corrective Actions

Dear Penny

Sorry being late please see below answers and attachments. Best regards,

Mustafa

# ATTACHMENT F

Noncompliances NC21 and NC2
Email correspondence between
Penelope Zuck of NOP

And ETKO

July 21 and July 23, 2015

October 15, 2015, and November 1, 2015

From: Zuck, Penelope - AMS [mailto:Penelope.Zuck@ams.usda.gov]

Sent: Tuesday, July 21, 2015 4:53 PM

To: ma@etko.org

Cc: 'Fatih AKSOY'; 'Mustafa Akyuz'

Subject: RE: Corrective Actions Email 16 FINISHED

#### Hello Mustafa,

Thank you so much for the documentation you submitted. I received all 16 emails. There are 2 items I still need:

- 1. NP4132LCA.NC2 The Corrective Action plan indicates corrected certificates including scopes of certification were attached, but I did not receive the certificate examples as an attachment to any of the emails.
- 2. NP4132LCA.NC1 The Corrective Action plan indicates you will certify each subcontracted facility during the 2015 production period. Can you please submit documented evidence of how this is being handled, such as notification letters to clients, etc.

Hopefully, that is all! Best Regards, Penny

From: ma@etko.org [mailto:ma@etko.org]
Sent: Thursday, July 23, 2015 11:10 AM

To: 'Zuck, Penelope - AMS'

Cc: 'Fatih AKSOY'

Subject: RE: Corrective Actions Email 16 FINISHED

Dear Penny

I prepared the notification as attached. As far as I know subcontracted handling / processing Operations covers only the ones as explained in definition processing. There are other subcontracted handling facilities such as storage, transport, forwarding etc which do not have any processing activities. These kind of subcontractors are not subject for separate certification. If I am mistaken here please inform me so I can renew the letter to clients.

Thank you in advance

Have a nice day

Mustafa

From: Zuck, Penelope - AMS [mailto:Penelope.Zuck@ams.usda.gov]

Sent: Thursday, October 15, 2015 3:18 PM

To: ma@etko.org

Subject: Noncompliance Report follow-up

Dear Mustafa,

There are still a number of items that need to be addressed in reference to the noncompliance report issued for ETKO's NOP renewal assessment as follows:

1. NP9222ZZA.NC21 - #4. - I understand an updated version of the NOP regulations was provided to all staff. Who will be in charge of making sure ETKO monitors the NOP's updates to the NOP regulations? And how will staff and inspectors be informed of the updates?

2. NP4132LCA.NC2 – Copy of a corrected certificate was submitted to NOP, but a description and documented evidence of how you will prevent a reoccurrence of this noncompliance was not submitted. What is ETKO's preventative action that will prevent this from occurring in the future?

3. NP4132LCA.NC3 – ETKO translated the following documents into Turkish and conducted training of staff: NOP 4002 Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix, NOP Penalty Matrix 2612, and NOP 4011 Adverse Action Appeal Process for the NOP. This raises an additional concern that ETKO is not translating all NOP instruction and guidance (NOP Handbook). How does ETKO ensure that its staff is well informed and knowledgeable of the NOP Regulations, including the remainder of the NOP Handbook? How will you address this concern and prevent this from occurring in the future?

In addition, it has come to our attention that the European Union and Canada have suspended ETKO's accreditations to provide organic certification to their standards. Please address these concerns by submitting the following to the NOP:

- Responses to nonconformances identified by IOAS according to EU Regulations and ISO Guide 65.
- Responses to nonconformances identified by CFIA according to the Canadian Organic Regulations.
- 3. Copies of Organic System Plans and Inspection Reports for the USDA organic certified operations mentioned in the IOAS and CFIA reports.

Please submit the above information/documentation directly to me by October 30, 2015. Let me know if you have any questions or need any clarification.

Regards, Penny



PENNY ZUCK | USDA-NATIONAL ORGANIC PROGRAM | ACCREDITATION MANAGER | USDA • AMS • NOP | 1400 Independence Ave SW | 2649-S | Washington DC 20250 
■ 202.260.9444 | Fax 202.205.7808 | Penelope.Zuck@ams.usda.gov | Join the NOP mailing list

From: ma@etko.org [mailto:ma@etko.org] Sent: Sunday, November 01, 2015 4:58 PM

To: 'Zuck, Penelope - AMS'

Cc: 'Fatih AKSOY'

Subject: RE: Noncompliance Report follow-up

Dear Penny

Please find below answers

Dear Mustafa,

There are still a number of items that need to be addressed in reference to the noncompliance report issued for ETKO's NOP renewal assessment as follows:

NP9222ZZA.NC21 - #4. - I understand an updated version of the NOP regulations was provided to all staff. Who will be in charge of making sure ETKO monitors the NOP's updates to the NOP regulations? And how will staff and inspectors be informed of the updates?

Mustafa Akyüz is responsible person follow up NOP updates and will inform ETKO staff and inspectors by translating the updates. Translated or original document will be transferred by email and/or as printed form. When necessary related staff members will be trained for specific updates. Training will be recorded for Training register and this register will be provided to USDA with annual reporting. See Training Register form

NP4132LCA.NC2 - Copy of a corrected certificate was submitted to NOP, but a description and documented evidence of how you will prevent a, reoccurrence of this noncompliance was not submitted. What is ETKO's preventative action that will prevent this from occurring in the future?

NOP Certificate format was updated, this form will be used from now on to avoid problems. See NOP Certificate

NP4132LCA.NC3 – ETKO translated the following documents into Turkish and conducted training of staff: NOP 4002 Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix, NOP Penalty Matrix 2612, and NOP 4011 Adverse Action Appeal Process for the NOP. This raises an additional concern that ETKO is not translating all NOP instruction and guidance (NOP Handbook). How does ETKO ensure that its staff is well informed and knowledgeable of the NOP Regulations, including the remainder of the NOP Handbook? How will you address this concern and prevent this from occurring in the future?

NOP Handbook will be checked regularly and related documents will be translated as an immediate effect. Translated documents will be studied with related staff and inspectors. We already ordered for translations of the yellow indicated documents in NOP Handbook See attached. Part of the documents were already translated. See Translated NOP Handbook

# ATTACHMENT G

Noncompliance NC3

Email correspondence between

Penelope Zuck of NOP

And ETKO

July 29, 2015

August 13, 2015

October 15, 2015 and November 1, 2015

**Sent:** Wednesday, July 29, 2015 3:53 PM

To: ma@etko.org
Cc: 'Fatih AKSOY'

Subject: RE: Corrective Actions

Dear Mustafa,

Thank you for sending the certificates and copy of the notification you plan to send to your clients.

Additional information is needed for the following noncompliances:

#### NP4132LCA.NC1

Facilities that are used for storage and transportation will still need to be included in an approved Organic System Plan and ETKO can determine if individual certification will be required based on the activities at the facilities. The draft letter you provided does not instruct your clients how to go about obtaining individual organic certification or a deadline/timeframe by which they must complete the certification. I will also need to know when you expect to send the notification. Your corrective action plan indicated you will certify each subcontracted processing facility during the 2015 production period. I need a timeline explaining how this will be accomplished along with the revised notification.

#### NP4132LCA.NC3

The updated procedures and adverse action templates you submitted are not in compliance with the regulations. Some of the issues are as follows:

- 1. ETKO's Notice of Proposed Suspension template and 7.5.9.1. Resolving the Non-compliances section of NOP Certification Procedure indicates corrective actions can be submitted to address the noncompliance(s). Only appeal or mediation can take place at this stage of compliance.
- 2. ETKO's Notice of Proposed Revocation indicates the operation has received a Notice of Proposed Suspension and Notice of Suspension. 7.5.9.1. Resolving the Non-compliances section of NOP Certification Procedure states: "Once the certification is suspended, if during the suspension period the certified operation fails to make a request to ETKO for the reinstatement of its certification, the Notification of Proposed Revocation (NOPR) (GP 18 F 15) is issued to the certified operator." A Notice of Suspension does not turn into a Notice of Revocation. An operation is either suspended OR revoked. The Notice of Proposed Revocation also indicates the operator can still submit corrective actions. Only appeal or mediation can take place at this stage of compliance.
- 3. Notice of Revocation indicates the operator can still submit corrective actions. A revocation cannot be corrected. A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, Except, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

These are just some of the noncompliant items contained in your adverse action templates and procedures. You will need to revise the procedures and templates to be sure they are following the NOP regulations. Please refer to the following resources:

- 7CFR §205.662 Noncompliance procedure for certified operations.
- Training module (2015) titled "Appeals and Settlement Agreement Updates" and training module (2014) titled "Appeals Update", which can be obtained from the following link to the NOP website:
   <a href="http://www.ams.usda.gov/AMISv1.0/ams.fetchTemplateData.do?template=TemplateN&topNav=NationalOrganicProgram&page=NOPTraining&description=NOP%20Training&acct=nopgeninfo">http://www.ams.usda.gov/AMISv1.0/ams.fetchTemplateData.do?template=TemplateN&topNav=NationalOrganicProgram&page=NOPTraining&description=NOP%20Training&acct=nopgeninfo</a>

Please submit the above information/documentation to me by August 12, 2015. Let me know if you have any questions or need any further clarification on these pending noncompliances.

