



United States Department of Agriculture

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Food Safety and  
Inspection Service

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Avenue, SW.  
Washington, D.C.  
20250

Dr. Nguyen Nhu Tiep  
Director General  
National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD)  
Ministry of Agriculture and Rural Development of Vietnam  
Hanoi, Vietnam

Dear Director Tiep,

The United States Department of Agriculture (USDA), Food Safety Inspection Service (FSIS) conducted an on-site initial equivalence verification audit of Vietnam's Siluriformes fish and fish products inspection system from May 14 through May 25, 2018. Enclosed is a copy of the final audit report. The comments received from the National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD) are included as an attachment to the report.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at [InternationalCoordination@fsis.usda.gov](mailto:InternationalCoordination@fsis.usda.gov).

Sincerely,

A handwritten signature in blue ink that reads "Janell Kause".

Janell Kause  
Acting International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN  
VIETNAM

MAY 14-25, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
FISH OF THE ORDER SILURIFORMES AND PRODUCTS OF SUCH FISH  
EXPORTED TO THE UNITED STATES OF AMERICA

August 22, 2018

Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

This report describes the outcome of an initial onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from May 14-25, 2018. The purpose of the audit was to verify whether Vietnam's food safety inspection system governing fish and fish products of the order of Siluriformes provides a level of public health protection equivalent to the level achieved by FSIS in the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Vietnam currently only exports raw intact Siluriformes fish and fish products.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

### **Government Statutory Authority and Food Safety and Other Consumer Protection Regulations**

- National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD) inspectors did not identify the failure to routinely document results of operational sanitation monitoring in all establishments.

### **Government Sanitation**

- In one establishment, results of Adenosine-Tri-phosphate (ATP) testing conducted as a verification of pre-operational sanitation were not recorded on sanitation SOP documents.
- One establishment failed to list scales coming in direct contact with product on their pre-operational monitoring sheet and verification records.
- At all establishments audited, results of operational sanitation monitoring were not fully documented.
- In one establishment, small blue specks of foreign material were observed in ice being used in the ice glazing area.
- In one establishment, employees in the boxing area were observed reaching into bags of product and directly handling frozen fillets of fish after contacting non-food surfaces (boxes).
- At two establishments, product rinsing/washing machinery was observed to be constructed with piping which could not be disassembled to enable full inspection to verify sanitation.
- In one establishment, the hard-plastic diverter paddles on the sides of a scaling conveyor belt were observed to be in deteriorating condition.

### **Government Hazard Analysis and Critical Control Points (HACCP) System**

- In one establishment the hazard analysis did not identify all potential hazards associated with each step of the process.

During the audit exit meeting, the NAFIQAD committed to address the preliminary findings as presented. The NAFIQAD also provided a brief overview regarding notification to establishments of findings observed by FSIS, and the actions the establishments had already implemented, or changes made to written programs. FSIS will evaluate the adequacy of the NAFIQAD's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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## **I. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Vietnam's food safety inspection system governing fish of the order Siluriformes fish and fish products from May 14-25, 2018. The audit began with an entrance meeting held on May 14, 2018, in Hanoi, Vietnam, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD).

## **II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**

This was an initial equivalence verification audit. The audit objective was to verify whether the food safety system governing fish of the order of Siluriformes and their products is functioning in a manner equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Vietnam has certified establishments that are eligible to export Siluriformes fish and fish products by HACCP process categories: raw non-intact and raw intact Siluriformes fish and fish products to the United States. Vietnam currently exports only raw intact Siluriformes fish and fish products to the United States.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, point-of-entry inspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS from March 1, 2016 to December 31, 2017, in addition to information obtained directly from the NAFIQAD through the self-reporting tool (SRT).

Representatives from the NAFIQAD accompanied the FSIS auditors throughout the entire audit. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs. The evaluation of all six equivalence components included a review and analysis of documentation previously submitted by the NAFIQAD as support for the responses provided in the SRT. The FSIS onsite audit included record reviews, interviews, and observations made by the FSIS auditors.

Administrative functions were reviewed at the NAFIQAD headquarters, one regional office, one branch office, and eight local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of eight establishments and two cold storage facilities were selected from a total of 13 slaughter and raw processing establishments certified by the NAFIQAD to export Siluriformes fish and fish products to the United States. This audit also included risk-based visits to two sites where fish raising, and pre-harvest operations are conducted. During the establishment and pre-harvest operations visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the NAFIQAD’s ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §557.2.

Additionally, one microbiological and chemical laboratory was audited to verify the ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD), Hanoi</li> </ul>
	Regional	1	<ul style="list-style-type: none"> <li>NAFIQAD Southern Regional Office, Ho Chi Minh City</li> </ul>
	Branch	1	<ul style="list-style-type: none"> <li>NAFIQAD Branch 6 Office, Can Tho City</li> </ul>
Chemical and Microbiological Laboratory		1	<ul style="list-style-type: none"> <li>NAFIQAD Branch 6 Laboratory, Can Tho City</li> </ul>
Siluriformes fish slaughter and raw processing		8	<ul style="list-style-type: none"> <li>Establishment No. DL 810, Chau Thanh District, Hau Giang Province</li> <li>Establishment No. DL 369, O Mon District, Can Tho City</li> <li>Establishment No. DL 15, O Mon District, Can Tho City</li> <li>Establishment No. DL 461, Thot Not District, Can Tho City</li> <li>Establishment No. DL 147, Cao Lanh City, Dong Thap Province</li> <li>Establishment No. DL 500, Cao Lanh City, Dong Thap Province</li> <li>Establishment No. DL 511, Chau Thanh District, Tien Giang Province</li> <li>Establishment No. DL 518, My Tho District, Tien Giang Province</li> </ul>
Siluriformes fish cold storage facility		2	<ul style="list-style-type: none"> <li>Establishment No. DL 500, Cao Lanh City, Dong Thap Province</li> <li>Establishment No. DL 511, Chau Thanh, Tien Giang Province</li> </ul>

Pre-harvest production sites	2	<ul style="list-style-type: none"> <li>• Registration Site No. 92-01-0183, Can Tho City</li> <li>• Registration Site No. 82-01-0028, Tien Giang Province</li> </ul>
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- The audit was performed to verify that Vietnam’s food safety inspection system governing Siluriformes fish and fish products met requirements equivalent to those under the specific provisions of United States’ laws and regulations, in particular:
- United States Code of Federal Regulations, Title 9, Chapter III, Subchapter F, Part 530. *Mandatory Inspection of Fish of the Order Siluriformes and Products of Such Fish*
- The Federal Meat Inspection Act (FMIA) (21 United States Code [U.S.C.] 601, et seq.

The audit standards applied during the review of Vietnam's inspection system for fish and fish products of the order Siluriformes included all applicable legislation originally determined by FSIS as equivalent as part of the initial review process.

### III. BACKGROUND

On December 2, 2015, FSIS published the final rule, “Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish.” The Final Rule established an 18-month transitional period, from March 1, 2016 to August 31, 2017. FSIS began fully enforcing all regulatory requirements on September 1, 2017.

From March 1, 2016 to December 31, 2017, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 12,250,858 pounds of raw intact and raw non-intact Siluriformes fish and fish products exported by Vietnam to the United States. Currently, Vietnam exports only raw intact products as the last shipment comprising of non-intact Siluriformes fish products imported into the United States was on October 5, 2017. FSIS also performed re-inspection for additional types of inspection, including testing for chemical residues and refused 337,922 pounds because of violative test results.

During the planning phases of the audit, the NAFIQAD informed FSIS that the number of eligible establishments initially certified to export Siluriformes fish and fish products to the United States had been reduced from 62 establishments to 13 establishments.

The FSIS final audit report for Vietnam's food safety inspection system will be available on the FSIS website at:

[http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports.](http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports)

### IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient

administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The NAFIQAD is a government agency within Vietnam's Ministry of Agriculture and Rural Development (MARD) and is the CCA FSIS directly communicates with on food safety matters. The NAFIQAD is headquartered in Hanoi and is supported by its subordinate agencies; the NAFIQAD - Central Region Authority located in Khanh Hoa province and the NAFIQAD - Southern Region Authority located in Ho Chi Minh City. These regional authorities are responsible for conducting audits and providing administrative support to the NAFIQAD branch locations.

The NAFIQAD has six branches located in Hai Phong, Da Nang, Khanh Hoa, Ho Chi Minh City, Ca Mau, and Can Tho. Branch locations provide direct inspection coverage to establishments and verify the compliance of slaughter and processing establishments eligible to export Siluriformes fish and fish products to the United States. The NAFIQAD branch locations are also responsible for issuance of an inspection certificate certifying each consignment of product for export, and samples live fish prior to harvest from growing ponds and harvest sites.

