



United States Department of Agriculture

Agricultural Marketing Service
National Organic Program

CERTIFICATE OF ACCREDITATION

BIO-HELLAS

103 Tatoiou Avenue, Metamorphosis, 144 51, GREECE

meets all the requirements prescribed in the USDA National Organic Program Regulations

7 CFR Part 205

as an Accredited Certifying Agent

for the scope of

Crops, Handling, Wild Crops Operations

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 .

Status of this accreditation may be verified at <http://www.ams.usda.gov>

Certificate No: **USDA-7-20**

Effective Date: **7/20/2017**

Renewal Date: **7/20/2022**

Jennifer Tucker, Ph.D.
Deputy Administrator
National Organic Program



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NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite initial audit of the Bio-Hellas Institute (BIOH) organic program was conducted on May 2 - 4, 2018. The National Organic Program (NOP) reviewed the corrective actions in response to noncompliances to assess BIOH's compliance to the USDA organic regulations. This report provides the results of the NOP's assessment.

GENERAL INFORMATION

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|---|---|
| Applicant Name | Bio-Hellas Institute |
| Physical Address | 27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece |
| Mailing Address | 27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece |
| Contact & Title | Ioannis Chalkias, NOP Department Manager / Quality Control Manager / Technical Manager |
| E-mail Address | ydp@bio-hellas.gr |
| Phone Number | 0030 210 8211940 |
| Reviewer & Auditor | Penny Zuck, NOP Reviewer; Lars Crail, Onsite Auditor |
| Program | USDA National Organic Program (NOP) |
| Review & Audit Date(s) | Corrective Action Review: October 2, 2018 NOP assessment: June 1, 2018 Onsite audit: May 2 - 4, 2018 |
| Audit Identifier | NOP-3-18 |
| Action Required | None |
| Audit & Review Type | Initial Assessment |
| Audit Objective | To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of BIOH's certification system. |
| Audit & Determination Criteria | <i>7 CFR Part 205, National Organic Program as amended</i> |
| Audit & Review Scope | BIOH's certification services in carrying out the audit criteria during the period: June 11, 2017 through May 4, 2018 |

Bio-Hellas Institute (BIOH) is a for-profit corporation. BIOH received USDA-NOP accreditation for the scopes of crops, wild crops, and handling on July 20, 2017. At the time of the onsite audit, BIOH certified 24 operations: Crops (22), Wild Crops (1), and Handlers (3). The certified operations are located in Greece and Bulgaria.

BIOH's office is located in Athens, Greece. BIOH administers their NOP certification program with seven staff members: administrative (3), certification reviewers (2), inspectors (2).

One witness audit was conducted by observing an additional announced inspection of a Crops, Wild Crops, and Handling/Processing certified operation located in Bulgaria. The operation's certified products were wholesale dried herbs, hydrosols, and essential oils.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether BIOH'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.

NP7136LCA.NC1 – Cleared

AP-41-18.NC1 – Cleared

AP-41-18.NC2 – Cleared

Non-compliances Identified during the Current Assessment and Corrective Actions

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NOP-3-18.NC1 – Accepted. 7 C.F.R. §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." NOP 2603 Organic Certificates, Section 3.1, Elements of the Organic Certificate, states that certificates should indicate the "Labeling category for each product certified under the handling/processing certification category (not required for products in the crops, wild crops, or livestock certification categories). Labeling categories: 100% Organic, Organic, Made with Organic (specified ingredients or food groups), and Livestock Feed (Organic or 100% Organic)."

Comments: *BIO-Hellas' handling/processing certificates do not indicate the labeling category for each product.*

Corrective Action: BIOH revised its organic certificate template to include labeling categories. The revised template was submitted to the NOP.