Thank you, Penny



From: Zuck, Penelope - AMS [mailto:Penelope.Zuck@ams.usda.gov]

Sent: Thursday, August 13, 2015 8:55 PM

To: ma@etko.org

Subject: RE: Corrective Actions

Hi Mustafa,

You are not required to have a Settlement Agreement template. The Settlement Agreement could be the outcome/goal of mediation and would be an agreement between ETKO and the certified operation that is agreed upon by both. Therefore, the Settlement Agreement may include different language for each situation.

Thank you for submitting the revised adverse action templates and procedures. I've reviewed the documents and the Notice of Suspension and Notice of Revocation are still incorrect. Also the procedure for these two adverse actions are not incompliance.

- The Notice of Suspension (NoS) indicates the operation has 30 days to avoid suspension by filing an appeal or requesting mediation. Appeal or mediation can only be requested during the Proposed Suspension period and before the NoS is issued. Once the Notice of Suspension is issued, the operation is no longer certified and must go through the reinstatement process. The NoS must also include a date the Suspension is effective.
- The Notice of Revocation (NoR) also indicates the operation has 30 days to avoid revocation by filing an appeal or requesting mediation. Appeal or mediation can only be requested during the Proposed Revocation stage and before the NoR. Once the Notice of Revocation is issued, the operation is no longer certified and is ineligible for certification for 5 years. The NoR must also include a date the Revocation is effective.
- The Certification Procedure section 7.5.9.1 Suspension or Revocation indicates the NoS and NoR become effective within 30 days if a response is not received to the NoS or NoR. It also indicates the certified operation may, after receipt of NoS or NoR file an appeal or request mediation.

As for your question, whether the NoS and NoR need to include the Noncompliances: The NoS and NoR do not need to include the noncompliances.

I know these procedure can be very confusing, so please let me know if you have any further questions or need to discuss in more detail. I'll look forward to receiving the revised NoS and NoR templates and Certification Procedure section 7.5.9.1 (Suspension or Revocation.) Please submit to me by August 21, 2015.

Best Regards, Penny



From: Zuck, Penelope - AMS [mailto:Penelope.Zuck@ams.usda.gov]

Sent: Thursday, October 15, 2015 3:18 PM

To: ma@etko.org

Subject: Noncompliance Report follow-up

Dear Mustafa,

There are still a number of items that need to be addressed in reference to the noncompliance report issued for ETKO's NOP renewal assessment as follows:

- 1. NP9222ZZA.NC21 #4. I understand an updated version of the NOP regulations was provided to all staff. Who will be in charge of making sure ETKO monitors the NOP's updates to the NOP regulations? And how will staff and inspectors be informed of the updates?
- 2. **NP4132LCA.NC2** Copy of a corrected certificate was submitted to NOP, but a description and documented evidence of how you will prevent a reoccurrence of this noncompliance was not submitted. What is ETKO's preventative action that will prevent this from occurring in the future?
- 3. NP4132LCA.NC3 ETKO translated the following documents into Turkish and conducted training of staff: NOP 4002 Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix, NOP Penalty Matrix 2612, and NOP 4011 Adverse Action Appeal Process for the NOP. This raises an additional concern that ETKO is not translating all NOP instruction and guidance (NOP Handbook). How does ETKO ensure that its staff is well informed and knowledgeable of the NOP Regulations, including the remainder of the NOP Handbook? How will you address this concern and prevent this from occurring in the future?

In addition, it has come to our attention that the European Union and Canada have suspended ETKO's accreditations to provide organic certification to their standards. Please address these concerns by submitting the following to the NOP:

- 1. Responses to nonconformances identified by IOAS according to EU Regulations and ISO Guide 65.
- 2. Responses to nonconformances identified by CFIA according to the Canadian Organic Regulations.
- 3. Copies of Organic System Plans and Inspection Reports for the USDA organic certified operations mentioned in the IOAS and CFIA reports.

Please submit the above information/documentation directly to me by **October 30, 2015**. Let me know if you have any questions or need any clarification.

From: ma@etko.org [mailto:ma@etko.org] Sent: Sunday, November 01, 2015 4:58 PM

To: 'Zuck, Penelope - AMS'

Cc: 'Fatih AKSOY'

Subject: RE: Noncompliance Report follow-up

Dear Penny

Please find below answers

## Dear Mustafa,

There are still a number of items that need to be addressed in reference to the noncompliance report issued for ETKO's NOP renewal assessment as follows:

1. NP9222ZZA.NC21 - #4. - I understand an updated version of the NOP regulations was provided to all staff. Who will be in charge of making sure ETKO monitors the NOP's updates to the NOP regulations? And how will staff and inspectors be informed of the updates?

Mustafa Akyüz is responsible person follow up NOP updates and will inform ETKO staff and inspectors by translating the updates. Translated or original document will be transferred by email and/or as printed form. When necessary related staff members will be trained for specific updates. Training will be recorded for Training register and this register will be provided to USDA with annual reporting. See Training Register form

2. NP4132LCA.NC2 – Copy of a corrected certificate was submitted to NOP, but a description and documented evidence of how you will prevent a reoccurrence of this noncompliance was not submitted. What is ETKO's preventative action that will prevent this from occurring in the future?

NOP Certificate format was updated, this form will be used from now on to avoid problems. See NOP Certificate

3. NP4132LCA.NC3 – ETKO translated the following documents into Turkish and conducted training of staff: NOP 4002 Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix, NOP Penalty Matrix 2612, and NOP 4011 Adverse Action Appeal Process for the NOP. This raises an additional concern that ETKO is not translating all NOP instruction and guidance (NOP Handbook). How does ETKO ensure that its staff is well informed and knowledgeable of the NOP Regulations, including the remainder of the NOP Handbook? How will you address this concern and prevent this from occurring in the future?

NOP Handbook will be checked regularly and related documents will be translated as an immediate effect. Translated documents will be studied with related staff and inspectors. We already ordered for translations of the yellow indicated documents in NOP Handbook See attached. Part of the documents were already translated. See Translated NOP Handbook

# ATTACHMENT H

Noncompliances NC4 and NC6

Email correspondence between

Penelope Zuck of NOP

And ETKO

November 19, 2015

December 1, 2015

Collection of

Cc: 'Fatih Aksoy'

Subject: RE: Additional questions on Corrective Actions

Dear Penny

Sorry being late please see below answers and attachments.

Best regards,

Mustafa

From: Zuck, Penelope - AMS [mailto:Penelope.Zuck@ams.usda.gov]

Sent: Thursday, November 19, 2015 9:59 PM

To: ma@etko.org

Subject: Additional questions on Corrective Actions

Hello Mustafa,

After further review of the Corrective Action submitted by ETKO in response to the Audit Assessment NP4132LCA, I have some additional questions:

1. NP4132LCA.NC1 – ETKO mailed a letter to clients informing and instructing them about all contracted operations required to be certified separately by December 31, 2015. How many contracted operations did this affect? Have they all obtained their own certification yet? If not, what is the status report on this and detailed plans to carry out your corrective action?

We contracted so far 26 handling/processing facilities and 24 already inspected, certification process going on. There will be few other will be inspected within December.

No subcontractor certification was accepted this year we comply this rule 100% this year.

- 2. NP4132LCA.NC4 ETKO conducted training for inspectors on these issues, however, how did ETKO follow up with the operations to be sure they are in compliance?
  - a. 1) Inspectors did not completely verify the information stated in the Organic Compliance Plans. If observations and interviews at the onsite inspection did not align with the Organic Compliance Plan, the inspector failed to state this finding as an issue of concern. Did ETKO follow up with the operation and inform them of the issues observed? Issue a Non-compliance?

Yes, inspectors verified OCPs during the inspection and identified NCs and minor issues. See examples of NONC + Minor issues from different inspectors.

b. 2) ETKO inspectors are responsible for collecting large amounts of information about the operations when the Organic Compliance Plan (OCP) is incomplete or in error. The inspector did not note the finding as an issue of concern, failing to indicate that the OCP is incomplete. The inspector did not record these findings in the inspection report. Was the operation informed of these issues/noncompliances? And how did they correct them?

Yes, inspectors checked carefully OCPs and identified several issues and informed operators, corrections were assessed during onsite inspections. See examples of Application Package review forms of operators. Note: First date is the review date and second date is inspection date.

3. NP4132LCA.NC6 — ETKO created forms and updated certification procedures for grower groups to require and verify Internal Control Systems. Have all grower groups come into compliance with this? If not, provide a status report and detailed plans on how and when you will carry out this corrective action. How many grower groups does this affect?

There are 5 grower groups inspected this year. Projects finalized their internal control for producers and ETKO to finish follow up inspections until end of December. The main issue is setting up the Quality Management System, one operator completed so far and the other 4 still under progress. We expect all to be ready until the end of December.

I would appreciate a response by November 27, 2015.