The NAFIQAD ensures compliance of eligible establishments that are certified to produce products to export to the United States through the presence of government inspection personnel at least once per production shift while producing product for export. Additionally, the NAFIQAD Regional personnel perform an audit of slaughter and processing facilities at least once per year.

The NAFIQAD holds the legal authority to delist an establishment as eligible to export product to the United States. A facility may also be decertified if it is determined to no longer meet Vietnam requirements or the import requirements of the United States. If the NAFIQAD branch inspection personnel determine corrective actions may have been ineffective, the NAFIQAD regional authority is notified, which in turn could result in an audit of the establishment being conducted. If the NAFIQAD audit determines the establishment failed to meet regulatory standards, certification is suspended until the NAFIQAD can determine subsequent corrective actions have regained control and standards are again met.

The NAFIQAD has a Siluriformes fish working group, which consists of NAFIQAD, Directorate of Fish (D-FISH) and Department of Animal Health (DAH), located at its headquarters in Hanoi that regularly review FSIS requirements, and reviews new advancements or trends in food safety. Departments within the working group will then disseminate information through Regional, branch or sub offices to government personnel, certified establishments, hatcheries, farms and feed manufacturers via postal letters, updates to government authority websites, workshops/seminars, training courses, or through direct notification to government inspectors who then directly notify the facilities.

Inspectors are direct employees of the NAFIQAD, with no funds or reimbursement coming from establishments. Government inspectors are required to be trained on subjects of inspection and food safety including Hazard Analysis and Critical Control Points (HACCP), Good Manufacturing Practices (GMPs), Sanitation Standard Operating Procedures (SSOPs), residues,



sampling, and export certification or auditing as applicable, and must pass the NAFIQAD certified testing standards. The NAFIQAD conducts additional advanced training when new regulations are issued, as well as yearly inspection trainings organized through the NAFIQAD headquarters. The NAFIQAD monitors and supervises performance of inspection personnel at a branch level either assigned to inspect at a certified processing establishment or assigned to perform the export consignment inspection. The NAFIQAD supervisors shadow NAFIQAD inspectors at least once per year while inspecting a consignment for export, and twice per year while monitoring establishment operations during processing. When evaluating an employee's performance, a supervisor uses a standardized checklist of items regarding the inspection tasks that a NAFIQAD inspector needs to conduct during his or her assignment.

The NAFIQAD defines a production lot as being fish sourced from a single farm (individual pond) on a single production day. The lot product code is assigned by the eligible establishments during the processing of the fish to enable rapid identification of production lots if a product recall is needed. During supervisory reviews, the NAFIQAD officials conduct evaluations of the adequacy of the tracking mechanism being implemented. Production lots are further defined by a unique shipping mark that is included on finished packaging during product boxing. The amount of product receiving an individual shipping mark is no more than what can be shipped in one shipping container. Each individual consignment that is sampled by the NAFIQAD is required to remain on hold until sampling results are received from the laboratory. The NAFIQAD does not issue an inspection certificate, which approves the product for export until all testing results are returned as acceptable.

Oversight of fish hatcheries and fish grow out farms in Vietnam is coordinated by the MARD amongst two other agencies: the D-FISH, and the DAH. The D-FISH is the government authority required to perform on-farm inspections and they certify decertify farms for production. The D-FISH also has oversight of the manufacture, distribution, and usage of feeds. The D-FISH ensures that the farm has been approved by local governmental authorities for construction of the farm at a suitable location, ensures that the farm is able to operate and maintain the required infrastructure, and that the farm's operations do not result in a negative impact on the environment, and that the environment does not cause contamination of fish produced at the farm.

Once a farm is certified, the D-FISH issues an individual registration number with each pond having a unique identifying code. A certified farm is then listed as a facility approved to produce *Siluriformes* to be harvested and further processed for export. This information is maintained on a central computer system, with access through an intranet site available to the various regional offices of the D-FISH. The data collected on the farmer, pond, and location is also shared with the DAH and the NAFIQAD, so that in the event of a recall, traceability can be ensured from the establishment to the individual farm pond.

The D-FISH performs an initial on-site inspection of the farm and ponds, and then at least once a year, the farm and ponds are re-inspected. Based on the result of an inspection, the farm is placed into a three-tier category. The first tier is for those farms meeting all requirements without issue, which results in routine site audits of once per year. Tier two and tier three farms are farms categorized as those where not all requirements were met at the previous inspection, or

a problem was detected through other mechanisms such as a testing result by an establishment, the NAFIQAD, or other government entity, including reports of a point-of-entry violation (POEV) from the United States. Increased site audits of two to four visits occur at farms categorized as tier two or tier three versus the routine once per year for tier one farms.

The D-FISH provides for monitoring of the Mekong River water quality twice a month at 26 locations along the river with results publicly posted by the D-FISH on their website. The actual sampling is performed and analyzed by personnel from Research Institute #2, a separate government institution that operates under the scope of the MARD. The farm operators can then review the D-FISH sampling information to know if water from the Mekong River can be safely used to operate their farms.

The DAH is responsible for the production, distribution, and proper usage of veterinary drugs, and also monitors farms for disease conditions, with all hatcheries and farms required to inform the DAH of reportable disease conditions. To monitor and ensure disease free status, the DAH makes random regional site visits, to include sample collections every month, during which they collect water and fish samples for analysis. On average, the DAH visits several farms with 4-5 water and fish samples per farm collected per region for a monthly average of 20 samples of water and fish. The DAH is responsible for the health of fingerlings and fish disease control. The DAH monitors the fingerling ponds by issuing certificates to farmers who own fingerling farms. The DAH requires that a fingerling producer maintain this additional certification, which allows for the movement of fingerlings between regions and ensures the control of disease across regions. The DAH sends out information to farms, establishments, the NAFIQAD and the D-FISH to inform them of any disease conditions through letters, emails, and their website.

The FSIS auditors reviewed documents regarding water and fish sampling for analytical testing. The documentation contains the name of the farmer, unique identification code of the farm, address with location as it appears on a global positioning system, and the phone number of the farmer. Other information on the form includes; type of sample, the order in which the samples were collected, and the pond's location using the pond identification code. The current hygienic condition of the farm at the time of sampling is noted on the document, which also includes results of observations of the health condition and age of the fish (specified in days) for each sample taken. Each sample is marked with a unique identification code with both the government inspector and the farmer signing the form.

The scope of this audit also included visits to three processing establishments (VN-DL15, VN-DL461, VN-DL147) which produced shipments of products, which resulted in POEV due to presence of Leucomalachite Green and two separate instances of Crystal Violet. A fish raising farm (supplier of VN-DL15) which had supplied fish contaminated with Leucomalachite Green was also audited. The FSIS auditors reviewed documents and interviewed the NAFIQAD's inspection personnel in response to these violations. In each incident, the NAFIQAD provided notification of the violation, ensured each establishment investigated and took immediate corrective actions, which included traceback of all affected product, segregation, and disposition as applicable. The FSIS auditors concluded that NAFIQAD inspection personnel reviewed establishment investigations and corrective actions to determine if the establishments' responses were appropriate and adequate. FSIS has accepted the corrective actions and closed the case for

two of the POEVs and is awaiting the NAFIQAD's response for the violation from the third establishment. During the audit, the NAFIQAD was also informed that an additional POEV has been identified by FSIS and a letter providing notification was formally issued by FSIS on June 19, 2018.

FSIS determined that Vietnam's government organizes and administers the country's Siluriformes fish inspection system, and that NAFIQAD officials enforce laws and regulations governing the production and export of fish and fish products of the order Siluriformes at establishments certified to export to the United States.

**V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)**

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The food safety inspection system is to provide for regulatory controls, including but not limited to, control over condemned materials; complete separation of eligible Siluriformes fish products from ineligible products; government inspection of production activities at least once per production shift when producing products for export to the United States; and periodic supervisory visits to certified establishments to evaluate the performance of inspection personnel.

The NAFIQAD has defined a product to be adulterated if a physical check (e.g. packaging, labeling, weight) or sensory check (e.g., texture, taste) do not meet requirements. Additionally, FSIS auditors verified through records review that product is considered adulterated if *Salmonella* is detected, prohibited antibiotics or chemicals are found, or residue levels exceed the permitted tolerance limit. Product determined to be adulterated is directly controlled by the NAFIQAD and an inspection certificate is not issued.

