



## **Foreign Supplier Verification Plan** **Standard Operating Procedure**

### **1. IMPORTER INFORMATION**

<b>Importer Name:</b> BUFALINDA USA LLC	
<b>Importer Address:</b> 20200 W. Dixie Highway Suite 604 Aventura, FL 33180	
<b>E-mail Address:</b> Debbie@bufalinda.com	
<b>Phone Number:</b> 1-786-505-9513	<b>Fax Number:</b> N/A
<b>Unique Facility Identifier (e.g., DUNS number):</b> 08-078-9661	

- **Purpose** - This SOP specifies the activities necessary to meet the FSVP requirements as required in 21 CFR Part 1 (Subpart L – Foreign Supplier Verification Programs for Food Importers) including programs to ensure that the imported food is:
  - Produced in a manner that provides the same level of public health protection as required under section 418 or 419 of the FD&C Act, as appropriate
  - Is not adulterated under section 402 of the FD&C Act
  - Is not misbranded under section 403(w) of the FD&C Act
- **Scope** - This SOP applies to all food imported or offered for import into the United States with the following exemptions:
  - Juice and seafood products subject to and in compliance with FDA's Hazard Analysis and Critical Control Point (HACCP) regulation
  - Food for research and evaluation
  - Food for personal consumption
  - Alcoholic beverages
  - Food that is imported for processing and future export
  - Certain meat, poultry and egg products regulated by the United States Department of Agriculture at the time of importation
- **Definitions** – The following definitions are applicable to this SOP
  - Facility – A domestic facility or foreign facility that is required to register under section 415 of the FD&C Act
  - Foreign Supplier – The establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further

**Reviewed by:** Mildred Perez de Zerpa  
(Qualified Individual)

**Date:** April 20, 2018

**Approved by:**

**Date:** April 23, 2018

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manufacturing/processing that consists solely of the addition of labeling or any similar activity of a minimal nature.

- Hazard – Any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury.
- Importer – The U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer.
- Known or Reasonably Foreseeable Hazard – A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.
- Qualified auditor - A person who is a qualified individual as defined in this section and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by 1.506(e)(1)(i) or 1.511(c)(5)(i)(A) of the FSVP regulation. Examples of potential qualified auditors include:
  - A government employee, including a foreign government employee; and
  - An audit agent of a certification body that is accredited in accordance with subpart M of this part.
- Qualified individual – A person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under the FSVP regulation, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual.
- U.S. owner or consignee - The person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.
- **Responsibilities-** It is the responsibility of Bufalinda USA LLC personnel to understand and comply with this SOP. Importers are required to develop, maintain and follow an FSVP for each food brought into the United States and the foreign supplier of that food. Importers are responsible for actions that include:
  - Determining known or reasonably foreseeable hazards with each food
  - Evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance
  - Using that evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers and determine appropriate supplier verification activities
  - Conducting supplier verification activities
  - Conducting corrective actions

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- Providing the importer identification number (e.g., DUNS) for each line entry of food that is imported
- **Recordkeeping and FDA Access** – All records related to the FSVP SOP will be kept for a minimum of 2 years after they were created or obtained. Records related to processes and procedures will be kept for a minimum of 2 years after their use is discontinued. Upon request, records will be made available to FDA for inspection and copying. If necessary, an English translation of the records will be provided within a reasonable timeframe.

## Procedure

In compliance with the **FSVP SOP**:

- Importer Identification Number. Bufalinda USA LLC will have a unique facility identifier (e.g., DUNS) that is acceptable to FDA for each line entry of food that is imported.
- Hazard Analysis. Bufalinda USA LLC will make every effort to have the foreign supplier provide a hazard analysis and verification of PCQI status. We will review and assess the hazard analysis conducted by the foreign manufacturer and document our assessment. If the foreign supplier does not provide a hazard analysis, Bufalinda USA LLC will conduct a written hazard analysis to identify and evaluate known or reasonably foreseeable biological, chemical or physical hazards for each type of food imported, to determine if any are hazards requiring a control. This hazard analysis will be recorded on the Hazard Analysis form. This hazard analysis will be part of the foreign supplier approval or denial process. Bufalinda USA LLC will conduct a separate hazard analysis for each food it imports from each foreign supplier.
- Evaluation of the foreign supplier's performance and the risk posed by a food. Bufalinda USA LLC will evaluate the food and foreign supplier performance as the basis for approving foreign suppliers; and determining appropriate foreign supplier verification activities. The following factors will be considered: the hazard analysis of the food, the entity that will control the hazard(s) and the foreign supplier's performance including the following criteria: the foreign supplier's food safety processes and practices; applicable food safety regulations and the foreign supplier's compliance history (including any FDA Warning Letters and Import Alerts); the foreign supplier's food safety history (e.g., results of testing, audit results, responsiveness in correcting problems); and other appropriate factors (e.g., storage and transportation practices). We will monitor our foreign suppliers for FDA compliance on an on-going basis by utilizing FDA supplier evaluation resources available at the following link: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm> Results will be recorded on the foreign supplier evaluation form. This assessment will be part of the foreign supplier approval or denial process.

