



**Livestock and Seed Program
Audit, Review, and Compliance Branch
Quality System Audit Report**

AUDIT INFORMATION

Applicant Name:	Institute for Marketecology (IMO) Switzerland
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Program:	USDA National Organic Program (NOP)
Audit Date(s):	February 20 - September 15, 2007
Audit Identifier:	NP7051GGA
Action Required:	Yes
Audit Type:	Surveillance - Accreditation Renewal Audit
Audit Objective:	To verify continuing compliance to the audit criteria; and to verify the implementation and effectiveness of corrective actions in addressing the previous non-compliances
Audit Criteria:	7 CFR Part 205 National Organic Program (NOP) Final Rule, dated December 21, 2000; updated September 11, 2006.
Audit Scope:	IMO's quality manual dated March 23, 2006, including personnel, processes, procedures, facilities, and related records.
Location(s) Audited:	The IMO main office in Weinfelden, Switzerland and the IMO Regional office in Konstanz, Germany. Witness inspections were observed in Ciudad, Spain; Lubeck, Germany; and two processing operations in Dalian, China.

IMO Switzerland is a non-profit entity held 100% by the Bio Foundation, which is a non-profit organization. The IMO Group AG, a holding company (limited), consists of 26 individual limited for profit companies (External offices of IMO) all directed by IMO Headquarters (IMO Switzerland). IMO also contracts with 11 "Partner companies" for which they perform the NOP certification for partner company clients. These companies are certified for standards such as EU but not NOP.

IMO Switzerland was accredited as a certifying agent by USDA as a department of the Bio Foundation on June 7, 2002. IMO currently certifies 717 crop, 40 wild crop, 18 livestock, 253 export/handling, 364 processing, and 118 grower group operations to the NOP Standards world wide. IMO currently applies the NOP Standards and is certified for ISO Guide 65 to certify to Bio Swiss and EU 2092/91 standards. The documents used in the certification process combine the various standards, but IMO also has specific procedures and documents pertaining to the NOP certification for clarification of the NOP requirements.



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The certification review process identifies non-compliances as they pertain to the applicable standard.

The certification process starts at the external/regional offices. The external offices make initial contact with clients, receive applications, reviews applications for completeness and ability to comply, set the inspection and inspector, review the inspection report, and make recommendations for certification approval/denial. They are also responsible for providing the cost estimates and receiving payments from the clients. The completed inspection report with recommendations and the application/OSP are forwarded to the IMO Headquarters office in Weinfelden, Switzerland for the final certification decision. IMO Switzerland receives a portion of the client's fees for the certification service they provide. The process is much the same with the Partner companies. The client documentation at the IMO office does not include verification that the initial review of the application for completeness or ability to comply is completed, nor does it consistently contain updates to the organic system plans (OSP), as interviews and records indicated updated OSPs are not required prior to the inspection. The only external office to have the authority to make the final certification decision is the IMO Germany office. IMO Switzerland is still in the process of absorbing this office since the Germany office relinquished its NOP accreditation earlier this year. All personnel records are maintained in the external offices with only a minimum of records maintained in Weinfelden, Switzerland.

The only oversight that IMO has over its external offices is the annual internal audit; however, the quality manager for each external office performs the internal audit of his/her own office. The quality manager for IMO then combines all of the internal audits from all of the offices into one overall report. The managers are not independent as they are auditing their own programs. IMO does not have a procedure in place that dictates that each office must be visited physically by any supervisory personnel from the headquarters office or that independent audits would be conducted. Limited documentation was available showing that some offices were visited; however, the documents do not indicate what or who was reviewed or the findings of the visits.

The staff, inspectors and certification personnel are qualified for the duties assigned per resumes/curriculum vitas reviewed, client files reviewed, and interviews of personnel except as noted for the inspectors during the China witness inspections. The personnel files for the staff and inspectors were not complete and did not contain current conflict of interest declarations, performance evaluations, and training records. IMO has not denied certification, but provided one pending case showing they are following the correct procedures. No appeals of certification decisions or mediation have been conducted by IMO as of the date of the audit.