NOP-3-18.NC2 – Accepted. 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;"

Comments: *The auditor's review of the "Notice of noncompliance" and "Notice of Proposed Suspension" templates indicate numerous inconsistencies and errors. For example, the Notice of noncompliance template did not clearly state a date by which the operation must respond to*

the notice. The notice stated a lengthy description of actions to be taken if notices of certification denial or proposed adverse actions were to be issued, which was unrelated to the purpose of the noncompliance and would be confusing to the recipient. The Notice of Proposed Suspension template indicates that operators may submit corrective actions to avoid a suspension of certification. The errors identified on the two notice templates and the unclear instructions stated on both notice templates indicate that BIOH's understanding of the process of issuing noncompliances, proposed adverse actions, and adverse actions is not adequate.

Corrective Action: BIOH revised its notice of noncompliance and notice of proposed suspension templates and submitted copies to the NOP.

NOP-3-18.NC3 – Accepted. 7 CFR § 205.501(a)(2) states, “Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart; Carry out the provision of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;”

Comments: *BIOH has not developed and was unable to provide the auditor notification templates for the following actions: correction of minor noncompliances as a condition of continued certification; Notice of Denial of Certification; Notice of Noncompliance and Denial of Certification; Notice of Noncompliance and Proposed Suspension; Notice of Proposed Revocation; Notice of Noncompliance and Proposed Revocation; Notice of Suspension; Notice of Revocation; Notice of Noncompliance Resolution; and notification in cases where results of residue testing indicates the product must not be sold, labeled, or represented as organic (i.e. 205.671). Since these templates were not available for review, the auditor determined that BIOH is not prepared to issue these notifications and comply with the related provisions of the regulations.*

Corrective Action: BIOH developed the following notice templates and submitted them to the NOP: Combined Notice of Noncompliance and Denial of Certification; Notice of Denial of Certification; Combined Notice of Noncompliance and Proposed Revocation; Combined Notice of Noncompliance and Proposed Suspension; Notice of Noncompliance Resolution; Notice of Proposed Revocation; Notice of Revocation; Notice of Suspension; Notice Residue not detected; Notice Residues present; and Notice Residues present above tolerance level.

NOP-3-18.NC4 – Accepted. 7 C.F.R. § 205.406(a)(3) states, “To continue certification, a certified operation must annually... submit the following information as applicable, to the certifying agent: ... An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification...”

Comments: *Bio-Hellas' organic system plan template is submitted by certified operations for complying with the annual update requirement; however, the template does not include a section for operations to describe the status of the correction of minor issues and noncompliances issued to the operation.*

Corrective Action: BIOH revised its Handling, Crops, and Wild Crops organic system plan templates (E NOP 500-6 and E NOP 501-4) to include a section to describe the status of correction of minor issues and noncompliances issued to the operation during the previous inspection. BIOH also revised its Inspection Report templates (E NOP 316-6 and E NOP 314-7) to include a section to describe the verification of corrective actions of noncompliances previously issued. The revised templates were submitted to the NOP.

NOP-3-18.NC5 – Accepted. 7 C.F.R. §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.”

Comments: *The Crops organic system plan template lacks sections requesting operations to describe their compliance to the following practice standards:*

1. *The crop rotation practice standard (§205.205).*
2. *The crop pest, weed, and disease management practice standard (§205.206) to include sufficiently informing operations of the requirement to use preventative and mechanic means to address pests and disease before using botanical and/or materials on the National List.*

Corrective Action: BIOH revised its Crops and Wild crops organic system plan template (E NOP 501-4) to include a section to describe crop rotation practices, including both annual and perennial crops, and a section informing the operation that the crop pest, weed and disease management practice regulations require the use of preventive and mechanical practices before using botanical and/or materials on the National list. The revised template was submitted to the NOP.