Best Regards, Penny

## ATTACHMENT I

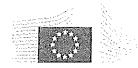
# **European Commission Report**

June 29, 2015

Note to the Regulatory Committee for Organic Production Delegates

Subject:

Serious and Widespread Irregularities concerning Import of Sunflower Cakes/Expeller



#### EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy B.4. Organics

Brussels, GYN/SM/agri.ddg1.b.4(2015)2654902

## NOTE TO THE REGULATORY COMMITTEE FOR ORGANIC PRODUCTION DELEGATES

Subject:

SERIOUS AND WIDESPREAD IRREGULARITIES CONCERNING IMPORT OF

SUNFLOWER CAKES/EXPELLER

Major, wide-ranging irregularities were notified by MS between November 2014 and March 2015 in relation to sunflower cakes/expeller (SCE) imported from Ukraine

This note contains the findings, conclusions and recommendations for the case in reference on the basis of information available which, despite the efforts, is still limited or missing. The verification of submitted information through objective evidence was beyond the scope of this exercise.

The note is intended to provide a <u>comprehensive overview of the situation</u>, to identify possible <u>non-compliances</u> with the <u>legislation</u>, <u>points of concern</u> as well as <u>promotable practices in order to improve the situation for the future</u>. It should be a basis for further work on more harmonised follow up measures by Member States.

The note is distributed to the delegates of the Regulatory Committee for Organic Production in order to eliminate any factual errors or misinterpretations, gather comments and add information to the file where necessary.

Delegates are invited to provide their feedback no later than 14 calendar days after the date of posting on CIRCA.

Frequently used abbreviations: Competent Authorities (CA), Control Authorities (CtrlA), Control Bodies (CB), Member States (MS), Organic Farming Information System (OFIS), EU irregularity number (OFIS EU), Third Country irregularity number (OFIS TC), Regulatory Committee for Organic Farming (RCOP), Sunflower cake/expeller (SCE), Third Country: TC

#### 1. Summary

The irregularities that have been detected between November 2014 and March 2015 as regards certain products sold as organic show the same pattern: all cases relate to (a) sunflower cakes (b) imports from Ukraine during the same period (c) multiple and often the same unauthorised pesticide residues.

The issue was raised in the meetings of the Regulatory Committee for Organic Farming in February and March<sup>1</sup>, entailed telephone contacts for clarification and a request for structured, comprehensive

<sup>&</sup>lt;sup>1</sup> 123<sup>rd</sup> and 124<sup>th</sup> meeting of RCOP (Ref. Ares(2015)797973 - 25/02/2015 and Ares (2015)1691990)

information<sup>2</sup>. The Commission services engaged into a dialogue with actors in Third Countries (TC) as well as MS Competent Authorities (CA) to ensure supervision and policy formulation.

The primary cause appears to be non-compliance with the prohibition of use of non-authorised plant protection products<sup>3</sup> by some of the operators in Ukraine; the results of investigation by one Control Body (ETKO) indicate that there was no objective evidence to confirm the traceability and thus the organic status of the sunflower cakes. The Control Body also indicated that some documents were doubtful or falsified, which implies intentionality and therefore allegation of fraud. Some of the operators' in the Third Country were de-certified by the Control Body. In most cases the Competent Authorities of the Member States declassified the sunflower cakes following the results of residue analysis which showed the presence of unauthorised pesticides.

Potential <u>non-compliances</u> with the <u>legislation</u> in the follow-up of the <u>cases</u> resulted in widespread distribution of the product within the EU and therefore aggravated the situation.

Certain Member States failed to communicate relevant information to the Commission and to the other Member States on cases of irregularities despite their obligations and the repeated requests of the Commission. Other Member States' communications were late and/or insufficient. This is not in line with the organic legislation that requires immediate communications on cases of irregularities or infringements affecting the organic status of a product, without delay and at the necessary level<sup>4</sup>.

In some cases the control authority/body did not block the products despite the substantiated suspicions and/or allowed to place products on the market with indications referring to the organic production albeit the doubts were not eliminated<sup>5</sup>.

Likewise, in some cases operators appear to have acted not in compliance with the legislation as, despite positive laboratory test results, they did not initiate procedures either to withdraw from the products any reference to the organic production method or to separate and identify the product. They marketed the products as organic without elimination of the doubts<sup>6</sup>. Some operators failed to inform the control bodies/authorities immediately of the doubts (i.e. test results)<sup>7</sup>. Some operators did not inform buyers of the irregularities (or such information was given too late to be effective) to ensure that the indications referring to the organic production method were duly removed<sup>8</sup>.

Certain control authorities/bodies and/or the competent authorities do not appear to have followed up these possible non-compliances, which is not in line with the requirements to set up and supervise a control system<sup>9</sup>

This leads also to the conclusion that some Member States did not take all necessary measures and sanctions to prevent fraudulent use of the relevant indications 10.

There are also weaknesses and other points of concern.

The lack of robust controls on certain operators, including the lack of taking and analysis of samples by control bodies/authorities, is seen as a weakness<sup>11</sup>.

Request for information from Competent Authorities – follow up of irregularities (Ref. Ares(2015)1036964 - 09/03/2015)

<sup>3</sup> Regulation (EC) No 834/2007 Article 12 (1)(h) and 16

<sup>4</sup> Regulation (EC) 834/2007 Article 30(2), Regulation (EC) 889/2008 Article 92a(1) and (2)

<sup>5</sup> See Regulation (EC) 889/2008 Article 91(2)

<sup>6</sup> See Regulation (EC) 889/2008 Article 91(1)

<sup>7</sup> Regulation (EC) 889/2008 Article 91(1)

<sup>9</sup> See Regulation (EC) 834/2007 Article 27(1)

<sup>10</sup> Regulation (EC) 889/2008 Article 91 (3)

<sup>11</sup> Regulation (EC) 889/2008 Article 65

The Commission services are therefore concerned by the weak follow up given by competent authorities and control bodies in some Member States that resulted in the following negative consequences: products were marketed as "organic" without being organic, ensuing costs were passed on to the consumer, and operators were treated differently. These consequences are susceptible to jeopardize the objectives of the legislation: delivery of goods contributing to the protection of the environment, transparency, consumer confidence, harmonisation, and fair competition.

<u>The impacts</u> are deep and wide-ranging: a high number of consumers in eleven countries are likely to be affected. Several operators were at competitive disadvantage.

As for recommended action, there is a visible progress at the level of controls in Ukraine: investigations revealed/prevented further irregularities. Moreover, the control body (CB) ETKO's accreditation was suspended by the accreditation body. The CB ETKO's recognition for imports to the EU is about to be withdrawn for all categories and countries. The monitoring of risk of occurrence of irregularities as regards other involved control bodies is ongoing. In the mid to long-term the Commission services will monitor the situation in order to properly assess the risk of CBs in Third Countries in the light of the present findings.

Close monitoring of the imports and of the market is to be carried out as it is likely that major quantities of products that are considered to be at risk of non-compliance with the organic legislation are still placed on the market in Member States and more of these products are expected to be imported in the EU, which requires appropriate action.

The Commission services flagged up to the Competent Authorities the risks associated with the products certified by ETKO.

Member States should also continue putting adequate controls in place, especially on importers and wholesalers.

However, reinforcement of controls is not enough, as deeper underlying causes should be treated. This note, including the proposed action to be taken and further discussion in the Regulatory Committee for Organic Production should contribute to close the gap between the harmonised production rules and diverging follow up measures by Member States in order to ensure an efficient control of organic products throughout the EU.

#### 2. Legal provisions: See Annex 3 for the main provisions.

#### 3. The case in a nutshell

- Product sunflower cake/expeller (SCE), a by-product used as ingredient in compound feed
- Quantity 15 000 tons
- Pesticides found: metalaxyl, carbendazim, thiamethoxam, fludioxonil, glyphosate, imidaeloprid
- Origin Ukraine (UA)
- Destinations
   AT, BE, DE, DK, ES, FR, NL, NO, PL, UK, USA

Feed and food were placed on the market as organic despite the detection of unauthorised substances.

The impact of the irregularities is

• deep: the entire supply chain was affected as the SCE was used as animal feed and the resulting animal products reached the consumers

- wide-ranging: the bulk of SCE appears to be used up in feeding the animals and the related animal products were placed on the market as "organic" Note the multiplier effect of SCE in compound feed, vividly demonstrated by the below example (Norway)<sup>12</sup>:
  - SCE used in manufacturing

9.6 tons:

- "organic" animal feed produced

590,0 tons.

#### 4. The causes

The <u>primary cause</u> appears to be related to non-compliance by operators in the TC. Information emerging from investigations by one CB (ETKO) and an accreditation body (IOAS) point towards intentionality and, therefore, alleged fraud,

In particular, the results of investigation by one Control Body (ETKO) indicate that there was no objective evidence to confirm the traceability and thus the organic status of the sunflower cakes. The Control Body also indicated that some documents were doubtful or falsified, which implies intentionality and therefore allegation of fraud. Some of the operators' in the Third Country were decertified by the Control Body. In most cases the Competent Authorities of the Member States declassified the sunflower cakes on the basis of the results of residue analysis which showed unauthorised pesticides.

<u>Secondary causes</u> include failings in preventative, detective as well as corrective controls via adequate corrective measures.

#### Third Country

The Accreditation Body IOAS carried out investigations and found significant failings in the inspection and certification procedures at the CB ETKO.