Witness inspections of wild crop harvesting in Ciudad, Spain and a livestock/crop operation in Lubeck, Germany were observed during the audit. Additionally, the inspections of two processing operations in Dalian, China were observed by two auditors of the audit team on August 28 and 29, 2007.

The following is the information concerning the inspections and an overview of the structure of IMO China.



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Overview of some key Chinese Government Offices associated with organic certification in China

The General Administration of Quality Supervision, Inspection and Quarantine (*AQSIQ*) and the State Environmental Protection Administration (*SEPA*) are just two of the administrations that fall directly under the China State Council. *AQSIQ* manages the China National Accreditation Association (*CNCA*) which was established in 2001 and charged with the responsibility to develop, promulgate, and implement the state laws, regulations and rules concerning certification and accreditation. One of the many regulations that give *CNCA* its authority is the *Regulation's of the People's Republic of China on Certification and Accreditation*, which became effective on November 1, 2003.

Under the approval of the *CNCA*, the China National Accreditation Service for Conformity Assessment (*CNAS*) was established March 31, 2006, by merging two former National Accreditation Boards (certifiers and laboratories). *CNAS* is responsible for the accreditation of all certification bodies and laboratories. There are currently thirty domestic certifiers accredited for domestic organic certification. Fifteen of these certifiers conduct organic certification only, and fifteen were system certifiers that added organic certification to their scope. Accreditation is valid for one year.

Accreditation is not required for foreign certification bodies; however, they must be registered and approved by *CNCA*. All certification bodies foreign and domestic must be registered with the *CNCA*. This includes but is not limited to ISO 9000, ISO 14000, HACCP, and organic certification bodies. In order to register with the *CNCA* the foreign certification body must: be established with a Chinese company; be accredited in their home country or region; and be engaged in certification activities for not less three years. Foreign certifiers can register as an equity joint venture (EJV) company or as sub-contracted company.

The China Certification and Accreditation Association (*CCAA*) is one of ten trade associations affiliated with *AQSIQ*. The *CCAA* is responsible for the accreditation of auditors, inspectors, and trainers. Inspectors must meet established minimum qualifications and their accreditation is valid for three years. National accreditation of inspectors began in 2006. Inspectors conducting only international inspections do not have to be accredited.

Land Stewardship

All land in China is owned by the government; however, it can be used for organic production in four different ways.

1. State Farm where government invests money in the land for agricultural production and pays farmers to manage the land.
2. Private Company rents the land from the State Farm and pays the farmers.
3. Private Company rents land that is not a State Farm (undeveloped) and pays the farmers.
4. Farmers rent land from the government and operate privately.



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IMO China On-site Audit Specific Information

As part of the 5 year re-accreditation audit of IMO Switzerland, there were two witness inspection audits conducted in China to verify inspection procedures were in compliance with the National Organic Program Standards. Additionally the structure, association, and personnel of the IMO China office with the IMO Switzerland office were reviewed; however, the IMO China regional office was not visited due to time and distance restraints. There were two IMO China inspectors utilized during the on-site witness inspections; Mr. Liu Xuantian, Lead Inspector and Reviewer for IMO China and Mr. Mei Siguo, Lead Inspector and translator. Interviews conducted with the two IMO China inspectors revealed that IMO China was established in 1998 and became an Equity Joint Venture (EJV) company in 2006. The EJV is between IMO Switzerland and IMO Controlle CN Co. Ltd (IMO China) with the majority (75%) of the shares of the company being controlled by IMO China. The General Manager of IMO China is Mr. Ding Wei and the company is registered with *CNCA* as required.

Interviews conducted with the inspectors revealed that Mr. Siguo became an organic inspector for IMO China in 2005. Prior to becoming an inspector he was translating organic files and standards; and had worked for more than ten years at a freezer manufacturing company in accounting, human resources, and technical documents management. Mr. Siguo stated his prior training consisted of three training sessions with IMO Switzerland and another training session when IMO Switzerland staff visited IMO China. He also has five to seven shadow inspections prior to conducting inspections on his own but was not sure how many of these were processor inspections. Mr. Siguo conducts inspections on producers and handlers for IMO China (see Findings). Mr. Huantian started conducting inspections for IMO China in May 2004 and stated he had a B.S. in agronomy. He previously worked for OFDC as a consultant for organic farmers and processors that were OFDC clients for one year; in quality control for an organic exporter for one year; three years as a farmer technical manager for a large agriculture company; and three years as a researcher at Nanjing Institute for Organic Agriculture. He had three to five training sessions with OFDC.