Currently, establishments in Vietnam only process fish of the family *Pangasius hypophthalmus* of the order Siluriformes for export to the United States. Establishments do not import any fish of the order Siluriformes for processing because domestic fish farms can provide adequate supplies of fish for both domestic consumption and for export to foreign markets. The NAFIQAD ensures proper labeling of product according to FSIS labeling requirements. The auditors verified that the labels include a statement that clearly identifies the product as being of the species *Pangasius hypophthalmus*; is a product of Vietnam; has safe handling instructions; has a handling statement; and includes the net weight; percent solution; and a signature line. The FSIS auditors observed that establishments segregated and stored product for export to the United States in distinctly marked locations from product intended for other markets. The FSIS auditors verified through a record review that the NAFIQAD requires establishments to have product coding systems to ensure segregation of products; each shipment has its own identification number and is produced separately (time/space) to ensure traceability.

The NAFIQAD specifically requires that all establishments involved with production of product (hatchery, farming, slaughter, processing) must be certified as eligible to produce for export to

the United States. The NAFIQAD requires establishments to maintain traceability of product for purposes of a possible recall, and in order to identify source of any violations. The FSIS auditors reviewed records that the NAFIQAD inspectors verify this traceability requirement during their performance of inspection duties, which occurs at least once per production shift during slaughter/processing and during the inspection process of a consignment for the issuance of an inspection certificate.

The NAFIQAD's "*Program on Controlling food safety of Order Siluriformes and products derived from such fish exported to the U.S.*" requires that dead or diseased fish must be removed at receiving, with those inedible products to be segregated into separate containers, clearly identified/marked and handled to avoid the spread of disease and environmental pollution. Establishment personnel are identified as responsible for removal of dead or diseased fish at receiving, with products collected and disposed of according to establishment protocols.

During observation of the production flow including the receiving process and intake of fish, FSIS auditors verified that unfit or dead fish were separated from live fish at several steps in the process. The removal steps occurred on the boat during transport, at unloading of fish from the boat, and at the cutting/bleeding step.

At each location, unfit fish are placed into a marked/designated container under establishment control, which can be verified by the NAFIQAD inspector. Establishment personnel document the weight of dead fish removed from the process flow at each location. Containers with dead or unfit fish are then transported to the rendering truck, where the driver of the truck verifies the amount of product placed on the truck from each location within the facility by signing the tracking form. Establishment management was able to provide copies of invoices and receiving records showing the amounts of materials moved to the rendering facility on a daily basis. The NAFIQAD inspectors verify establishment activities (removal of dead or diseased fish) at least once per production shift, and record verifications on inspection results records.

Non-compliances are documented with written and verbal notification provided to the establishment. The NAFIQAD's "*Program on Controlling food safety of Order Siluriformes and products derived from such fish exported to the U.S.*" provides for inspection personnel to temporarily stop production if needed, as was observed by FSIS auditors during establishment audit visits when control actions were necessary. The NAFIQAD's "*National Technical Regulation, Fisheries Food Business Operators-General Conditions for Food Safety*" requires establishments develop GMPs for each stage of processing on every line, and specifies regulations and instructions on worker practices, responsibilities, and records for adequate GMP implementation.

An establishment certified as eligible to produce product for export must notify the NAFIQAD branch every week on Friday if they plan to produce Siluriformes fish or fish products to export to the United States during the upcoming week. This gives the NAFIQAD the time required to ensure that inspection personnel are available to provide coverage in all establishments. The NAFIQAD creates a weekly assignment/staffing plan for NAFIQAD inspectors at certified establishments to ensure inspection coverage at a rate of at least once per production shift. There are more NAFIQAD inspectors than establishments; therefore, the NAFIQAD is able to ensure

that coverage is available to all eligible establishments to provide coverage at least once during each production shift.

An establishment must provide notification to the appropriate branch office of the NAFIQAD indicating their intent to produce product for United States export by the end of the previous week. The NAFIQAD branch Office will assign a NAFIQAD inspector, with the NAFIQAD inspector submitting an inspection plan of the minimum inspection items to be verified on each production day to the branch office head. FSIS auditors reviewed the inspection plans on file, which provided assurance that all available tasks based on products produced are performed at a minimum once per week, with other tasks at increased frequencies based on food safety risk associated with noncompliance (e.g. daily HACCP and operational sanitation, pre-operational sanitation and labeling tasks less than daily). After approval, the NAFIQAD inspector will perform and document the inspection results according to the daily inspection plan.

A report is generated for each production shift of the production day and includes results of all inspection procedures as well as information including farm supplier information and pond code number and testing results of the NAFIQAD live fish testing (prior to harvest). If non-compliance is observed, the report identifies the observation, the establishment's response of corrective actions, and the NAFIQAD inspector's verification of the corrective actions. After completion of production, the establishment reports information to the NAFIQAD including the product produced (name), total amounts, lot code, unique shipping marks, name of customer receiving product, dates of production, and farm supplier information.

The NAFIQAD Regional authority assigns an inspection team (two to four NAFIQAD inspectors) to annually audit an establishment's complete system at each facility. All results of these inspection activities are recorded and include the name of establishment, date and time, and the NAFIQAD inspectors performing the activities. The NAFIQAD provides the resulting audit report, which identifies minor and major findings with a conclusion as to the facilities compliance. Establishments are required to provide corrective action responses to NAFIQAD, along with timeframes of when the actions will be completed. NAFIQAD is then able to confirm the establishment's completion of the corrective actions and verify if the corrective actions were effective.

During analysis of findings observed at each individual establishment, the following issue regarding government oversight and inspection was observed:

- At each establishment audited, the FSIS auditors found that the establishments only document results of routine scheduled mid-shift wash-down procedures. The NAFIQAD inspectors did not identify the establishments' failure to routinely document results of operational sanitation monitoring.

The FSIS auditors verified that establishments perform monitoring of the percent solution or water pickup by conducting measurements (weighing) of a batch of fillets prior to and after tumbling with solution. The percent pickup is then calculated to ensure the label accurately reflects the maximum percent retained water and solution. The NAFIQAD inspectors routinely verify that establishments follow their program.

Issuance of an Inspection Certificate for product to be exported is a detailed process, which occurs according to the following protocols. An establishment applies for export certification and provides information to the branch office indicating what product is to be exported and the specific details of the product including lot codes, number of packages, product name, shipping mark, name of customer, farm supplier information, and date of production. The NAFIQAD branch will then send a NAFIQAD inspector qualified to inspect a consignment for export to the establishment. The FSIS auditors observed the NAFIQAD inspector verify documentation requesting export certification (provided by the establishment) sent to the branch matches the consignment, verify documentation from the processing date of the consignment (NAFIQAD's in plant inspection files) also correspond to the information provided to the branch.

After review of documentation, the NAFIQAD inspector then inspects the overall consignment presented for integrity of boxes and packaging, labeling, quantity/count and to ensure shipping marks match the requesting paperwork. Product is further checked based on random selection of six boxes from which the NAFIQAD inspector samples product for net weight, sensory evaluation including color, smell, condition, foreign material and parasite presence (on-site by the NAFIQAD inspector) after product is thawed. Samples are also taken and sent to be analyzed for *Salmonella* and chemical analysis.

The NAFIQAD currently performs sampling of each individual consignment of product with one unique shipping mark, with the consignment size being no more than one shipping container. The NAFIQAD inspector also verifies and records United States requirements regarding labeling including; name of product, producer of product, handling statement, safe handling instructions (are included on label), as well as identifying information for tracking purposes such as source farm and shipping mark. Prior to completion of the process and issuance of the Inspection Certificate, the NAFIQAD branch will perform a shipping review of all documents as provided by the establishment, as well as inspection reports from the production day, and the reports submitted as a result of the inspection of the consignment. The Inspection Certificate is issued, after which the exporting establishment must perform a pre-shipment review prior to releasing and shipping the product.

The FSIS auditors concluded that Vietnam's inspection system provides for the legal authority with systems designed to ensure that only product which meets FSIS requirements is certified for export. However, the absence of verification by the NAFIQAD that all results of sanitation monitoring performed by the establishment is documented, does not meet FSIS requirements.

## **VI. COMPONENT THREE: GOVERNMENT SANITATION**

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the NAFIQAD requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (sanitation SOPs) to prevent direct product contamination or insanitary conditions.

The NAFIQAD inspectors verify that Siluriformes fish and fish products are produced separately by time and space to ensure there is no comingling of product which is not intended for United

States export. The NAFIQAD inspectors verify this requirement of at least once per production shift is met, with activities recorded on monitoring records which document name of the establishment, date and time of verification, and the NAFIQAD inspector who performed the activity. The FSIS auditors observed that several establishments exclusively produce products for export to the United States, while other establishments only produced products for United States export on specific days to ensure adequate separation of product.