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*[Signature]*





- Re-evaluation. Bufalinda USA LLC will conduct a re-evaluation if it becomes aware of new information regarding the performance factors, and at least every 3 years. If concerns about safety of imported food are revealed, we will promptly determine whether it is appropriate to continue importing food from that foreign supplier and whether foreign supplier verification activities need to be changed.
- Foreign Supplier Approval. Bufalinda USA LLC will ensure that they import foods only from approved suppliers. These procedures will address approval of suppliers, approval or rejection of particular shipments of foods, and documentation of receipt from approved suppliers.
- Foreign Supplier Verification. Bufalinda USA LLC will ensure appropriate verification activities are conducted to ensure that the hazards requiring a control identified in the hazard analysis are significantly minimized or prevented. These verification activities (and their frequency) will be based on the evaluation of the food and foreign supplier.
  - Appropriate verification activities include:
    - Onsite audit within the first year of importing;
    - Sampling and testing of food;
    - Review of foreign supplier's food safety records; and/or
    - Other appropriate verification activities
  - If there is a reasonable probability the hazard in the imported food would cause serious adverse health consequences or death to humans or animals (SAHCODHA), annual onsite auditing will be conducted unless Bufalinda USA LLC determines (and documents) that other verification activities or less frequent audits are adequate to control the hazard. The onsite audit will be conducted by a qualified auditor.
- Corrective Actions. Bufalinda USA LLC will take prompt corrective actions if it determines that a foreign supplier does not produce food in compliance with applicable processes and procedures that provide same level of protection as FDA requirements. If Bufalinda USA LLC determines by means other than verification activities or re-evaluation of food and foreign supplier (e.g., consumer, customer, or other complaints related to food safety), that a foreign supplier does not produce food in compliance with applicable processes and procedures that provide the same level of protection as FDA requirements, we will conduct an investigation to determine whether the FSVP needs to be modified. Such corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed.
- Importer Identification. Bufalinda USA LLC will ensure that, for each line entry, the following information is provided to U.S. Customs and Border Protection:

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Date: April 23, 2018

*Mildred Perez-Jacobs*  
*[Signature]*





- Importer's name;
  - Importer's email address; and
  - A unique facility identifier acceptable to FDA
- Record Review. Bufalinda USA LLC will ensure that a qualified individual signs and date records concerning the FSVP upon initial completion and upon any modification of the FSVP.