The CB SGS Austria certified around 26% of the irregular products and was involved in the certification of operators related to other quantities of irregular products. This Control Body ceased its activities in all third countries and its recognition was consequently withdrawn. The assessment of this CB's replies is in progress.

#### EU Member States

#### a) Controls

The lack of adequate controls on importers and wholesalers, which could have prevented the flow of products into the EU, is of a particular concern. There is still no sufficient (or any) evidence that robust controls are in place despite the major influx of quantities, see findings concerning the Netherlands, Spain and the United Kingdom in Annex 2.

Exceptions include controls in Germany that first detected the problems and triggered other notifications. This is seen as a promotable practice. Auto controls by the operator (OFIS EU 1479) and the subsequent notification by France can also be mentioned as a a good practice, albeit one must note that the products were eventually sold as "organic" on the basis of the CAs decision.

#### b) Communication of irregularities

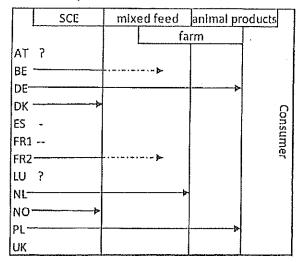
Certain Member States failed to communicate relevant information to the Commission and to the other Member States on cases of irregularities despite their obligations and the repeated requests of the Commission. Other Member States' communications were late and/or insufficient. This is not in

Only limited information is made available on this aspect by MS. France advised of small quantities of SCE in compound feed. Information from RASFF shows an average of 14,5% SCE content in Germany in feed.

line with Regulation that requires immediate communications on cases of irregularities or infringements affecting the organic status of a product, without delay and at the necessary level<sup>13</sup>.

#### c) Follow up/corrective measures

The causes also include the manner in which some MS followed up the irregularities which varied considerably. The table below shows, in broad terms, the scope of action.



The Commission services are faced with data limitations which affect fundamental aspects such as timeliness of the actions and the exact quantities of SCE successfully intercepted, despite repeated requests.

Subject to the above limitation, it appears that compliance with the organic production was better ensured in Germany and Poland where the controls initially picked up the irregularities (in Germany) and the impacts were mitigated by suspending the marketing of the products (both MS). See more details in Annex 2.

In principle, the timelier the action was (often depending on the notifying party), the more products were declassified and the less impact was transferred to consumers.

As the practices followed on this case are understood to be based on established policy, it is assumed that similar situations would be treated in the same manner in the future.

#### 5. Conclusions and recommendations for action

#### 5.1. Third Countries

#### Actions already taken

DG AGRI took steps vis-à-vis the CBs in TCs and accreditation bodies, with a view to tighten up controls.

As a result, the CB ETKO unravelled irregularities and their potential causes. The Accreditation Body (IOAS) of this CB found significant failings in its inspection and certification procedures. The ISO 17065 accreditation of ETKO with the scope of IACB standard (known as the IOAS EU Equivalence Programme) is suspended for all EU product categories and in all countries. ETKO will subsequently be delisted from Annex IV of Commission Regulation (EC) No 1235/2008.

<sup>13</sup> Regulation (EC) 834/2007 Article 30(2), Regulation (EC) 889/2008 Article 92a(1) and (2)

Another CB (SGS Austria) ceased operations in Ukraine and its recognition for imports in the EU was therefore withdrawn. It retained its accreditation and continues to operate in the EU). The assessment of this CB's replies is in progress.

Moreover, DG AGRI cooperated with the services of the Directorate-General on Taxation and Customs Union in order to raise awareness of the EU custom authorities through a Risk Information Form (RIF)<sup>14</sup>.

#### 5.2. Member States

#### Actions already taken

MS are fully aware of the issue. Information was requested on inventories of stocks and expected future quantities: the UK and the Netherlands reported major quantities in stock, the UK also reported major expected future quantities.

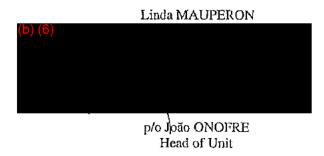
Controls in several MS were reported to be tightened up. Only a limited number of MS provided feedback on their measures applicable to similar cases.

#### Actions to be taken

Short term (controls): effective, risk-based controls should be carried out, focusing on importers and wholesalers where problems can be remedied before they take effect. An enhanced supervision of the CB, including regular review of their risk assessment, is desirable.

Mid to long term (policy redesign): the findings show that harmonised production rules are not complemented by harmonised follow up actions/measures. Harmonised follow up actions developed at EU level together with MS would close the gap.

Policy design should also consider rules in cases where (a) unauthorised products are used in processed or compound products and/or (b) the irregularity is not directly attributable to the operator which is in possession of the product at the time of detection.



#### List of annexes:

Annex I - Overview of OFIS notifications

Annex 2 - Follow Up by Member States

Annex 3 - Main regulatory provisions

<sup>&</sup>lt;sup>14</sup> The purpose of the RIF is to provide risk information to support targeting of consignments for customs controls, under the Community Risk Management Framework as laid down in Regulation (EC) No 648/2005 and its implementing rules.

# Annex 1 - Overview of OFIS notifications

QBS EU No	NC:	NC 2	Notification	Detection	Substance	RASFF/INTC	Lot ID/deliveries/MS involved
INEU15/2015	PL	DE	11/03/2015	11/03/2015	etocsicine, metalaxyl propyzamide		
	NL	UA	29/01/2015	08/01/2015		INTC 245	Total City 3.297 MT 8E 61.700 kg DE 50.880 kg FR 506.240 kg NI 2.611.689 kg AT 55000 kg
(NEU 14/2015	PL	DE	22/01/2015	30/01/2015	etocsicine, metalaxyi, propyzamide		
1/2015(1498)	DE	NL	05/01/2014	23/12/2014	carbendazim flutloxonil metafaxyl thiamethoxam		INTC 228 Lot No PTR140491-01 Total City: 1.967 MT DE 843.771 kg USA 250.030 kg INTC 244 Total City: 1.906 MT NL 408.680 kg DK 839.550 kg DE 974.480 kg AT 24.660 kg
371/2014(1490)	B€	NL	17/12/2014	10/12/2014	thlamethoxam metalaxyl	2014.1627	Let no LT0005529 redistribution from BE: FR, LU, NL, DE
354/2014(1479)	FR.	E5	03/12/2014	30/07/2014	Samples 1 & 2 carbendazime, carbendazime MBC, enomyl, clothianidin/thiametoxam (total), imidactopride, thiametoxam Sample 3 fluodioxoni Sample 4 carbendazime, fluodioxonii, metalaxyl	INTC 222	Tatal Qty: 3 685 MT UK, ES, FR
361/2014(1473)	DE	NL	01/12/2014	10/11 <i>/</i> 381 <i>x</i>	thiamethoxam metalaxyl	RASFF 2014.1627 INT 224	Lot No LT0005529 Oty 4000 MT BE 423.600 kg DK 796.680 kg DE 263.600 kg FR 286.520 kg USA 285.915 kg

## Annex 2 - Follow up action by Member States

N)

Austria did not provide any information despite being a host country to a recipient of SCE. This prevents the Commission services from forming an opinion on whether an effective follow up was given to the irregularity.



### Belgium

There are data limitations and aspects to clarify<sup>15</sup>.

a) Scope

The SCE and the compound feed were blocked at the level of feed companies. The CA's policy was to declassify compound feed with minimum 50% SCE content. Feed companies were supposed to recall these products from farmers. Feed with up to 49% SCE content remained "organic" and farmers could sell the resulting animal products as "organic". Information received on 16 January 2015 classified compound feed on the above basis.

b) Quantities of SCE/compound feed blocked and decertified

Not confirmed. Estimates indicate that around 85 % of the compound may not have been declassified.

c) Informing buyers

Farmers were informed. No confirmation that buyers were informed.

d) Timeliness

The irregularity was notified on 28/11/2014 (DE to NL) yet the BE CA was not aware of it until 10/12/2014.

e) Other issues

BE is implied in a second case (OFIS TC 245). No OFIS notification or other information is available from BE on these quantities.

# 3)

#### Germany

There are data limitations and aspects to clarify.

a) Scope

Stocks of feed were blocked at the level of farmers. Prohibition to label products as organic for a period of 6 to 10 weeks, initially only in one Federal State. Other Federal States followed this practice later.

Mecklenburg-Vorpommern provided additional information on 29 May 2015, indicating that the competent authority notified all the other involved authorities and removed references to organic production in accordance with Article 30 of Regulation (EC) No 834/2008, including from the animals fed with the non-compliant products.

b) Quantities of SCE/compound feed blocked/decertified

OFIS EU 1473: not confirmed.

<sup>&</sup>lt;sup>15</sup> The CA indicated in OFIS (EU 1490) that a decision on the action to be taken at the level of farmers was pending. Whilst making available supplementary information on 16 January 2015, it did not confirm action on farmers and/or quantities of SCE intercepted:

OFIS EU 1498: 45% (905 tons out of 2000 tons) of SCE.

c) Informing buyers

The farms involved informed buyers of the products.

d) Timeliness

Information available<sup>16</sup> shows that deliveries of irregular compound feed were made to and accepted by German farmers after (a) the first detection of the irregularity (15 deliveries out of total of 18), (b) blocking feed and marketing ban (13 deliveries), and (c) after the RASFF notification (6 deliveries).

e) Other issues

As concerns OFIS EU 1473, DE reported that "altogether 14 farms (cattle, eggs, laying hens and chicks) received decrees according to article 30 (1) EEC Reg. 834/2007 with the prohibition of labelling products as organic for a time period between 6 and 10 weeks".