The NAFIQAD requires the development of sanitation SOPs to ensure Siluriformes fish and fish products are received and processed under sanitary conditions, which are maintained by the establishment. Establishment sanitation SOPs as reviewed by the FSIS auditors, include procedures to be followed prior to the start of operations and during operations, identify employees responsible for implementation and maintenance of the programs, and were signed to show the programs were implemented. Establishment pre-operational procedures are written and identify that all equipment and tools used for processing are cleaned and sanitized on a daily basis prior to the start of operations.

A standard operational sanitation practice in Vietnam includes establishments performing routine scheduled mid-shift wash-downs, followed by sanitizer, then a fresh water wash down every two hours during production. This procedure is performed on food contact surfaces in all areas of the establishment including receiving of live fish, cutting, bleeding, filleting, trimming, and grading. Machines and tanks used for bleeding or washing are drained and the same wash down protocol is used with fresh water added prior to the restart of operations. Each establishment documents monitoring of the performance and effectiveness of the wash down on an operational sanitation hygienic wash down form. Establishments are also required to perform operational monitoring of the production process.

During review of establishments' sanitation records, the following was noted:

- One establishment performs ATP testing as a verification of pre-operational sanitation, but the establishment failed to document results of the testing.
- One establishment failed to list all equipment (scales) on their pre-operational monitoring sheet that was listed in their pre-operational sanitation washing procedures.
- At each establishment audited, it was noted that establishments only document results of routine scheduled mid-shift wash-down procedures.

NAFIQAD inspectors perform pre-operational inspection by randomly checking conditions of food contact surfaces, as well as directly observing establishment personnel performing their sanitation procedures and monitoring of their procedures according to the establishment's written sanitation SOPs. If the NAFIQAD inspector observes equipment that does not meet sanitary requirements, they apply a reject tag and inform establishment personnel of the need for corrective actions. The NAFIQAD inspector will then reinspect the area or equipment after establishment actions to ensure the adequacy of their corrections, and then relinquish their regulatory control.

Auditors reviewed establishments written programs for pre-operational and operational, procedures as well as programs designed to address requirements for the facility, equipment and employee's actions to ensure product is not affected in a negative manner. Establishments

audited use well water, which is treated on site prior to usage. Testing of water and ice is performed on a routine basis in excess of four samples per year per facility. Establishment programs address the flow of products as well as the flow of employees into the buildings in accordance with the NAFIQAD requirements that each area have a separate entrance for employees working in that specific area. Chemicals and additives used within the processing area must be identified, labeled, and stored properly to ensure their use is in accordance with their intended and approved usage. Establishments identify employee hygienic procedures, which must be followed, and place restrictions on employees who may be sick, have cuts, sores or open lesions. These policies are reviewed with each employee as part of their training programs prior to working in the food processing environment.

Establishment programs are written to ensure the NAFIQAD requirements are met. These include the lighting intensity and protective covers of lights, controls of wastewater and waste materials to prevent backflow and maintain separate storage areas or compartments where waste is stored prior to movement off site under establishment control, as well as pest control programs to prevent the entrance of vermin or flies into the facility. Footbaths and handwashing procedures are in place for employee entry into the facility, as per the NAFIQAD requirements, with employee training including requirements as such.

FSIS auditors did observe isolated findings regarding failures of sanitation programs as follows:

- In one establishment, blue specks of foreign material were observed in ice in use in the ice glazing area;
- In one establishment, employees in the boxing area were observed reaching into bags of product and directly handling frozen fillets of fish (with gloved hands) after contacting non-food surfaces (boxes);
- At two establishments, product rinsing/washing machinery was observed to be constructed with piping which could not be disassembled to enable full inspection to verify adequacy of sanitation procedures; and
- In one establishment, the hard-plastic diverter paddles on the sides of a scaling conveyor belt were observed to be in deteriorating condition, which would be hard to clean and could pose a threat of contamination of product with small pieces of plastic.

Provincial sub-department of D-FISH carries out inspection and supervision of farms, to ensure veterinary hygiene, environmental safety, and safety of products during farming and harvesting operations. Requirements include farm owner or technical staff tests of pond water, and farm owner reports dead/dying/diseased fish (if a reportable disease condition) to veterinarian or animal health agency with notification to surrounding farms.

Good Aquaculture Practices serve as a guide for sanitary practices employed by farms including regular daily monitoring of fish for health condition (disease checks), periodic growth tracking, daily sampling of water for dissolved oxygen, temperature, and pH. Quality or growth checks are periodically completed for each pond and include documentation for tracking of weight, color, eyes, body, fins, tail, throat observations of live fish as well as dissection to check condition of internal organs and muscle for signs of abnormality or disease conditions. The pond environment is checked daily (dissolved oxygen, pH and temperature) and every three to five days for alkalinity, ammonia (NH<sub>3</sub>), and hydrogen sulfide (H<sub>2</sub>S) and calcium carbonate (CaCO<sub>3</sub>)



to ensure acceptable values with samples taken from all corners of the pond, and then composited for analysis.

Prior to harvest, ponds are sampled for antibiotics and pesticides to ensure safety of the fish and meet purchasing requirements of establishments. Farms require workers to be healthy, equipment is constructed to ensure cleaning and that it will not cause harm or damage to fish. Equipment including nets, transport devices, and tanks are cleaned and sanitized. Fish often have feed withheld two days prior to harvest to aid in the processing step at the establishments. Boat holding tanks have water and oxygenation devices in the tanks to ensure fish arrive at facilities in good health condition.

Farm owners are permitted to harvest or treat diseased fish in accordance with regulations but may not move fish from one pond to another. Records of treatment must be maintained to ensure adequate withdrawal period and traceability are achieved. All ponds are subjected to clean out protocols between harvest and restocking of fish including: drainage of water, dredging and removal of mud, and application of calcium carbonate followed by refilling and treatment of water with chlorine or another approved chemical to eliminate incidental trash fish from source water. Domestic sewage may not be discharged into a pond, additionally, the water supply and drainage system must be kept separate (separate location for waste/sludge treatment).

The analysis and onsite verification activities of the FSIS auditors indicate that the Siluriformes fish inspection system of Vietnam requires that all certified establishments develop, implement, and maintain sanitation programs to prevent the creation of insanitary conditions and direct product adulteration. The government inspection personnel verify daily monitoring of sanitary conditions included as part of their routine inspection procedures but did not identify the establishments' failure to adequately document operational sanitation results. With the exceptions of the FSIS auditors' observations regarding operational recordkeeping, and of isolated findings regarding the sanitation programs, all other aspects of Vietnam's inspection program met FSIS requirements.

## **VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM**

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

The NAFIQAD requires that establishments conduct a hazard analysis during which they identify hazards that can occur before, during or after the process of receiving raw materials, through the production, packaging, and shipment of fish or fish products of the order Siluriformes. NAFIQAD requires establishments to develop critical control points (CCP) and a HACCP plan for hazards identified as likely to occur, including procedures to ensure implementation, monitoring, verification, and record keeping requirements are met. The NAFIQAD inspectors verify establishment development, implementation, and maintenance of a HACCP system as part of the performance of their inspection plans for each shift of operations.

Establishments develop CCPs for hazards that are identified as likely to occur, with all establishments identifying that residues of chemicals, antibiotics or prohibited substances are hazards that are likely to occur in the absence of any controls. As such, the FSIS auditors noted that each establishment developed a HACCP Plan with CCPs in an effort to prevent the production of any products which could contain a harmful substance.

The NAFIQAD officials informed the FSIS auditors during the audit that as of September 2017, they have requirements to be followed in the event that an establishment's export consignment is found to contain chemicals or residues which do not meet FSIS requirements and results in refusal of a shipment. Upon notification of a POEV, the NAFIQAD will temporarily suspend the facility until a complete investigation, corrective actions, and verification of corrective actions can occur. The establishment is required to conduct an investigation and notify the NAFIQAD of their findings as well as proposed corrective actions in response to the findings. The NAFIQAD will determine acceptability of the investigation and the proposed corrective actions, after which follow-up investigation by the NAFIQAD occurs in order to verify the establishments' completion of the corrective actions and to determine if the actions were effective.

FSIS auditors reviewed establishment HACCP system records including the Hazard Analysis, HACCP Plans, corrective actions (if applicable), and supporting documentation. The following isolated observation was noted at one establishment:

- One establishment's hazard analysis did not identify all potential hazards associated with each step of their process, specifically the establishment identified no potential hazards existed regarding biological hazards associated with the transport/shipping step despite pathogen growth existing as a potential hazard in cold storage. This finding was discussed at the establishment and it was apparent that the firm had controls in place including pre-requisite programs designed to ensure the acceptability of shipping containers and that the containers would be maintained at a suitable temperature.