IMO China has seven full-time and three part-time inspectors for agriculture. They also have one additional inspector for aquaculture and three additional inspectors for textiles. Applications are submitted to IMO China and reviewed three times. The first review is conducted by Ms. Luolihoag who conducts a general review and then passes the file on to IMO China agriculture department. The second review is a compliance review and is conducted by Mr. Xuantian. At this stage, more information is collected from the client if needed. The general manager conducts a final review and approval to make an estimate to the client. An estimate is sent to the client and if accepted a contract is signed. Once the inspector is assigned and the inspection is completed, an electronic inspection report and the hard copy documents of information collected is sent to IMO Switzerland. IMO Switzerland evaluates the file and may communicate with the inspector to clarify the information. Additional information may be requested from the client if necessary. IMO Switzerland makes the certification decision and sends the information via electronic mail to IMO China where it is translated into Chinese and sent to the client.

The first witness inspection was conducted at Dalian New-Ox Food Co. The company processes a variety of conventional and organic beans and seeds. Dalian New-Ox is the applicant and pays for the



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certification of their main supplier, Yingchun Farm. The inspector was going to continue the inspection at the farm after completing the processor inspection. Both inspectors were utilized during the inspection of Dalian New-Ox. Mr. Mei Siguo was the lead inspector and Mr. Liu Xuantian was the second inspector. They stated this was standard procedure when a new inspector is assigned to inspect the company as inspector assignments are rotated. The IMO China inspector/interpreter had very limited understanding of spoken English making it very difficult to communicate simple questions. Fortunately the marketing/sales manager at Dalian New-Ox served as the interpreter. During the inspection, a sample was collected from the client but no sample receipt was provided to the client (see Findings).

The second witness inspection was conducted at Dalian Bio Agricultural Products Co., Ltd. The company was established in December 2005 and started processing organic products in January 2007. The company processes organic beans, seeds, and cereals with simple processing conducted at one plant and oil processing conducted at a second plant. Both plants were at two different locations within Dalian, China and had been transferred to the company by another previously certified operation in January 2007. The lead inspector was Mr. Xuantian. As stated previously, the IMO China inspector/interpreter had very limited understanding of spoken English making it very difficult to communicate simple questions and had to be asked throughout the inspection to translate the conversations between the other inspector and the client. A sample of organic flax seed was collected during the inspection. In the previous year, the IMO China office had collected 110 samples and 25 were submitted for testing. The inspectors stated that samples are pulled on all operations but only submitted if they receive a compliant or if instructed by IMO Switzerland.

Grower Group Certification: In order for the grower group to qualify for a reduced rate of inspection (where not all farmers are inspected by IMO) the operator must have an internal control system (ICS) and one hundred percent of the farmers need to be inspected by the ICS. IMO conducts inspections of the ICS annually and utilizes minimum rates for inspecting the farmers within the group. These minimums are based on the risk classification of the ICS which are Normal, Medium, and High Risk. The number of farms to visit during the inspection will be based on the square root of the number of farmers or a minimum of 10, 12, or 14 farmers respectively. The risk classification of the operator is evaluated and included in the inspection report. Sanctions for non-complying operations range from a re-inspection to suspension of the operator and are applied based on the category placed on the non-compliance's identified. Non-compliances and their associated category are described in the *IMO Catalogue of Sanctions, IMO I, 4.5.2 G*.

FINDINGS

Observations made, interviews conducted, and procedures and records reviewed verified that IMO Switzerland is not operating in compliance to the audit criteria as identified in the non-compliances below. Three non-compliances from previous audits were cleared as a result of this audit; however, two non-compliances were unable to be verified for effectiveness or implementation during this audit. There were thirteen (13) non-compliances identified during the audit.