However, information available hows that at least 19 laying hen farms received the contaminated feed.

<u>Denmark</u>

There are data limitations and aspects to clarify.

The CA's basis for action was based on the limited content of SCE in the affected feed.

a) Scope

The SCE not yet used up was declassified. Animal products and animals retained their organic label.

b) Quantities of SCE/compound feed blocked/decertified

Not confirmed.

c) Informing buyers

Not confirmed.

d) Timeliness

CtrlA initiated action on 11/12/2014 whilst the initial OFIS notification (DE to NL) was made on 28/11/2014.

e) Other issues

DK did not notify the irregularities via OFIS EU.

It is unclear how the CtrlA ensured that all SCE was declassified as declared by the operators (and not used up in organic production) given that no on-the-spot visits took place at the operators. Only an administrative control is indicated by the CtrlA, carried out on a single day (11/12/2014) on all operators and all quantities.

DK is implied in a second case (OFIS TC 244, 839 tons). No OFIS notification is made. The authorities' communications, including those on inventory of SCE, did not contain information on this lot which implies that they may not have been aware of it. These quantities were reported by NL to be declassified.

Spain (see also France)

<sup>16</sup> DistributieDeEendrachtnaarDuitsland.xls, source: RASFF

<sup>&</sup>lt;sup>17</sup> DistributieDeEendrachtnaarDuitsland.xls, source: RASFF

There are data limitations and aspects to clarify.

a) Scope

SCE is released as "organic".

b) Quantities of SCE/compound feed blocked/decertified

#### None.

c) Informing buyers

## Not confirmed.

#### d) Timeliness

The ES operator (first consignee wholesaler) does not appear to have taken any action in relation to the products.

The CtrlA incurred a delay of nearly two months to temporarily suspend the use of the term "organic" (notification on 28/01/2015 vs suspension on 03/12/2014). At that time only 1 109 tons were on stock out of the total 3 655 tons.

#### e) Other issues

The notification by FR (OFIS EU 1479, TC 222) was based on the results of two analyses showing several pesticide residues (carbendazime, carbendazime MBC and benomyl, clothianidin/thiametoxam (total), imidaclopride, thiametoxam). Contrary to the French authorities' opinion, the ES CtrlA did not consider the results relevant (samples were taken by the operator and the traceability of the product was limited).

Eventually the product was blocked by ES CtrlA on 28/01/2015 and samples were taken which showed no residues (however, metalaxyl does no appear to be within the scope of these tests). Note also that earlier controls by the ES CtrlA in September and November 2014 do not appear to include the initially detected substances in their scope 18.

The remaining products, after a short period of blocking, were released as "organic" as, according to the CtrlA, no irregularities were established at the Spanish operator.

France, on the basis of ES decision, released the products as organic. However, prior to this FR carried out a <u>third analysis</u> and found residues of a new substance (fluodioxonil). No action was taken by ES and (initially) by FR.

Soon after, as sales of the SCE recommenced, the FR CB identified once again irregularities in relation to the same lot on the basis of a fourth analysis (carbendazime, fluodioxonil, metalaxyl).

The ES authorities considered that the results do not necessitate action. The CA argued, inter alia, that "the new positive results came again from samples taken by (the FR operator's name) and not official samples taken by Ecocert (the CBs). Given the margin of error of these results, all parameters could be well below 0,01mg/kg. These levels are very low and could possibly be due to adventitious contamination or even derived from the sampling methodology detected".

As pointed out during the RCOP meeting in March 2015, the fact that ES did not block the product until end January 2015 and, despite the substantiated suspicions and ongoing investigations, the CtrlA released the product as "organic" does not appear in line with Regulation (EC) No 834/2007 Article 30(1) and Regulation (EC) No 889/2008 Article 91(1) and (2).

<sup>&</sup>lt;sup>18</sup> France indicated that "the Eurofins lab used larger screening than Agrolab Iberica SLU", suggesting that the substances detected in France were not included in the Spanish tests' scope.

The Spanish delegate confirmed during RCOP meeting on 22 May that the Ministry of Agriculture enacted a decision at national level to carry out testing during customs checks at 100%.

France (see also Spain)

There are data limitations and aspects to clarify<sup>19</sup>.

a) Scope

OFIS EU 1479 (TC 222)

The SCE was initially blocked however, in view of the ES CA decision, see point above, was released as "organic". The FR CA justified its decision as follows: "À la suite des investigations des autorités espagnoles et de l'organisme certificateur en Ukraine (Etko), l'origine de la contamination n'a pas pu être déterminée. Aucun non-respect de la réglementation n'a été identifié et des analyses négatives ont contredit la première detection".

As for the new detection of substances (cf. fourth analysis) the authorities advised that "Les investigations sur les causes de la contamination sont en cours<sup>20</sup>".

OFIS EU 1473 (TC 224)

The lots of SCE were blocked and declassified at the level of feed companies. The feed not used up was declassified and recovered from the farmers by the feed companies. The animals and animal products were not declassified on the basis of proportionality considerations (Art 30 of Regulation (EC) 834/2007) in view of, inter alia, the limited percentage of SCE in the compound feed, the limited percentage of the affected feed in the rations, the limited period of exposure. The Dutch authorities' decision to maintain the certification of animal products was also cited for reference.

b) Quantities of SCE/compound feed blocked/decertified

OFIS EU 1479 (TC 222): None.

OFIS EU 1473 (TC 224): Not confirmed but it appears that a significant portion of the quantities flowed through the chain ("..de nombreux lots d'aliments avaient déjà été consommés par les animaux.").

c) Informing buyers

OFIS EU 1479 (TC 222): Not confirmed.

OFIS EU 1473 (TC 224): "Les clients de ces opérateurs en possession de stocks d'aliments contenant ces produits ont tous été informés".

d) Timeliness

OFIS EU 1473 (TC 224): the information submitted is insufficient to confirm this element.

e) Other issues

OFIS EU 1479 (TC 222): As pointed out during the RCOP meeting in March 2015, the fact that the sunflower cakes were released as "organic" despite the substantiated suspicions and ongoing investigations appears to constitute non-compliance with Regulation (EC) No 834/2007 Article 30(1) and Regulation (EC) No 889/2008 Article 91(1) and (2).

<sup>&</sup>lt;sup>19</sup> France provided additional information, which was received by DG AGRI on 9/6/2015. This information is yet to be fully assessed.

The authorities indicated in their letter dated 5/6/2015 (again, yet to be assessed) that under the case OFIS EU 1479 (TC 222) the CB ECOCERT decided to declassify new sunflower cakes coming from the same Spanish supplier. The decision is made on the basis of evidence of presence of pesticides (fluodioxonil and metalaxyl)

OFIS EU 1473 (TC 224): FR has not notified these irregularities in OFIS.

Luxembourg did not provide any information despite being a host country to a recipient of SCE. This prevents DG AGRI from forming an opinion on whether an effective follow up was given to the irregularity.

## C) Norway

The CA's rational was based on the limited content of SCE in the affected feed, in view of Article 30(1) of Regulation (EC) No 834/2007 (proportionality).

#### a) Scope

SCE and mixed feed were blocked at the level of the feed company. SCE were sent back to Denmark, the mixed feed was declassified. The CA did not recall the mixed feed or the animal products from the market.

b) Quantities of SCE/compound feed blocked/decertified

•	SCE received	20 t
	SCE intercepted	10 t
6	SCE used in manufacturing	9,6 t
•	"Organic" animal feed produced:	590,0 t
•	Distributed to farmers and used:	552,0 t

c) Informing buyers

Consumers were not informed.

#### d) Timeliness

Norway acted on the basis of RASFF notification on 18/12/2014. The initial OFIS notification (DE to NL) was made on 28/11/2014.

## )) <u>Poland</u>

There are data limitations and aspects to clarify.

#### a) Scope

Withholding the marketing of the feed from the relevant German supplier.

Suspension of operator (i.e. documentary evidence suspended for a defined period) and blocking product.

## b) Quantities of SCE/compound feed blocked/decertified

Not confirmed. The CA advised that "11 pigs and approximately 270 000 eggs were placed on market before detection of irregularity. No withdrawal possible because of date of selling (probably all products are consumed)".

#### c) Informing buyers

The CA advised that consumers know about the issue and also pointed out that an open parliamentary debate that covered the issue on 19 February 2015<sup>21</sup>.

<sup>&</sup>lt;sup>21</sup> Posiedzenie nr 87, 2015-02-19

#### d) Timeliness

The parliamentary debate raised the issue of timeliness of communications between CB as it appears that some CB may have been alerted 15 days after the initial notification. The CA reported that it assessed this aspect via checks and initiated improvements.