The analysis and onsite verification activities of the FSIS auditors indicate that the Siluriformes fish inspection system of Vietnam requires that all certified establishments develop, implement, and maintain a HACCP system in order to prevent the production of adulterated or misbranded product.

## **VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS**

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of fish for chemical residues identified by the exporting inspection authorities or by FSIS as potential contaminants.

The NAFIQAD is the responsible group for testing of live fish for the National Residue Monitoring Program, with the NAFIQAD inspectors sent to fish farms to obtain live specimens for analysis. The NAFIQAD performs analysis of the fish that were collected live from the

farms, and then posts a monthly report of residue violations to their internet website. As reviewed by the FSIS auditors during the audit, the NAFIQAD also currently tests each shipment of product and requires acceptable results prior to issuance of an Inspection Certificate (certifying product for export) according to their program. Prior to the onsite visit, FSIS' residue experts reviewed the Vietnam's Residue Program for the year 2017, associated methods of analysis, and additional SRT responses outlining the structure of Vietnam's chemical residue testing program.

The core objective of Vietnam's Residue Monitoring Program (RMP) is to ensure the food safety of fishery products at all stages of production from the pond to the finished packaged products. The program is based on prevention and monitoring so that fishery products are free of chemical residues. Controls are applied at the aquaculture stage during fish raising to eliminate the possibility of loss of product due to recall or positive test results for chemical residues by domestic regulators or by the importing country.

The NAFIQAD designs and implements RMP to monitor and prevent chemical residues in aquaculture fish and fishery products as stipulated in *Circular No. 31/2015/TT-BNNPTNT of October 6, 2015*. The sampling plan is based on production volume for each species, periodic monitoring results, and violative shipments exported to the importing countries. The NAFIQAD bases the list of banned chemicals and list of approved veterinary drugs in accordance with Maximum Residues Level (MRL) of importing country's requirement.

In verifying the requirements of government chemical residue testing programs, the auditors reviewed documents and interviewed officials of the NAFIQAD who are directly responsible for planning and implementing stages of RMP. Other entities in the MARD, which collaborate with the NAFIQAD in achieving the intent of the RMP, include the D-FISH, the DAH, the Department of Agricultural and Rural Development (DARD) and their respective sub-departments in provinces and cities having jurisdiction on fish aquafarms. These directorates play crucial roles in their respective authority when a live fishery farm, hatchery or fish feed enterprise failed testing under the RMP. For example, if a chemical testing violation is reported under the RMP or by the importing country, the NAFIQAD notifies the D-FISH who then notifies the violative farm in writing with a record of non-compliance documented and the requirement of a full investigation to identify the cause with official intensified residue sample follow up collections on the farm by the D-FISH. The NAFIQAD verifies the necessary traceback of any affected products used for production and requires all establishments to recall the violative product associated with the test result if product was shipped.

The planning and execution of the RMP for the subsequent testing year involve the branches, Regions, and the local competent authorities (sub-departmental entities located in provinces and or cities) of the NAFIQAD. Personnel assigned to offices in provincial or city (local authority) locations are responsible to implement the testing plan, collect samples at the primary production sites, and transport them to the NAFIQAD's branch laboratory. In addition, the NAFIQAD generates and submits monthly reports on the sampling, which includes the basic hygiene status of the source of samples taken at the aquafarms under their supervision. The report would include actions based on the testing result and observed hygienic conditions of the farm, or recommendations for an increase or change to the monthly sampling plan.

Lastly, local authorities are required to conduct investigations into the causes of any unacceptable testing results at the farm and report findings to their respective regional authority. Regions analyze the reports and recommendations from the local authority to adjust the current sampling plan, as well as the subsequent annual RMP. Regions also provide monthly monitoring reports and information on violative cases to the NAFIQAD headquarters, which in turn communicate any noncompliant aquafarms to other directorates (discussed above) for investigation. The auditors reviewed examples of communications and reports between the involved entities during the onsite audit to a Siluriformes fish grow out farm. No concerns were identified as a result of the laboratory audit.

The FSIS auditors confirmed that the NAFIQAD has a system to define a production lot as the amount of raw product with common source drawn from one or multiple batches processed on the same production line and under the same production conditions within 24 hours at a processing establishment. The NAFIQAD ensures that establishments processing Siluriformes fish for export to the United States maintain lot identification in terms of chemical independence. Provisions in the *Circular No. 03/2011/TT-BNNPTNT of January 21, 2011* require establishments processing Siluriformes fish and fish products to develop and implement an effective traceability and recall program as part of their food safety program. The FSIS auditors verified traceability of products produced and recall programs were in place at audited establishments. The NAFIQAD inspectors routinely verify that these programs are current, effective, and maintained as required.

The NAFIQAD indicated they are currently testing each consignment of Siluriformes fish and fish products based on the unique shipping mark applied to products. This may result in a frequency of testing that is more than one sample taken per production day or production lot, as an establishment lot is defined as product produced on one production day from one farm's pond, while each shipment of product for export can be no more product than what one shipping container can hold with only one unique shipping mark on that product. Samples are analyzed for Malachite green, Crystal violet and their metabolites (Leucomalachite green and Leucocrystal violet), antibiotics (Enrofloxacin and Ciprofloxacin), and Nitrofurazone. All such shipments of product are put on hold until negative results are returned which is required prior to issuance of the inspection certificate certifying the product for export.

The auditors also reviewed the chemical residue testing plan that establishments have put in place in accordance with their HACCP verification plan. The auditors noted that processing establishments identify chemical hazards at the raw product receiving stage and control the hazard through a CCP. Monitoring and verification of raw product involves testing of raw product for dyes, heavy metal, and antibiotic or other prohibited chemicals. Samples collected by establishments can be analyzed by either in-house laboratories or sent to a third party laboratory. All establishments analytical test results are available for the NAFIQAD inspectors for their review; however, if any positive tests occur, the NAFIQAD must be notified immediately. The auditors verified monitoring and verification records related to the CCPs and concluded that establishments follow requirements of their HACCP system as intended.

During the audit of the South Regional Authority, the FSIS auditors verified the 2018 RMP targeted 73 fish raising farms covering 18 provinces in the region and sampled nine different aquaculture species including *Pangasius hypophthalmus* of the family *Pangasiidae*. The scope of the chemicals tested are: selected compounds from groups (A1,3, 6 and B1, 2a, 3a, 3c and 3e) of chemicals listed in Annex 1 of *Council Directive 96/22/EC*. The audit of NAFIQAD's branch 6 and the South Regional Authority indicates that Vietnam's RMP was on target for the current year.

The verification of this component also included a site audit of the chemical laboratory located at Branch 6 in Can Tho City. The FSIS auditors confirmed that the audited laboratory and other branch laboratories within NAFIQAD are government owned, operated and are under direct supervision of the branch directorate. The branch directors are accountable to the director general of the NAFIQAD and provide the former with administrative and technical support in the delivery of Siluriformes fish inspection. The directorate verifies that analytical methods used by the laboratories are validated and remain in compliance with international standards. The FSIS auditors reviewed the most recent audit report for accreditation conducted by the national ISO/IEC 17025:2005 accreditation body in Vietnam known as "Chung Chi Cong Nhan." The accreditation certificate verified on file is valid through June 2018.

During the laboratory audit, the FSIS auditors reviewed the Laboratory's Quality Manual and the Standard Operating Procedures for equipment calibration and validation of test methods. Additionally, the auditors requested records pertaining to staff qualifications, credentials and training, internal audits, noncompliance, and corrective actions. The FSIS auditors reviewed proficiency testing programs for the audited laboratory and no concerns were noted.

The analysis and onsite verification activities of the FSIS auditors indicates that Vietnam developed and implemented a chemical residue testing program that is organized and administered by Vietnam's national government. The FSIS auditors verified that the NAFIQAD takes steps to ensure complete corrective actions are implemented by establishments with measures to prevent recurrence in each instance of a POEV.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that prepared for export to the United States are safe and wholesome.

Vietnam currently has presented 13 establishments certified as eligible to export Siluriformes fish and fish products to the United States. These establishments do not produce any low-acid canned or ready to eat Siluriformes fish products for export to the United States; therefore, government microbiological verification testing for *Listeria monocytogenes* and *Salmonella* is not required. FSIS does not have any regulatory requirements for microbiological sampling of raw intact Siluriformes fish and fish products. As a result, FSIS concluded that the NAFIQAD has developed and implemented a microbiological testing program that meets FSIS criteria for this component.

## **X. CONCLUSIONS AND NEXT STEPS**

An exit meeting was held on May 25, 2018, in Hanoi, Vietnam with the NAFIQAD. At this meeting, the preliminary findings from the audit were presented by the FSIS auditors. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

### **Government Statutory Authority and Food Safety and Other Consumer Protection Regulations**

- In all establishments audited, the government inspectors did not identify the establishments' failure to routinely document results of operational sanitation monitoring.