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NP4254GGA.NC2 – Major- Cleared
NP517100A.NC1 – Minor –Cleared
NP6244NNA.NC1 – Major – Cleared

NP517100A.NC3 – Minor – Outstanding – NOP §205.404 states that if the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the plan, the agent shall grant certification. *IMO 5.7 Contract NOP Finance states, "...furthermore it reserves the right to unannounced spot check controls and sampling for analysis, these costs are also covered by the mandatory. Also in I 2.1.1 G-e section 1.5 states, "All expenses necessary to conduct the inspections, evaluations, and certification will be charged to the mandatory. Requiring clients to pay for analysis is an additional requirement and cannot be used as a determination for certification. Corrective Action:* IMO has indicated that reference to costs of sampling analysis will not be included in the general invoice for inspection and certification but will be billed separately. This still indicates that clients will be billed for analysis of samples. **Corrective Action (January 22, 2007):** IMO has reviewed NOP §205.404 and concluded that there is nothing to indicate that the certifying body cannot charge for any sampling analysis that is conducted. However, according to NOP §205.670 b, "The administrator, applicable State organic program's governing State Official or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic" "organic" or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense." **Corrective Action (April 7, 2007):** IMO submitted updated procedure, IMO I 5.1 CH-e IMO Standard Program for Certification to the NOP Rule PCB, from May 2006. Section 10.3 Costs and Services states, "the costs for analyses in NOP certifications are not charged to the client." **Onsite Audit Verification Activities (Feb. – Sept. 2007):** The IMO contract, the IMO working procedure V70, and additional references in the procedures require the cost of testing to be born by the producer or client. This is contrary to the requirement of this clause.

NP517100A.NC4 – Minor – Outstanding – NOP §205.501(a)(6) states that a private or governmental entity accredited as a certifying agent under this subpart must: (6) Conduct an annual performance evaluation of 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 implement measures to correct any deficiencies in certification services... *A review of the annual performance evaluations revealed that IMO was not conducting annual performance evaluations for personnel involved in certification located in offices other than Switzerland. Corrective Action:* IMO has developed a new form for annual performance evaluations. Performance evaluations for this year will be completed March 31, 2006. **Onsite Audit Verification Activities (Feb. – Sept. 2007):** Records did not support that annual performance evaluations are performed. The director keeps all performance evaluations separate from the personnel files; however, the files he maintains did not contain current performance evaluations for the personnel reviewed. A new system is currently being implemented with a new checklist for performance



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evaluations, but it had not been fully implemented prior to the date of the audit. IMO Germany has not performed any evaluations for any inspectors working from that office.

NP7051GGA.NC1 – NOP §205.303(b) states, “Agricultural products in packages described in §205.301(a) and (b) must: (2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product....” *Finished product packaged as “Aunt Patty’s Organic Sunflower Kernels” packed by Dalian New-Ox in Dalian, China stated “Certified Organic by QAI”. The applicant stated this was because the distributor receiving the product (Glorybee Foods, Eugene, OR) was certified by QAI and they did not want to have to repackage the product. The inspector identified a non-compliance for the name of the company (Dalian New-Ox) not being on the bags but did not mention the certification agent.*

NP7051GGA.NC2 – NOP §205.307(b) states, “Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.” *Bags of soybean meal kept in the oil processing warehouse in Dalian, China did not contain any form of identification on the bags. There were no records to verify that the product was in fact organic and it was transferred from one company to the next. The company stated this was because they considered it an internal transfer. However, they are operating as two separate certified operations.*

NP7051GGA.NC3 – NOP §205.401(d) states, “The application must include the following information: Other information necessary to determine compliance with the Act and the regulations in this part.” Additionally, IMO I – 2.1.01 G-e Standard Procedures for certification Section 7.2 and IMO’s Work Instruction Number 53 for NOP Labeling Requirements version July 2007 require the approval by IMO for all export and final consumer labels prior to printing. *Records show that most labels are currently being evaluated and approved by the contract or staff inspectors during the onsite inspections. This is contrary to the company procedure, and NOP standards, which require the ACA to review application materials (§205.404(a), §205.405(a) and §205.406(c)) and inspectors to verify information (§205.403(c)).*