## 19 The Netherlands

There are data limitations and aspects to clarify.

a) Scope

Farmers were authorised to sell the eggs, milk, meat on the basis of, inter alia, compliance with general food law.

b) Quantities of SCE/compound feed blocked/decertified

Around 85 % of the feed was delivered to clients (1 576 tons were blocked out of total 11 173 tons at the level of importers/wholesalers).

No information is available at the level of farmers.

c) Informing buyers

See point a).

d) Timeliness

The following delays are not accounted for:

### OFIS TC 245

CtrlA notified	12/01/2015
CtrlA blocking the stock	19/01/2015
OFIS notification	29/01/2015

#### OFIS EU 1498/TC 244

OFIS notification	06/01/2015
CtrlA is notified	12/01/2015
CtrlA blocking the stock	20/01/2015
Notification of clients:	23/01/2015

#### OFIS EU 1473/1490/TC 224

OFIS notification	28/11/2014
Notification of clients	19/12/2014

Albeit the NL CtrlA was notified on 28/11/2014, 6 out of the 18 deliveries of compound feed were still made to German clients after that date. The CtrlA blocked the products at the importer on 01/12/2014. The deliveries of mixed feed were still made on the same date or after, which implies that blocking the product may not have been effective at the level of feed companies.<sup>22</sup>

#### OFIS EU 1498/TC 228

Date of sampling	09/07/2014
Date of analysis report	09/12/2014

The result was positive (glyphosate), however no notification of clients, CB and other MS was made. Skal (CtrlA) was notified of irregularities as of 23/12/2014.

<sup>&</sup>lt;sup>22</sup> See table DistributieDeEendrachtnaarDuitsland.xls, source: RASFF 2014.1627

#### a) Other issues

<u>Under OFIS TC 228</u> the operator's samples were repeatedly showing positive results<sup>23</sup>, the first of such detection was made already on 24/07/2014. However, the operator does not appear to have notified the CtrlA, nor did it block the product or informed buyers. This does not appear in line with Article 91 (1) of Regulation (EC) No 889/2008 and as such probably contributed to the irregular conditions in that it did not prevent major quantities of irregular products from entering the EU market. There is no information to suggest that the CtrlA or the CA took any action vis-à-vis this operator, which raises concerns over controls and supervision.

OFIS TC 245: the operator's samples showed residues<sup>24</sup> already on 08/01/2015, it notified the CtrlA. The CtrlA blocked the product on 12/01/2015. Buyers/clients were notified only as of 03/02/2015.

As for the lot concerned (3 297 tons), this was transported in bulk in one ship and was redistributed to three different ships, forming three smaller lots. Only the quantities transported in one smaller ship, showing residues, were declassified (809 tons), albeit the CtrlA blocked all 3 lots initially. This approach raises questions given that the regulatory requirements necessitate that the entire lot affected by the irregularity should be declassified<sup>25</sup>. Note also that investigations by the TC CB revealed major risks, including lack of traceability and the potential for fraud.

The Netherlands notified <u>21 000 tons of additional SCE originating from UA</u>. These are considered by the CA and CtrlA organic.

The relevant table initially indicated two laboratory tests for these major quantities, the samples were taken by the operator and not by the independent CtrlA. Moreover, the authorities advised that 8 importers were asked about imports from Ukraine (not only in relation to sunflower cakes), 18 samples were taken (it is not clear whether these concern sunflower cakes also). It is not clear whether these samples were taken by the operators or by the CtrlA as part of independent checks. The authorities advised that "In the 18 samples in 4 samples low levels of residues (under mrl action limit) were found." (emphasis added). No follow up seems to be given to these results.

However, the organic regulation prohibits the use of non-authorised plant protection products<sup>26</sup>, independently of Maximum Residue Levels (MRLs). The practice therefore may constitute non-compliance with the Regulation.

Overall, the lack of robust controls by the CtrlA in the given circumstances is a point of concern.

Supplementary information received on 27 May shows that the CtrlA carried out 4 unannounced checks between 2 and 9 February. These checks, included sampling of corn, barley, and wheat from Ukraine, are considered as a step in the good direction.

The United Kingdom did not initially provide any information, despite that the importer of SCE notified under OFIS EU 1479 (TC 222) is based in the UK.

Eventually, the UK CA notified 34 517 tonnes of Ukrainian sunflower cakes in stock, all tested negative by the operators, none of it was tested independently by CBs: all of it is considered organic.

Indeed, no action was reported on the already notified OFIS cases: DEFRA is not aware of any irregularities.

The CA was requested to confirm whether the operators' tests included in their scope the unauthorised substances reported in OFIS. The review of the CA's reply<sup>27</sup> shows that operators' tests

<sup>25</sup> Art 30(1) of Regulation (EC) 834/2007

<sup>&</sup>lt;sup>23</sup> On 24/07/2014, 09/12/2014, and 12/12/2014; glyphosate/metalaxyl

<sup>24</sup> Glyphosate

<sup>26</sup> Regulation (BC) No 834/2007 Article 12 (1)(h) and 16

were not broad in scope, they excluded some of the pesticides that were later found in the irregular sunflower cakes. Also, tests by one operator (out of the two operators) were carried out by a laboratory which does not appear to be accredited for the tested substances.

The CA expects up to 45 000 tonnes of future SCE supplies (March 2015 to April 2016).

However, whilst the CA considers the product high risk, it envisages only "normal organic controls" which does not appear to include independent laboratory tests by CBs.

The lack of robust, independent controls by the CB in the given circumstances is a point of concern.

<sup>&</sup>lt;sup>27</sup> Email 20 May 2015

## Annex 3 - Main regulatory provisions

Article 30(1) of Regulation (EC) No 834/2007 provides that "where an irregularity is found as regards compliance with the requirements laid down in this Regulation, the control authority or control body shall ensure that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by this irregularity, where this would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities".

Article 30 (2) of Regulation (EC) No 834/2007 provides that "Information on cases of irregularities or infringements affecting the organic status of a product shall be immediately communicated between the control bodies, control authorities, competent authorities and Member States concerned and, where appropriate, to the Commission.

The level of communication shall depend on the severity and the extend of the irregularity or infringement found.

Regulation (EC) No 889/2008 Article 91 (1) to (3) requires that where an operator considers or suspects that a product which he has produced, prepared, imported or that he has received from another operator, is not in compliance with organic production rules, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He may only put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method. In case of such doubt, the operator shall immediately inform the control body or authority. The control authority or control body may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.

Where a control authority or control body has a substantiated suspicion that an operator intends to place on the market a product not in compliance with the organic production rules but bearing a reference to the organic production method, this control authority or control body can require that the operator may provisionally not market the product with this reference for a time period to be set by that control authority or control body. Before taking such a decision, the control authority or control body shall allow the operator to comment. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the control authority or control body is sure that the product does not fulfil the requirements of organic production.

However, if the suspicion is not confirmed within the said time period, the decision referred to in the first subparagraph shall be cancelled not later than the expiry of that time period. The operator shall cooperate fully with the control body or authority in resolving the suspicion.

Member States shall take whatever measures and sanctions are required to prevent fraudulent use of the indications referred to in Title IV of Regulation (EC) No 834/2007 and Title III and/or Annex XI of this Regulation.

Article 92a (1) to (3) provides that, where a Member State finds irregularities or infringements relating to the application of this Regulation with regard to a product coming from another Member State and bearing indications as referred to in Title IV of Regulation (EC) No 834/2007 and in Title III and/or Annex XI to this Regulation, it shall notify the Member State which designated the control

authority or approved the control body, the other Member States and the Commission without delay via the system referred to in Article 94(1) of this Regulation.

Where a Member State finds irregularities or infringements as regards compliance of the products imported in accordance with Article 33(2) or (3) of Regulation (EC) No 834/2007 with the requirements laid down in that Regulation or Regulation (EC) No 1235/2008, it shall notify the other Member States and the Commission without delay via the system referred to in Article 94(1) of this Regulation.

Where a Member State finds irregularities or infringements as regards compliance of the products imported in accordance with Article 19 of Regulation (EC) No 1235/2008 with the requirements laid down in that Regulation and Regulation (EC) No 834/2007, it shall notify the Member State which issued the authorisation, the other Member States and the Commission without delay via the system referred to in Article 94(1) of this Regulation. The notification shall be sent to the other Member States and to the Commission in case the irregularity or infringement is found with regard to products for which the Member State itself issued the authorisation referred to in Article 19 of Regulation (EC) No 1235/2008.

The Member State which receives a notification relating to non-compliant products in accordance with paragraph 1 or 3 or the Member State which issued the authorisation referred to in Article 19 of Regulation (EC) No 1235/2008 for a product for which an irregularity or infringement was found, shall investigate the origin of the irregularities or infringements. It shall take appropriate action immediately. It shall inform the Member State which sent the notification, the other Member States and the Commission of the result of the investigation and of the action taken by replying to the original notification via the system referred to in Article 94(1). The reply shall be sent within 30 calendar days from the date of the original notification.

The Member State which sent the original notification may ask the replying Member State for additional information, if needed. In any case, after receiving a reply or additional information from a notified Member State, the Member State which sent the original notification shall make the necessary entries and updates in the system referred to in Article 94(1).