### **Government Sanitation**

- In one establishment, results of Adenosine-Tri-phosphate (ATP) testing conducted as a verification of pre-operational sanitation were not recorded on sanitation SOP documents.
- One establishment failed to list scales coming directly in contact with product on their pre-operational monitoring sheet and records results.
- At all eight establishments audited, results of operational sanitation monitoring were not fully documented.
- In one establishment, small blue specks of foreign material were observed in ice being used in the ice glazing area.
- In one establishment, employees in boxing area were observed reaching into bags of product and directly handling frozen fillets of fish.
- At two establishments, product rinsing/washing machinery was observed to be constructed with piping which could not be disassembled to enable full inspection to verify sanitation.
- In one establishment, the scaling conveyor paddles constructed of hard plastic were observed to be in deteriorating condition.

### **Government Hazard Analysis and Critical Control Points (HACCP) System**

- In one establishment the hazard analysis did not identify all potential hazards associated with each step of the process.

During the audit exit meeting, the NAFIQAD committed to address the preliminary findings as presented. The NAFIQAD also provided a brief overview regarding notification to establishments of findings observed by FSIS, and the actions the establishments had already implemented, or changes made to written programs. FSIS will evaluate the adequacy of the NAFIQAD's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

# APPENDICES

## **Appendix A: Individual Foreign Establishment Audit Checklists**



United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION  Fish growing Farm; supplier of D115, DL810 Can Tho City Vietnam	2. AUDIT DATE May 15, 2018	3. ESTABLISHMENT NO. . 92-01-0183	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF  OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT  <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	O	33. Scheduled Sample	
8. Records documenting implementation.	O	34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.	O	35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	O	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	O	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	O	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .	O	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	O	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.	O	44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	O	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	O	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	O	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	O	<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling	O	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

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**60. Observation of the Establishment**

There were no findings after consideration of the nature, extent, and degree of all observations.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

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**62. DATE OF ESTABLISHMENT AUDIT**

Enter Date Here

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION  Fish growing Farm; supplier of DL511 Tien Giang Province Vietnam	2. AUDIT DATE May 21, 2018	3. ESTABLISHMENT NO. . No. 82-01-0028	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF  OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT  <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	O	33. Scheduled Sample	
8. Records documenting implementation.	O	34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.	O	35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	O	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	O	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	O	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .	O	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	O	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.	O	44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	O	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	O	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	O	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	O	<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling	O	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

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**60. Observation of the Establishment**

There were no findings after consideration of the nature, extent, and degree of all observations.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

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**62. DATE OF ESTABLISHMENT AUDIT**

Enter Date Here

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION NTSF Seafoods Joint Stock Company Lot 1,2,3,4,5, Thot Not Industrial Zone Thoi Thuan Ward, Thot Not District, Can Tho City	2. AUDIT DATE May 17, 2018	3. ESTABLISHMENT NO. DL 461	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	O
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

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**60. Observation of the Establishment**

13,51;

Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs. NAFIQAD inspectors failed to identify establishment not recording results of operational sanitation SOP monitoring which occurs between scheduled washdowns.

45;

During observation of establishment operations, a product washing machine was observed to be constructed with piping which could not be disassembled to enable inspection for verification of the cleaning process.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

**62. DATE OF ESTABLISHMENT AUDIT**Enter Date Here

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Van Duc Tien Giang Food Export Company Dong Hoa Hamlet, Song Thuan Village Chau Thanh District, Tien Giang	2. AUDIT DATE May 21, 2018	3. ESTABLISHMENT NO. DL 511	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	O
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

13, 51;

Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs. NAFIQAD inspectors failed to identify establishment not recording results of operational sanitation SOP monitoring which occurs between scheduled washdowns.

15, 51;

Establishment does not identify potential biological hazard of pathogen growth associated with the step of shipping product.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

05/21/2018



United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Vinh Hoan Corporation 1645 National Road 30, Ward 11 Cao Lanh City, Dong Thap	2. AUDIT DATE May 18, 2018	3. ESTABLISHMENT NO. DL 147	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	O
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

13,51;

Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs. NAFIQAD inspectors failed to identify establishment not recording results of operational sanitation SOP monitoring which occurs between scheduled washdowns.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

Enter Date Here

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Workshop 3, Vinh Hoan Corporation 1643 National Road 30, Ward 11 Cao Lanh City, Dong Thap	2. AUDIT DATE May 18, 2018	3. ESTABLISHMENT NO. DL 500	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	O
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

13,51;

Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs. NAFIQAD inspectors failed to identify establishment not recording results of operational sanitation SOP monitoring which occurs between scheduled washdowns.

45, 46, 51;

In scaling conveyor area, auditors observed surfaces with deteriorating plastic which is hard to clean and poses a threat of contamination of product with foreign material.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

05/18/2018

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Europe Joint Stock Company Block 69, My Tho Industrial Zone, Bin Thao Hamlet, Trung An Commune, My Tho City, Tien Giang	2. AUDIT DATE May 21, 2018	3. ESTABLISHMENT NO. DL 518	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	O
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

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**60. Observation of the Establishment**

13,51;

Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs. NAFIQAD inspectors failed to identify establishment not recording results of operational sanitation SOP monitoring which occurs between scheduled washdowns.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

**62. DATE OF ESTABLISHMENT AUDIT**Enter Date Here

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Bien Dong Seafood Co., Ltd. Lot II, 18B1-18B2, Tra Noc 2 Industrial Zone Phuoc Thoi Ward, O Mon District, Can Tho City	2. AUDIT DATE May 17, 2018	3. ESTABLISHMENT NO. DL 15	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	O
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

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**60. Observation of the Establishment**

13,51;

Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs. NAFIQAD inspectors failed to identify establishment not recording results of operational sanitation SOP monitoring which occurs between scheduled washdowns.

45;

During observation of NAFIQAD employee performing pre-operational inspection, a fillet washing machine was observed to be constructed with piping which could not be disassembled to enable inspection for verification of the cleaning process.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

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**62. DATE OF ESTABLISHMENT AUDIT**May 17, 2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Mekong Delta Food Factory - CASEAMEX	2. AUDIT DATE 05/16/2018	3. ESTABLISHMENT NO. DL 369	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

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**60. Observation of the Establishment**

13,51;

Establishment does not record results of ATP testing which is included as a SSOP procedure to verify sanitation. Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs. NAFIQAD inspectors failed to identify establishment not recording results of operational sanitation SOP monitoring which occurs between scheduled washdowns.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

**62. DATE OF ESTABLISHMENT AUDIT**05/16/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Bien Dong Hau Giang Seafood Joint Stock Company (Bien Dong Seafood Co., Ltd.)	2. AUDIT DATE 05/15/2018	3. ESTABLISHMENT NO. DL 810	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

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**60. Observation of the Establishment**

13, 51;

Establishment SSOP record does not include results of sanitation inspection of scales used for weighing/sorting. Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs. NAFIQAD inspectors failed to identify establishment not recording results of operational sanitation SOP monitoring which occurs between scheduled washdowns.

46;

In ice glazing area, auditors observed blue foreign material in ice being used to chill glaze water. In boxing area, auditors observed boxing employees reach into product bags and handle product; establishment personnel indicated employees are not to directly handle product.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

**62. DATE OF ESTABLISHMENT AUDIT**05/15/2018

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**Appendix B: Foreign Country Response to the Draft Final Audit Report**



NAFIQAD

**MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT OF VIETNAM**  
**National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD)**

*Add.: 10 Nguyen Cong Hoan, Ba Dinh, Hanoi, Vietnam*  
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Ref. No. 1632 /QLCL-CL1

*Hanoi, 10 August 2018*

Ms. Janell Kause,  
Acting International Coordination Executive  
Office of International Coordination  
Food Safety Inspection Services (FSIS)

Dear Ms. Janell Kause,

In response to your official letter of Jun 29, 2018 enclosed with the draft final audit report of Vietnam's inspection system governing Siluriforms fish and fish products, I would like to communicate with you as follows:

NAFIQAD highly appreciates the professionalism of the audit team: inspite of the short audit mission in Vietnam, the auditors has made a comprehensive assessment of Vietnam's food safety control system for Siluriforms fish and fish products. NAFIQAD basically agrees with the findings mentioned in the report. However, NAFIQAD also would like to put forward some comments so that FSIS could consider for the final report:

1. Audit scope:

According to the working plan by mutual consent as well as in practice, FSIS auditors visited Vietnamese competent authorities, 02 farms and 08 processing plants. However, the draft report included 02 cold storage facilities which are not independent facilities but belong to DL 500 and DL 511, 02 among 08 processing establishments audited. Actually, all cold storage facilities of 08 processors were visited without any findings observed by FSIS. Therefore, FSIS is kindly requested to remove 02 cold storage facilities from the draft report.