NP7051GGA.NC4 – NOP §205.402(a) requires the certifying agent to accept applications for certification and must: (1) review the application for completeness; (2) determine if the applicant does or has the ability to comply with the regulation; (3) verify if an applicant has previously applied to another certifying agent; and (4) schedule the on-site inspection. (b) requires the certifying agent within a reasonable time to: (1) review application materials received and communicate its findings to the applicant; and (2) provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent. *The duties detailed in this section of the regulation are performed at the regional offices. The completion of these duties could not be verified in the materials maintained at the office in Weinfelden, as the records for the review process are maintained in the regional offices. The IMO office in Weinfelden, Switzerland receives the completed inspection report, the OSP, and the recommendation from the regional office. The timeframe for the process could not be verified with the information available in the client files at the Weinfelden office.*



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NP7051GGA.NC5 – NOP §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 and at a time when land, facilities, and activities... can be observed...” *During the China witness inspection, the processor was not in production and the inspector stated that the inspection would count towards certification. An inquiry on the 2006 inspection verified that the operation was not in production at the time of that inspection either. During the witness inspection, the inspector which also conducted the previous inspection stated that the company was not in production at the time of the 2006 inspection.*

NP7051GGA.NC6 – NOP §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 regulations in this part.” *An audit trail on the incoming product and production record for a lot of soybeans was conducted by the inspector during the witness audit in Dalian, China. However, the calculations conducted did not account for the oil production from the soybeans. The inspectors stated the IMO checklist does not require this and thus was not considered in the calculations. The difference in the unaccounted product was 56.8 metric tons. During the tour of one processor, the inspectors reviewed two pallets of organic product and did not review or observe the other two pallets. Additionally, none of the six to eight pallets of conventional product were reviewed. Pallets were covered with tarps and could not be observed unless the tarps were lifted. An audit trial conducted on product did not account for all product used during production.*

NP7051GGA.NC7 - NOP §205.501(a)(5) states “Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.” *The inspector had limited experience with processors in general and of organic processing and handling techniques. The inspector indicated the client needed to maintain a “buyers list”. When asked to which standard the requirement to maintain a buyers list came from he was not sure. When questioned on whether the requirement was a USDA National Organic Standard requirement he did not know.*

NP7051GGA.NC8 – NOP §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector.” *A sample was collected from two processors during the witness inspections in Dalian, China but no receipt was provided to the operations. The inspectors stated they only provide a receipt if the operation requests a copy. The second operation was asked if they would like a receipt but they stated they did not.*

NP7051GGA.NC9 – NOP §205.406(a)(1) states, “To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: An updated organic production or handling plan...” *IMO does not require the submission of an updated organic system plan. A review of 13 files identified only one having an updated organic system plan prior to arrangements for inspection. The inspector is required to update the organic system plan at the time of inspection.*

NP7051GGA.NC10- NOP §205.501(18) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the



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correction of minor non-compliances.” *IMO does not currently have a procedure for conveying the results of certification decisions back to the inspector who performed the inspection.*

NP7051GGA.NC11 – NOP §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....” *Client file reviews and on-site witness inspections revealed that the label approval is being performed by the inspector during the inspection. Training documents revealed that the inspectors have not received specific training in label requirements for NOP.*

NP7051GGA.NC12– NOP §205.501(a)(11)(v) requires 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. *A review of personnel files disclosed that: Five of eight Certification Officers conflict of interest disclosure reports were at least fourteen (14) months since the last declaration, and six of twelve inspectors conflict of interest declarations were at least thirty (30) days past due.*

NP7051GGA.NC13 – NOP §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.” *IMO has established a new fee structure for 2007, which clients have been charged for their 2007 certification services. The new fee structure has not been filed with the Administrator. Fee structure are different for each country in which IMO does business, and the fee structure for partner companies is not published at all. The fee structure is a flat fee for certification.*