NOP-3-18.NC6 – Accepted. 7 CFR § 205.501(a)(2-3) 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; Carry out the provision of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;”

Comments: *BIOH’s inspection report template does not include:*

1. *A section for inspectors to record traceability activities and to record verification that operations have sufficient documentation/records that reflect compliance of the production and/or handling of certified organic ingredients and products.*
2. *Verification of Crop Rotation per §205.205.*

Corrective Action: BIOH revised its Inspection Report templates (E NOP 316-6 and E NOP 314-7) to include a section for recording traceability activities and verification that the operation has sufficient documentation/records to demonstrate compliant production and/or handling of certified ingredients and products. In cases where a new applicant has not produced any organic products by the inspection, the inspector verifies traceability of the operation’s conventional products. BIOH revised its Crops Inspection Report template (E NOP 314-7) to include a section to verify the operation’s crop rotation practices. The revised templates were submitted to the NOP. BIOH conducted inspector training in September 2018.

NOP-3-18.NC7 – Accepted. 7 C.F.R. §205.403(e)(2) states, “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.”

Comments: *In two of the three residue analysis cases reviewed by the auditor, test results were not sent to the operations.*

Corrective Action: BIOH emailed the residue analysis results to the operations and submitted copies of the emails to the NOP. BIOH conducted training in September 2018 for office staff who review residue analyses. BIOH staff plan to attend the NOP certifier training in 2019.

NOP-3-18.NC8 – Accepted. 7 C.F.R. §205.403 (c)(1), (2), and (3) states, “The on-site inspection of an operation must verify: The operation’s compliance or capability to comply with the Act and the regulations of this part; 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; That prohibited substances have not been and are not being applied to the operation”

Comments: *During the auditor’s review of an inspection report, an operation certified to the scope of wild crops, crops, and handling, consisted of 145 production fields, 78 wild fields, and one processing facility located in the vicinity of three distinct regions. The initial inspection report indicated the inspection occurred and concluded in a single day, which would have not been sufficient time to adequately inspect each location due to the amount of travel and effort necessary.*

Corrective Action: BIOH revised its Inspection and Sampling Procedure O NOP 300-10 (sections 4.1.1.7 and 4.1.1.8) to define how many inspection days will be required for a specific type of operation. BIOH revised its Inspection Report templates (E NOP 316-6 and E NOP 314-7) to include a section to record starting and ending inspection dates. BIOH conducted inspector training in September 2018. BIOH notified the inspector of the noncompliance. BIOH will conduct a field evaluation of the inspector in 2018.

NOP-3-18.NC9 – Accepted. 7 C.F.R. §205.403(c)(2) states, “The on-site inspection of an operation must verify: 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;...”

Comments: *After conducting a witness audit and review of inspection reports, the auditor concluded that inspections are not sufficiently verifying the organic system plans and operations’ practice standards. The following issues were identified by the auditor as examples:*

- 1. There were no issues of concern identified by the inspector for incomplete maps inadequately indicating or reflecting buffer zones; missing map details such as processing and storage buildings; and distinct boundaries of production fields.*
- 2. There were no issues of concern identified for lack of organic system plan descriptions or adequate flow charts for all handling processes. In the case of one operation, there was a flow chart and description for only one of the three types of products produced.*
- 3. Inspectors are not identifying that organic system plans are incomplete and recording this as an issue of concern in inspection reports. For example, the operation indicated that it would consider replanting lavender fields in the coming year; however, there was no indication in the organic system plan how the operation will conduct replanting or seeding. The organic system plan identifies this activity as not applicable.*
- 4. During the witness audit, the inspector did not identify as an issue of concern that the operation was not complying with §205.203, Soil fertility and crop nutrient management practice standard. The operation did not indicate in its organic system plan or by an inspection of the fields that it was managing crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.*

Corrective Action: BOIH issued a Notice of Noncompliance to the operation for the issues observed by the NOP auditor as part of this noncompliance. BIOH conducted inspector training

in September 2018. BIOH notified the inspector of the noncompliance. BIOH will conduct a field evaluation of the inspector in 2018.

NOP-3-18.NC10 – Accepted. 7 C.F.R. §205.403(c)(1) states, “The on-site inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part;...”