2. Observation on government oversight and inspection:

NAFIQAD would like to provide comments to FSIS observation on Vietnamese government oversight and inspection (Annex 1) so that FSIS could consider amendments to the draft.

3. Findings:

- 3.1. *“NAFIQAD inspectors did not identify the failure to routinely document results of operational sanitation monitoring in all establishments” and “at all establishments audited, results of operational sanitation monitoring were not fully documented”:*



Processing establishments' reports and NAFIQAD's monitoring showed that operational sanitation monitoring in processing plants was performed and fully documented in accordance with the establishments' sanitation SOPs (once every one or two hours depending on production stage and establishment sanitation procedure). This is in line with the US requirements at 9 CFR 416.13 (c). An example of DL 15's sanitation SOPs and monitoring records (enclosed), it is laid down in "2. Implementing, monitoring and keeping record" of the sanitation SOPs that QC must access sanitation at least every two hours and document the monitoring on daily sanitation monitoring form; QC performed and documented sanitation monitoring at prescribed frequency. During every shift inspection, NAFIQAD inspectors also verified operational sanitation and establishment's monitoring of their sanitation implementation. These findings were raised in the exit meeting on 25 May 2018 and it was agreed that there was a misunderstanding due to interpretation during document check and interview at the establishments.

Therefore, FSIS is kindly requested to take account of the above clarification and enclosed documents to exclude these findings from the draft.

### 3.2. Findings noted at DL147 and DL461:

During the audits to DL 147 and DL 461, no observations were noted; the auditors even highly appreciated their food hygiene and safety conditions. However, it was noted in the audit checklists that their SSOP records did "not include results of sanitation inspection of scales used for weighing/sorting" (food contact surface) on their pre-operational monitoring sheet. Actually, this observation was noted at DL810 and not at any others.


Therefore, FSIS is kindly requested to exclude this findings from the audit checklists to DL147 and DL461.

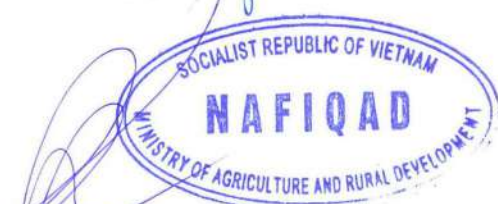
### 3.3. Other findings:

Enclosed is the report on corrective actions taken by audited processing establishments (Annex 2).

At the time of audit, NAFIQAD inspectors also observed noncompliance and required involved establishments to take appropriate corrective actions, including suspending operation, separating final products, semi-products for follow-up actions. These activities should be noted in the final report.

Thank you and please accept the assurances of my highest consideration.

Sincerely yours, 



Nguyen Nhu Tiep

Director General of NAFIQAD

## ANNEX 1

## NAFIQAD RESPONSE TO FSIS OBSERVATION ON VIETNAMESE GOVERNMENT OVERSIGHT AND INSPECTION

No.	Page	Draft report	Comments/Proposed amendments	Justification
1.	Page 4, lines 6↓ and 10↓	... located in <u>Kha Hoa</u> province... ... located in Hai Phong, Da Nang, <u>Kha Hoa</u> ,...	... located in <u>Khanh Hoa</u> province... ... located in Hai Phong, Da Nang, <u>Khanh Hoa</u> ,...	Correct name of province
2.	Page 4, lines 13 - 15↓	The NAFIQAD branch locations are also responsible for issuance of an inspection certificate certifying each consignment of product for export, <u>and samples live fish prior to harvest from growing ponds and harvest sites</u>	The NAFIQAD branch locations are also responsible for issuance of an inspection certificate certifying each consignment of product for export.	The NAFIQAD branches do not take samples of live fish prior to harvest at growing ponds. In fact, - Under the national residues monitoring program: Provincial NAFIQAD take samples of live fish prior to harvest for analysis at NAFIQAD laboratories. - Under the HACCP Plan: the establishments take samples for analysis at NAFIQAD laboratories or others.
3.	Page 4, lines 7- 12↑	The <u>NAFIQAD</u> has a Siluriformes fish working group,...Departments within the working group <u>will then disseminate information through Regional,branch or sub offices to government personnel, certified establishments, hatcheries, farms and feed manufacturers viapostal letters</u> ,...	The <u>MARD</u> has a Siluriformes fish working group,... Departments within the working group <u>ensure food safety and disease prevention of Siluriformes fish and fish product in certified establishments including hatcheries, farms, feed manufacturers and processing plants through Regional branch or sub offices then disseminate information</u> via postal letters,...	The working group was founded by MARD.



No.	Page	Draft report	Comments/Proposed amendments	Justification
4.	Page 5, lines 18- 20↑	The D-FISH is the government authority required to perform on-farm inspections and they <u>certify</u> <u>decertify</u> farms for production. The D-FISH also has oversight of the manufacture, distribution, and usage of feeds	The D-FISH is the government authority required to perform on-farm inspections ( <u>including proper usage of veterinary drugs</u> ) and they <u>certify or decertify</u> farms for production. The D-FISH also has oversight of the manufacture, distribution, and usage of feeds, <u>fingerlings and aquaculture environmental treatment products</u> .	On-farm inspections include oversight of usage of veterinary drugs. The D-FISH has oversight of not only the manufacture, distribution, and usage of feeds, but also fingerlings and aquaculture environmental treatment products.
5.	Page 6, lines 11 - 22↓	The DAH is responsible for the production, distribution, and <u>proper usage of veterinary drugs</u> , ... <u>inform the DAH</u> .... To monitor and ensure disease free status, <u>the DAH</u> makes .... On average, <u>the DAH</u> visits .... <u>The DAH</u> is responsible for .... <u>The DAH</u> monitors .... <u>The DAH</u> requires that .... across regions. The DAH sends out ....	The DAH is responsible for the production <u>and</u> distribution of veterinary drugs, ... <u>inform the local competent authority (Provincial Sub-department of Animal Health)</u> .... To monitor and ensure disease free status, <u>the provincial DAH</u> makes .... On average, <u>the provincial DAH</u> visits .... <u>The provincial DAH</u> is responsible for .... <u>The provincial DAH</u> monitors .... <u>The aquatic animal health regulation in Vietnam</u> requires that ... across regions. <u>Information of veterinary drug management, disease surveillance are reported to Regional office, then to the DAH.</u> The DAH sends out ....	<ul style="list-style-type: none"> <li>- As mentioned at No. 4, D-FISH is responsible for proper usage of veterinary drugs at farms.</li> <li>- DAH does not directly monitor disease free status. This task is undertaken by Provincial DAH.</li> </ul>
6.	Page 7, line 2↑	The NAFIQAD specifically requires that <u>all</u> establishments involved with production of	The NAFIQAD specifically requires that <u>all slaughtering and processing establishments must be certified as</u>	NAFIQAD only requires slaughtering and processing establishments to be certified as eligible to produce for export

No.	Page	Draft report	Comments/Proposed amendments	Justification
		product ( <u>hatchery, farming, slaughter, processing</u> ) must be certified as eligible to produce for export to the United States.	eligible to produce for export to the United States; <u>other establishments (hatchery, farming) must be certified for food safety in compliance with national technical regulations.</u>	to the US.
7.	Page 9, line 15↓	... testing results <u>of the NAFIQAD live fish testing</u> (prior to harvest)	... testing results <u>of live fish</u> (prior to harvest)	As mentioned in No. 2, testing of live fish (prior to harvest) may be performed by NAFIQAD laboratories or others.