## ATTACHMENT J

# ETKO Response to

The Audit of ETKO by IOAS

March 10-13, 2015

"Explanation of the Issues Raised by IOAS for Ukraine

And Situation of Turkey for Mentioned Issues"

## Explanation of the issues raised by IOAS for Ukraine and situation of Turkey for mentioned issues

## Issues Raised by IOAS Accreditation body during ETKO office audit

Follow up previous CBs inspection reports to take over a project "Kvark":

We had only one case in Ukraine Operator Kvark transferred from IMO. We referred only NC reports issued by IMO to accept the operator for inspection and certification decision.

In Turkey correct and complete procedure is followed, for transfer between CBs there is also National database where we can control the status of the producer, product, fields, and nonconformities pending from previous CB.

**Investigation irregularities:** Related to SFC from Ukraine: The issues are now clearly identified, responsible parties were found and sanctions implemented. Major issue was falsification of documents for the raw material and final product exported by the exporting companies. Product flow and traceability are not supported by reliable documents.

**Retroactive acceptance** of former farming system was made based on the declaration of the local authorities for international projects in Ukraine, Kazakhstan, Russia and Ethiopia.

In Turkey ETKO follows the Turkish regulation for accepting former farming system and Ministry of Agriculture approves the retroactive acceptance.

**Issues raised by IOAS for follow up nonconformities** for Ukrainian operators, this was related to delays in original operator files form the Ukrainian inspector.

Follow up NCs are done regularly for Turkish operators. **Inspection documents** were already updated for a better understanding of the operations and for inspector to identify and report the problems easier.

**Document control** of the involved subcontractors and complex structures were difficult to follow only in Ukraine. In Turkey there is no such complex structure.

**Review and certification decision** was only made by one person so far, but for upcoming season more technical staff will be involved with review and certification decision. This was only for foreign files but Turkish operator's files were complete for reviews and certification decisions made certifier Fatih Aksoy.

**Issuing Number for operators:** There was only one case for sister companies UFC and Prodexim, there is no other example that ETKO odes this systematically. This was a clerical mistake.

**NC01:** ETKO are not correctly reporting the number of sub-contractors and sub-licensees under their EU certification system.

Annual Reporting requirement of IOAS and EU Commission: We will assign a new person for reporting, there was misunderstanding of the requirements by the person prepared these reports.

**NC02:** ETKO list of approved outsourced services does not include all service providers, agreements are not in place with all providers and the annual performance review policy of ETKO is not being met.

Laboratories worked with will be evaluated annually. Sampling will be done according to new procedure of ETKO, evaluation of the analyses results will be done properly by an expert. A person will be assigned for this purpose. Norm reference: ISO 65 4.4, ISO 17065 6.2.2

## Explanation of the issues raised by IOAS for Ukraine and situation of Turkey for mentioned issues

**NCO3: ETKO does not ensure that its web-site** stated as source of information to the operators about all changes in the certification standards and procedures provides correct and current information Norm reference: ISO 65 6, ISO 17065 7.10, EC 1235.10.2.f.

Website issues related to latest version of Standard and Regulations will be solved with the new website. Reference to certified operators list will be updated according to EC 1235.10.2.e. Control measures will be linked on the website about the changes.

**NCO4: ETKO are not managing sample taking in line with relevant norms;** sampling protocols were not always available in the ETKO office, retained samples are not left with the operator, samples are stored by the inspectors if not analyzed and ETKO does not have a procedure how to organize suitable storage conditions:

We will not make sampling just for keeping in ETKO Office in Ukraine or anywhere else. We will take samples for analyses only and correct procedure will be followed as it is explained in OP 03 Testing procedure. Sampling procedure will be updated for storage conditions.

**NCO5:** ETKO are not regulating the use of non-organic seed in Ukraine and the inspectors appear to be denying what appears to be common knowledge that GMO seed for crops commonly grown in ETKO projects (maize, soybean) are widely available and used, despite the authorities not permitting them. Norm reference: 889.45 and 889.9

The standard text of the inspection report leads inspectors to make mistakes, this will be eliminated with the new report forms. Training will be done to all inspectors and reviewers for seed material rule. For each export of corn and soybean GMO analyses is obligatory. GMO analyses are done for Turkish operators as a regular in case they export corn and soybean.

**NC06:** ETKO are underreporting to the Commission the number of derogations permitted for non-organic seed. Norm reference: 1235,12.

Seed approvals were not in line with the IACB standard especially for the hybrid varieties such as corn and sunflower in Ukraine. Seed approvals are regularly done for Turkish producers.

**NC07: Control Measures:** ETKO is not able to demonstrate the effective application of control measures. OCP, production plans, assessment reports and inspection reports are generic, partly obviously not reflecting the real situation on site (e.g. reproduction of maize and sunflower seeds from. Norm reference: ISO 65 No. 4.9.1, 4.3 "elite Plants" on farm)

Standard terminology will be excluded from the reports. Propagation material will be dealt with by ETKO stuff before sowing period. We will solve this problem with the new inspection reports. OCP forms will be updated as well according to IACB.

**NCO8: ETKO nonconformity forms** are not completed in line with ETKO own requirements; no major/minor classification is indicated and regulation 889/2008 is referenced and not the equivalent standard, the IACB standard. Norm reference: ISO 17065 7.1.2, 7.4.6, ETKO procedure 'Guide to inspection'.

Existing procedures for handling NCs were updated recently NCs will be classified according to the nature of it, according to TI 15 Control Guide. Sanctions will be implemented as explained TI 46 Catalogue of Measures

NC09: ETKO are permitting subcontracted producers to put product on the market 834.28. We allowed this practice for sister companies in Ukraine as owners are the same for these companies. It

## Explanation of the issues raised by IOAS for Ukraine and situation of Turkey for mentioned issues

is a close system, product flow is under inspection system. Same owner has two companies and several farms under each company. When A company needs export certain product he can buy the products from B company farms. This is not in practice in Turkey for any certified projects.

**NC 10 A-Lack of processing records and traceability is problem**: We identified the source of the problems as they were falsifying documents in Ukrainian SFC cases. We do not have this problem in Turkey with any operator.

B-Sampling records are all available for OFIS Cases for the samples we took during investigation audits. Sampling records are available for Turkish operators.

**NC 11 Payment of ETKO Inspectors:** Ukraine office to be supported therefore we thought paying a percentage rate was not against impartiality. There is office expenditure, personnel and taxes to be paid in Ukraine.

For Turkey we have full time and freelance inspectors which they receive fix rates. ISO 65 4.2.m, 17065 4.2.2

**NC12 Organic Compliance Plans:** OCP reports will be updated for a better information flow from the operators.

**OCP production plans** were similar for many operators from Ukraine due to the consultants working for the companies (Alexy Kachkovsky, Andrew Greben) also because of the personnel transfer between companies lead having similar phrases in these documents. 10 years ago there were only a few companies dealing with organic production, several companies were created later on by the people working for these companies, so information was transferred in this way.

**NC 13: ETKO Inspections are not investigative:** ETKO old documents for inspections are not very investigative, we updated inspection forms for the new season in a better way, in line with IACB Standard. This will allow inspectors to make a better assessment.

NC 14: Last date of non-allowed material applications not demonstrated: We updated inspection documents and we will implement this rule for following years.

**NC 15: Parallel cropping not prohibited:** This was a case from a Kazakh project, we do not have any example in Turkish projects.

NC16: ETKO are not following their own policy of completing a risk assessment form for each operation on an annual basis Norm reference: 889.65.4, 92c.2,

All risk assessment forms are present for Turkish operators.

NC17: ETKO are not conducting input: output audits at on-site inspections of handling and processing units. Norm reference: 889.66.2.

This was also a problem related to old inspection documents. The section was completed for each farm according to marketing results as a summary, inspector did not need to make a balance calculation hand written. But with the new documents inspectors are obliged to make balance calculations by hand writing.

Prepared by ETKO

Mustafa Akyuz: 13.04.2015



1400 Independence Ave. SW Room 2642 - South, STOP 0268 Washington, D.C. 20250

#### Settlement Agreement

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and Ecological Farming Control Organization (ETKO).

USDA, AMS, the National Organic Program (NOP), and ETKO have decided to compromise and settle the issues among them related to alleged violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA) and the USDA organic regulations (7 CFR Section 205).

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- USDA, AMS agrees not to issue a formal Administrator's Decision charging ETKO with alleged violations of the OFPA and the USDA organic regulations for any actions disclosed by the investigation which gave rise to this agreement.
- 3. USDA, AMS and ETKO admit to the following:
  - A. NOP issued a December 22, 2015 Notice of Proposed Suspension of Accreditation to ETKO in Bornova, Izmir, Turkey. ETKO was given the opportunity to appeal the Notice, and this Settlement addresses this Notice.
  - B. ETKO has been given the opportunity to consult with legal counsel regarding this Settlement, is executing this agreement of its own free will, and understands and accepts the terms of this Settlement.
  - C. No alteration or variation of the terms of this Settlement shall be valid unless made in writing and signed by both parties.
- 4. USDA, AMS, NOP agrees to the following actions:
  - A. NOP agrees to withdraw its Notice of Proposed Suspension of Accreditation.
  - B. Upon execution of this settlement, the NOP agrees to accept ETKO's corrective and preventive actions submitted in response to the NOP's May 13, 2015 Notice of Noncompliance.
- 5. ETKO agrees to the following actions:
  - A. ETKO agrees to a site-evaluation at ETKO's expense, in accordance with 7 CFR Parts 205.508(b) and 205.640(a), within twelve (12) months of signing this settlement agreement.