Comments: *During the auditor's review of an inspection report, a sales invoice reviewed by the inspector indicated a sale and shipment of product to Canada; however, the inspector did not verify that the product or records complied with the terms of the US – Canada Equivalency Arrangement.*

Corrective Action: BIOH revised its Handling, Crops and Wild Crops organic system plan templates (E NOP 500-6, E NOP 501-4) to include a section to describe if the operation exports NOP certified products directly to Canada so that BIOH's reviewers and inspectors can verify whether the product and/or records comply with the terms of the US–Canada Equivalency Arrangement. BIOH's inspectors record the verification in BIOH's revised inspections reports (E NOP 316-6 and E NOP 314-7). The revised templates were submitted to the NOP. BIOH conducted inspector training in September 2018.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Bio-Hellas Institute’s (BIOH) initial accreditation application to become a U.S. Department of Agriculture (USDA) accredited certifier on October 12, 2016. The NOP has reviewed BIOH’s application, conducted an onsite audit, and reviewed the audit report to determine BIOH’s capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

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|---|---|
| Applicant Name | Bio-Hellas Institute (BIOH) |
| Physical Address | 27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece |
| Mailing Address | 27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece |
| Contact & Title | Maria Kornarou, Quality Manager |
| E-mail Address | ydp@bio-hellas.gr |
| Phone Number | 0030 210 8211940 |
| Reviewer & Auditor | Rebecca Claypool, NOP Reviewer; Lars Crail, Auditor. |
| Program | USDA National Organic Program (NOP) |
| Review & Audit Date(s) | Review of the corrective actions: June 28, 2017 On-site Audit: June 11, 2017 |
| Audit Identifier | NP7163LCA |
| Action Required | None |
| Audit & Review Type | Pre-decisional Audit |
| Audit Objective | To evaluate the conformance to the audit criteria; and to verify the completeness of BIOH’s certification system. |
| Audit & Determination Criteria | <i>7 CFR Part 205, National Organic Program as amended</i> |
| Audit & Review Scope | BIOH’s certification services in carrying out the audit criteria. |

Bio-Hellas was previously accredited as a USDA National Organic Program certifying agent on February 13, 2009 to the accreditation scopes of crops, wild crops, and handling/processing. In 2010, Bio-Hellas requested and was granted the livestock scope. Bio-Hellas surrendered accreditation on July 31, 2012 after the US - EU Equivalency Arrangement was established.

Bio-Hellas’ office is located in Athens, Greece. Their certification staff consists of eight individuals including two contract inspectors. Bio-Hellas’ request for NOP accreditation is a result of operations seeking USDA organic certification. These operations produce and process non-food organic products that cannot be certified to the European Union organic regulations. The European Union organic regulations allow for non-food plant propagation; however, plant

processing of non-food products cannot be certified and therefore cannot be traded under the US - EU Equivalency Arrangement.

During the Pre-Decisional onsite audit, NOP conducted a witness audit of Bio-Hellas' inspections of a crop producer and a handler. The inspections were conducted to determine compliance to the USDA organic regulations.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether BIOH's corrective actions adequately addressed the previous noncompliance. 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. Any noncompliance labeled as "**Accepted**" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next onsite audit.

NP7058LCA.NC1 - Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP7163LCA.N1 – Accepted. 7 C.F.R. §205.403(d) states, "The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern."

Comments: *During the witness audit of a producer, Bio-Hellas' inspector informed the operator of a noncompliance and obtained a corrective action to record in the inspection report. The inspection report gives the perception that the inspector is issuing noncompliances and receiving corrective actions from the operator. An inspector's role is to identify issues of concern and request any additional information, not to issue noncompliances, obtain corrective actions, and assess those corrective actions for adequacy.*

Corrective Actions: Bio-Hellas modified their inspection report templates by removing the term "noncompliance" and adding "Issues of Concern." Bio-Hellas modified the Exit Interview section of the inspection report to include a location for the inspector to record a regulatory citation that corresponds to each "Issues of Concern" identified in the inspection report. Bio-

Hellas conducted training on June 26 and 27 with certification staff that covered inspection report template modifications and clarification regarding the inspector's role. BioHellas provided NOP with a copy of the training presentation and records of participating certification staff.