**Mildred de Zerpa**

RIF: V-05145639-0

mildredzerpa@gmail.com

Celular: 0416 - 303.09.02

Coindustria N° del Consultor: 686

Sercamer N° de Consultor Registro Nacional: 3802

de Registro Consultor INPSASEL N° MIR075145639

Auditor Lider IRCA en ISO 9001 (CALIDAD) N° LA2/11/VE/38805

Auditor Lider IRCA en OHSAS 18001 (SEGURIDAD Y SALUD LABORAL) N° OHS/12/VE/8779

Auditor Lider IRCA en ISO 14001 (AMBIENTE) N° 11/7/17/28-09-12

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**Approved by:**

*Mildred Perez de Zerpa*  
*[Signature]*

**Date: April 20, 2018**

**Date: April 23, 2018**





## Foreign Supplier Verification Program

### 1. IMPORTER INFORMATION

<b>IMPORTER's Name:</b> Bufalinda USA LLC	
<b>IMPORTER's Address:</b> 20200 West Dixie Highway Suite 604 Aventura, FL 33180	
<b>Phone Number:</b> 1-786-505-9513	<b>Fax Number:</b> N/A
<b>Unique Facility Identifier:</b> 08-078-9661	
<b>Qualified Individual:</b> Mildred Perez de Zerpa	
<b>Company Overview:</b> Bufalinda USA LLC is an international trading company located in Aventura, Florida specialized in importing, exporting, and distributing specialty foods throughout North America and the Caribbean. Initially the company will concentrate on importing all natural buffalo mozzarella products from its affiliate manufacturing company, Hato El Oso, in Venezuela, S.A. The list of products is the following: Mozzarella di Bufala Ciliegine, Mozzarella di Bufala Bocconcini, Mozzarella di Bufala Large Size, and Buffalo Milk Burrata. Bufalinda USA is responsible for buying the product, clearing customs, agriculture, FDA, and selling the product to: brokers, distributors, retailers, and restaurants throughout the nation. Currently, Debbie Shlesinger, is in charge of the operations at Bufalinda USA with a plan to grow the company and its employees. She is currently supported by the shareholders and board of directors of Bufalinda.	
<b>Purpose of the Plan:</b> The Foreign Supplier Verification Program (FSVP) is the primary document that ensures our foreign suppliers meet established food safety standards. This Foreign Supplier Verification Program has been designed to verify that the food we import is produced in compliance with applicable FDA regulatory requirements. The foreign supplier verification program was developed by a qualified individual.	
<b>Scope of the Foreign Supplier Verification Program:</b> This Foreign Supplier Verification Program addresses the importation of the following Mozzarella Cheese products (made with water buffalo milk) from Hato El Oso C.A., Km 32 Carretera Maturin Barrancas, Maturin, Monagas, Venezuela: Mozzarella di Bufala Bocconcini, Mozzarella di Bufala Ciliegine, Mozzarella di Bufala Large Size, Buffalo Milk Burrata. The Foreign Supplier Verification Program includes a hazard analysis to identify and evaluate, 'known or reasonably foreseeable' biological, chemical, and physical hazards for each type of food imported, written procedures to ensure that food is imported from foreign suppliers that have been evaluated and approved and that appropriate supplier verification activities have been conducted. Additionally, the Foreign Supplier Verification Program addresses the need for corrective action and re-evaluation of the FSVP if it is determined that the food is not in compliance with applicable laws and regulations. Lastly, the FSVP addresses the requirement for importer identification at entry.	

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## 2. FOREIGN SUPPLIER AND PRODUCT PROFILE

### SUPPLIER INFORMATION

<b>Foreign Supplier Name:</b>	HATO EL OSO C.A.
<b>Manufacturing Address:</b>	Km 32 Carretera Maturin Barrancas, Maturin, Monagas, Venezuela.
<b>Point of contact (Name, title and contact information):</b>	Alberto Duhau - CEO <a href="mailto:aduhau@bufalinda.com">aduhau@bufalinda.com</a> +58-4249049287
<b>FDA registration number:</b>	17084190186
<b>Facility website:</b>	<a href="http://www.bufalinda.com">www.bufalinda.com</a>
<b>Number of full-time employees:</b>	60
<b>Facility size:</b>	10,000 sqft.
<b>Products Imported:</b>	Mozzarella di Bufala Bocconcini, Mozzarella di Bufala Ciliegine, Mozzarella di Bufala Large Size, Buffalo Milk Burrata
<b>PCQI (Foreign supplier)</b>	Miguel Venales: PCQI certified, certified in HACCP Principles for the Food Service Industry –International HACCP Alliance (IHA) Approved, Good Manufacturing Practices Course ISO 9001:2015 Mod. 1-4 HACCP Mod 1, Food Safety Objectives and Management Course

### PRODUCT DESCRIPTION

<b>Common Product Name:</b>	Mozzarella Cheese (made with water buffalo milk)
<b>Ingredients:</b>	Water buffalo milk, salt, rennet, lactic cultures, citric acid, and water
<b>Detailed Product Description:</b>	Fresh, soft, and elastic mozzarella cheese with a fibrous structure composed of long strands of oriented protein that trap water and fat. It is of a shiny intense white color. The cheese is of high moisture content; it is not ripened and does not contain rennet granules nor eyes. It has a protective rind of up-to 1/8" in thickness that is harder and drier than its soft and juicy interior. It has a shape of football, generally round with two slightly pointed ends. The milk used is