- a. ETKO agrees that the site-evaluation will focus on verifying implementation of the corrective and preventive actions that ETKO submitted in response to the NOP's May 13, 2015 Notice of Noncompliance.
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- B. ETKO agrees that any noncompliance identified at the site-evaluation may result in future adverse action from USDA, AMS, NOP.
- C. ETKO agrees that failure to meet settlement terms above may result in future noncompliance procedures and possible adverse action from USDA, AMS, NOP.

This agreement will become & upon the appellant's signature below.

**ETKO** 

Deputy Administrator, National Organic Program

USDA, AMS

Date: 6 April 2016

 From:
 Kuhn, Meg - AMS

 To:
 ma@etko.org

Cc: "Richard Siegel"; Courtney Cheri - AMS

Subject: Executed Settlement Agreement, ETKO - APL-008-16 (Sent Registered)

 Date:
 Wednesday, April 13, 2016 4:24:59 PM

 Attachments:
 Exec Settlement Cover.ETKO APL-008-16.pdf

Exec Settlement.ETKO.APL-008-16.pdf

image001 jpg
Importance: High

Dear Dr. Akyuz,

Thank you for your signed settlement. It has now been counter-signed and is attached for your records. Additional follow-up regarding your accreditation status will come to you directly from the NOP's Accreditation & International Activities Division. Should you have any questions, please do not hesitate to contact me.

Thank you,

Meg

Meg Kuhn Appeals Specialist USDA-NOP-ODA (202) 205-9644

From: ma@etko.org [mailto:ma@etko.org] Sent: Friday, April 01, 2016 12:19 PM

To: Kuhn, Meg - AMS Cc: 'Richard Siegel'

Subject: RE: Registered: Proposed Settlement Agreement - ETKO, APL-008-16

Dear Meg

Thank you very much for proposal of Settlement Agreement which we signed it. You can find it attached.

I will send original letter by Express courier to your address following:

**USDA** 

1400 Independence Ave. SW Room 2642 – South STOP 0268 Washington, D.C. 20250 USA

Sincerely

Mustafa Akyuz

ETKO Turkey +90-232-3397606 +90-232-3397607 www.etko.org

From: Kuhn, Meg - AMS [mailto:Meg.Kuhn@ams.usda.gov]

**Sent:** Friday, March 25, 2016 5:20 PM

**To:** Richard Siegel **Cc:** Mustafa Akyuz PhD

Subject: RE: Registered: Proposed Settlement Agreement - ETKO, APL-008-16

Hi Richard – my apologies for the oversight. Here is the cover letter.

Thank you, Meg

Meg Kuhn Appeals Specialist USDA-NOP-ODA (202) 205-9644

From: Richard Siegel [mailto:rsiegel@rdslaw.net]

Sent: Friday, March 25, 2016 9:26 AM

To: Kuhn, Meg - AMS Cc: Mustafa Akyuz PhD

Subject: Re: Registered: Proposed Settlement Agreement - ETKO, APL-008-16

Dear Meg,

Thank you for advising me of the NOP's decision to offer ETKO a proposed settlement. The settlement agreement (2 pages) was attached to your email message, but there was no cover letter attached. Please send the cover letter, so that I can begin discussing this with my client ETKO.

Many thanks,

Richard Siegel

----- Forwarded message -----

From: "Kuhn, Meg - AMS" < Meg.Kuhn@ams.usda.gov >

Date: Mar 25, 2016 1:23 AM

Subject: Registered: Proposed Settlement Agreement - ETKO, APL-008-16

To: "rsiegel@rdslaw net" <rsiegel@rdslaw net>

Cc:



This is a Registered Email® message from Kuhn Meg - AMS.

Dear Mr. Siegel,

Thank you for your patience as the National Organic Program's Appeals Team has reviewed your client's, ETKO, appeal request of a December 22, 2015 Notice of Proposed Suspension of Accreditation from the NOP.

Attached to this email is a proposed settlement agreement for you to review. Also attached is a letter ("SettlementCover" attachment) explaining the proposed settlement and providing options to you for moving forward with organic certification. Please take a moment to read through the documents; if you have any questions or concerns, I can be reached via email (<a href="mailto:meg.kuhn@ams.usda.gov">meg.kuhn@ams.usda.gov</a>) or phone 202-205-9644. I will give you a call tomorrow (Friday, March 25) to touch base with you and answer any questions you may have.

Thank you, Meg

### Meg Kuhn

Appeals Specialist
Office of the Deputy Administrator

National Organic Program U.S. Department of Agriculture Room 2649-So. (Stop 0268) 1400 Independence Ave SW Washington, DC 20250-0268 Main Office: 202.720.3252

Direct: 202.205.9644 Cell: 202.603.5158

meg.kuhn@ams.usda.gov www.ams.usda.gov/nop

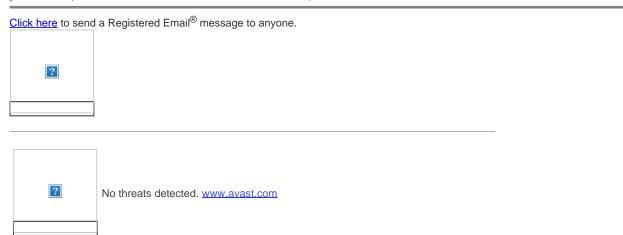
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From: Kuhn, Meg - AMS

Richard Siegel (rsiegel@rdslaw.net) To:

Proposed Settlement Agreement - ETKO, APL-008-16 (Sent Registered) Subject:

Date: Friday, March 25, 2016 1:22:17 AM Attachments: Settlement.ETKO.APL-008-16.pdf

Importance:

Dear Mr. Siegel,

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Attached to this email is a proposed settlement agreement for you to review. Also attached is a letter ("SettlementCover" attachment) explaining the proposed settlement and providing options to you for moving forward with organic certification. Please take a moment to read through the documents; if you have any questions or concerns, I can be reached via email (meg.kuhn@ams.usda.gov) or phone 202-205-9644. I will give you a call tomorrow (Friday, March 25) to touch base with you and answer any questions you may have.

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## Meg Kuhn

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1400 Independence Ave. SW Room 2642 - South, STOP 0268 Washington, D.C. 20250

## **Settlement Agreement**

THIS SETTLEMENT AGREEMENT is entered into by the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS), and Ecological Farming Control Organization (ETKO).

USDA, AMS, the National Organic Program (NOP), and ETKO have decided to compromise and settle the issues among them related to alleged violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA) and the USDA organic regulations (7 CFR Section 205).

Accordingly, the parties agree to the following:

- 1. The Secretary of Agriculture has jurisdiction in this matter.
- 2. USDA, AMS agrees not to issue a formal Administrator's Decision charging ETKO with alleged violations of the OFPA and the USDA organic regulations for any actions disclosed by the investigation which gave rise to this agreement.
- 3. USDA, AMS and ETKO admit to the following:
  - A. NOP issued a December 22, 2015 Notice of Proposed Suspension of Accreditation to ETKO in Bornova, Izmir, Turkey. ETKO was given the opportunity to appeal the Notice, and this Settlement addresses this Notice.
  - B. ETKO has been given the opportunity to consult with legal counsel regarding this Settlement, is executing this agreement of its own free will, and understands and accepts the terms of this Settlement.
  - C. No alteration or variation of the terms of this Settlement shall be valid unless made in writing and signed by both parties.
- 4. USDA, AMS, NOP agrees to the following actions:
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	<u> </u>
Dr. Mustafa Akyuz	Date:
ETKO	
	Date:
Miles V. McEvoy	
Deputy Administrator, National Organic Program	
USDA, AMS	

This agreement will become effective upon the appellant's signature below.

From: Kuhn, Meg - AMS
To: "Richard Siegel"
Cc: Mustafa Akyuz PhD

Subject: RE: Registered: Proposed Settlement Agreement - ETKO, APL-008-16

**Date:** Friday, March 25, 2016 11:20:00 AM

Attachments: <u>~WRD000.jpg</u>

Settlement Cover.ETKO.APL-008-16.pdf

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Thank you, Meg

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Date: Mar 25, 2016 1:23 AM

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To: "rsiegel@rdslaw net" <rsiegel@rdslaw net>

Cc:



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Direct: 202.205.9644 Cell: 202.603.5158

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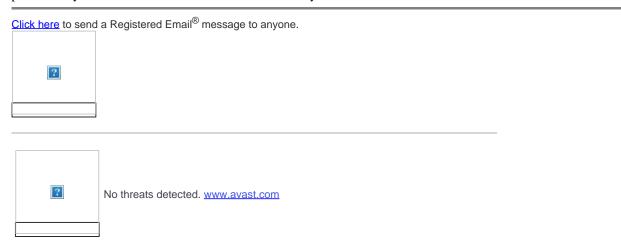
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ETKO	
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Miles V. McEvoy	
Deputy Administrator, National Organic Program	
USDA, AMS	

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