## ANNEX 2

## RESPONSE / CORRECTIVE ACTIONS TAKEN BY THE ESTABLISHMENTS

No.	Processors	Findings	Causes identified	Applied corrective actions	Finish day	Enclosed documents
1.	Bien Dong Hau Giang Seafood Joint Stock Company (DL810)	In ice glazing area, auditors observed blue foreign material in ice being used to chill glaze water	At the end of the previous production day (May 14, 2018), the maintenance employee cut and ground four water pipe ends used for the glazing step. He did not clean the insides of the water pipes. On the morning of May 15, 2018, because of not being informed about the maintenance, QC did not pay attention to the insides of cut water pipes, as result, ice water was contaminated with the plastic foreign materials.	<ul style="list-style-type: none"> <li>- The establishment temporarily suspended production and replaced contaminated ice water by clean ice water.</li> <li>- The establishment separated all contaminated products (77ctns) manufactured from the beginning of production date until non-compliance found (NAFIQAD fixed non-compliance tag when detecting) and sold them to by-products establishments.</li> <li>- Informing to relevant units about the non-compliance and re-train the maintenance employee on the cleaning procedures. Adopting the regulation that requires post-maintenance endorsement from QC/QA and revising the maintenance monitoring form.</li> </ul>	18 May 2018	<ul style="list-style-type: none"> <li>- Corrective Action Report (CAR) (document 1.1);</li> <li>- Photos of separated products (document 1.2).</li> </ul>
		In boxing area, auditors observed boxing employees reach into product bags and handle	<ul style="list-style-type: none"> <li>- The employee did not respect GMP</li> <li>- Bags had not been closely sealed that</li> </ul>	<ul style="list-style-type: none"> <li>- Separating non-compliant products and selling them to by-products establishments (total is 77 ctns including the contaminated products</li> </ul>	18 May 2018	<ul style="list-style-type: none"> <li>- CAR (document 2.1);</li> <li>- Revised GMP at packing/carton</li> </ul>

No.	Processors	Findings	Causes identified	Applied corrective actions	Finish day	Enclosed documents
		product	resulted the employee could contact directly with products	<p>mentioned in the previous finding); requiring employees not to directly handle products.</p> <ul style="list-style-type: none"> <li>- Regulating that all product bags must be closely sealed prior to being removed to packing/carton packing area.</li> <li>- Training employees at packing/carton packing area about potential contamination when handling directly with products.</li> </ul>		packing step (document 2.2).
		Establishment SSOP record does not include results of sanitation inspection of scales used for weighing/sorting	The cleaning of scales was regulated in SSOP as same as direct product contact surfaces but the listing was not included in the monitoring form.	<ul style="list-style-type: none"> <li>- Revising the monitoring form by adding list of product scales cleaned.</li> <li>- Re-training QC and relevant employees about the revision.</li> </ul>	16 May 2018	<ul style="list-style-type: none"> <li>- CAR (document 3.1);</li> <li>- SSOP record (document 3.2).</li> </ul>
		Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs	<p>The establishment's response:</p> <ul style="list-style-type: none"> <li>- FSIS auditors did not note this observation during the audit to the establishment;</li> <li>- The establishment performed and recorded operational sanitation monitoring every two hours in accordance with its SSOPs;</li> <li>- The observation should be removed from the final report.</li> </ul>			



No.	Processors	Findings	Causes identified	Applied corrective actions	Finish day	Enclosed documents
2.	Mekong Delta Food Factory - CASEAMEX (DL 369)	Establishment does not record results of ATP testing which is included as a SSOP procedure to verify sanitation	When drawing up monitoring form, the establishment only intended to fill the SSOP record if the result of ATP testing was not satisfactory.	<ul style="list-style-type: none"> <li>- Including the results of ATP testing into the monitoring form.</li> <li>- HACCP team decided to include all results of testing if used into monitoring form.</li> </ul>	18 May 2018	<ul style="list-style-type: none"> <li>- CAR (Document 4.1);</li> <li>- SSOP record (document 4.2).</li> </ul>
		Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs	The establishment's response: <ul style="list-style-type: none"> <li>- FSIS auditors did not note this observation during the audit to the establishment;</li> <li>- The establishment performed and recorded operational sanitation monitoring every two hours in accordance with its SSOP;</li> <li>- The observation should be removed from the final report.</li> </ul>			
3.	Bien Dong Seafood Co., Ltd. (DL 15)	A fillet washing machine was observed to be constructed with piping which could not be disassembled to enable inspection for verification of the cleaning process	Pipes were quarterly disassembled for maintenance and inspection for cleanliness. However, it was difficult to clean and inspect pipes with curved corners.	<ul style="list-style-type: none"> <li>- The establishment has repaired piping system with joints which could be easily disassembled to enable inspection for cleanliness.</li> <li>- Publishing guidelines for cleaning piping system daily after production. Taking samples for microbiological test after cleaning.</li> </ul>	23 May 2018	<ul style="list-style-type: none"> <li>- CAR (document 5.1);</li> <li>- Photos taken before and after corrective actions (document 5.2);</li> <li>- Record for cleaning pipes of washing equipment (document 5.3);</li> <li>- Result of microbiological test of pipe's inside</li> </ul>

No.	Processors	Findings	Causes identified	Applied corrective actions	Finish day	Enclosed documents
						surface after cleaning (document 5.4).
		Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs	<p>The establishment's response:</p> <ul style="list-style-type: none"> <li>- The establishment performed and recorded operational sanitation monitoring every two hours in accordance with its SSOPs;</li> <li>- The observation should be removed from the final report.</li> </ul>			
4.	NTSF Seafoods Joint Stock Company - NTSF SEAFOODS (DL461)	Establishment SSOP record does not include results of sanitation inspection of scales used for weighing/sorting	<p>The establishment's response:</p> <ul style="list-style-type: none"> <li>- FSIS auditors did not note this observation during the audit to the establishment;</li> <li>- In fact, the establishment SSOP record include results of sanitation inspection of scales used for weighing/sorting;</li> <li>- The observation should be removed from the final report.</li> </ul>			
		A product washing machine was observed to be constructed with piping which could not be disassembled to enable inspection for verification of the cleaning process	<p>The establishment's response:</p> <ul style="list-style-type: none"> <li>- FSIS auditors did not note this observation during the audit to the establishment;</li> <li>- In fact, the product washing machine is constructed with piping which is disassembled to enable inspection for verification of the cleaning process;</li> <li>- The observation should be removed from the final report.</li> </ul> <p>At the establishment, the auditors even appreciated their food hygiene and safety conditions and confirmed no finding observed.</p>			
5.	Vinh Hoan Corporation (DL 147)	Establishment SSOP record does not include results of	<p>The establishment's response:</p> <ul style="list-style-type: none"> <li>- FSIS auditors did not note this observation during the audit to the establishment;</li> <li>- In fact, the establishment SSOP record include results of sanitation inspection of scales used for</li> </ul>			



No.	Processors	Findings	Causes identified	Applied corrective actions	Finish day	Enclosed documents
		<p>sanitation inspection of scales used for weighing/sorting</p> <p>Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs</p>	<p>weighing/sorting;</p> <p>- The observation should be removed from the final report.</p> <p>The establishment's response:</p> <p>- FSIS auditors did not note this observation during the audit to the establishment;</p> <p>- The establishment performed and recorded operational sanitation monitoring every one or two hours (depending on processing stage) in accordance with its SSOP;</p> <p>- The observation should be removed from the final report.</p>			
6.	Workshop 3 – Vinh Hoan Corp. (DL 500)	In scaling conveyor area, auditors observed surfaces with deteriorating plastic which is hard to clean and poses a threat of contamination of product with foreign material	<p>- The scaling conveyor had been strongly scrubbed and washed by hard plastic brush.</p> <p>- The scaling conveyor was not maintained timely.</p>	<p>- The establishment stopped running the scaling conveyor (NAFIQAD stuck non-conformity tag right on detection).</p> <p>- Requiring to use net mesh fabric to scrub and wash scaling conveyor. Increasing the regular maintenance frequency from once a month to once a week.</p> <p>- Replacing white separating bar by blue bar for easier detection of plastic contamination to product.</p>	22 May 2018	<p>- CAR (document 6.1);</p> <p>- Photos taken before and after corrective actions (document 6.2).</p>
7.	Van Duc Tien Giang Food Export Company (DL 511)	Establishment does not identify potential biological hazard of pathogen growth	The establishment did not identify the hazard in the HACCP Plan because the product	- The establishment revised the HACCP Plan, including the hazard of pathogen growth at shipping step.	22 May 2018	<p>- CAR (document 7.1);</p> <p>- Revised HACCP Plan (document 7.2);</p>

No.	Processors	Findings	Causes identified	Applied corrective actions	Finish day	Enclosed documents
		associated with the step of shipping product	had been frozen ≤ -18°C and transported outside the factory.	<ul style="list-style-type: none"> <li>- Revising GMP at shipping step.</li> <li>- Refreshing training for QC and loading staff.</li> </ul>		- Revised GMP (document 7.3).
		Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs	<p>The establishment's response:</p> <ul style="list-style-type: none"> <li>- The establishment performed and recorded operational sanitation monitoring every two hours in accordance with its SSOP;</li> <li>- The observation should be removed from the final report.</li> </ul>			
8.	Europe Joint Stock Company (DL 518)	Establishment employees do not record results of operational sanitation SOP monitoring, which occurs during production periods between scheduled wash downs	<p>The establishment's response:</p> <ul style="list-style-type: none"> <li>- The establishment performed and recorded operational sanitation monitoring every two hours in accordance with its SSOP;</li> <li>- The observation should be removed from the final report.</li> </ul>			