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	100% water buffalo milk. The mozzarella balls and a salt brine and citric acid solution are jointly filled into a hermetic tub (see primary packaging section).																																																																																
Microorganisms used during fermentation:	Lactic acid producing bacteria: -Lactococcus lactis ssp. lactis -Streptococcus thermophilus -Lactobacillus delbrueckii ssp. bulgaricus																																																																																
Key Product Characteristics:	<table><tr><th>Characteristic</th><th>Percentage</th></tr><tr><td>Sodium chloride</td><td>&lt; 3</td></tr><tr><td>Moisture</td><td>&lt; 60</td></tr><tr><td>Protein</td><td>&lt; 25</td></tr><tr><td>Fat</td><td>&lt; 35</td></tr><tr><td>Moisture on a fat-free basis</td><td>&gt; 68</td></tr></table>	Characteristic	Percentage	Sodium chloride	< 3	Moisture	< 60	Protein	< 25	Fat	< 35	Moisture on a fat-free basis	> 68																																																																				
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	<table><tr><th rowspan="2">Characteristic</th><th rowspan="2">n</th><th rowspan="2">c</th><th colspan="2">Limit</th><th rowspan="2">Testing Method</th></tr><tr><th>m</th><th>M</th></tr><tr><td>Coliforms MPN/gl (*) (1)</td><td>5</td><td>2</td><td>150.0</td><td>1,100.0</td><td>COVENIN 1104</td></tr><tr><td>Coliforms cfu/g (*) (2)</td><td>5</td><td>2</td><td>1.5x10<sup>2</sup></td><td>1.1x10<sup>3</sup></td><td>COVENIN 3276</td></tr><tr><td>Fecal coliforms MPN/g (*) (1)</td><td>5</td><td>2</td><td>9.0</td><td>43.0</td><td>COVENIN 1104</td></tr><tr><td>Escherichia coli cfu/g (*) (2)</td><td>5</td><td>0</td><td>&lt;10.0</td><td>-</td><td>COVENIN 3276</td></tr><tr><td>Escherichia coli MPN/g (*) (3)</td><td>5</td><td>2</td><td>4.0</td><td>11.0</td><td>COVENIN 1104</td></tr><tr><td>Escherichia coli cfu/g (*) (3)</td><td>5</td><td>2</td><td>&lt;10.0</td><td>-</td><td>COVENIN 3276</td></tr><tr><td>Staphylococcus aureus cfu/g (**)</td><td>5</td><td>2</td><td>1x10<sup>2</sup></td><td>1x10<sup>3</sup></td><td>COVENIN 1292</td></tr><tr><td>Salmonella in 25g (**)</td><td>5</td><td>0</td><td>0</td><td>-</td><td>COVENIN 1291</td></tr><tr><td>Listeria monocytogenes in 25g (**)</td><td>5</td><td>0</td><td>0</td><td>-</td><td>COVENIN 3718</td></tr><tr><td>Molds cfu/g (*)</td><td>5</td><td>2</td><td>1x10<sup>2</sup></td><td>1x10<sup>3</sup></td><td>COVENIN 1337</td></tr><tr><td>Yeasts cfu/g (*)</td><td>5</td><td>2</td><td>1x10<sup>2</sup></td><td>1x10<sup>3</sup></td><td>COVENIN 1337</td></tr><tr><td colspan="6">n = number of samples by lot c = number of defective samples m = minimum or only limit M = maximum limit * Recommended microbiological requirements (see COVENIN 409) ** Mandatory microbiological requirements (see COVENIN 409)</td></tr></table>	Characteristic	n	c	Limit		Testing Method	m	M	Coliforms MPN/gl (*) (1)	5	2	150.0	1,100.0	COVENIN 1104	Coliforms cfu/g (*) (2)	5	2	1.5x10 <sup>2</sup>	1.1x10 <sup>3</sup>	COVENIN 3276	Fecal coliforms MPN/g (*) (1)	5	2	9.0	43.0	COVENIN 1104	Escherichia coli cfu/g (*) (2)	5	0	<10.0	-	COVENIN 3276	Escherichia coli MPN/g (*) (3)	5	2	4.0	11.0	COVENIN 1104	Escherichia coli cfu/g (*) (3)	5	2	<10.0	-	COVENIN 3276	Staphylococcus aureus cfu/g (**)	5	2	1x10 <sup>2</sup>	1x10 <sup>3</sup>	COVENIN 1292	Salmonella in 25g (**)	5	0	0	-	COVENIN 1291	Listeria monocytogenes in 25g (**)	5	0	0	-	COVENIN 3718	Molds cfu/g (*)	5	2	1x10 <sup>2</sup>	1x10 <sup>3</sup>	COVENIN 1337	Yeasts cfu/g (*)	5	2	1x10 <sup>2</sup>	1x10 <sup>3</sup>	COVENIN 1337	n = number of samples by lot c = number of defective samples m = minimum or only limit M = maximum limit * Recommended microbiological requirements (see COVENIN 409) ** Mandatory microbiological requirements (see COVENIN 409)					
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Intended Use:	For retail sale																																																																																
Intended Consumers:	General public																																																																																
Packaging:	Primary packaging is a PP film heat sealed PP sanitary tub: -Jokey JSB 16 tub -Jokey LSB 16 cap -Jokey LSBS 16 cap Secondary packaging: - a polyethylene shrink-wrapped carton tray																																																																																
Shelf Life:	60 days after production date																																																																																
Storage and Distribution:	Distributed in containers by land, air, or sea at temperatures of 2°C.																																																																																

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Date: April 23, 2018

*Mildred Perez de Zerpa*





### 3. HAZARD ANALYSIS REVIEW AND ASSESSMENT

Hato El Oso C.A. provided a written food safety plan for the mozzarella cheese (made with buffalo milk) produced at their facility. A review of the hazard analysis found that they identified and documented the significant hazards in the processing of mozzarella cheese (made with buffalo milk) along with an appropriate preventive control:

- Biological contamination of raw milk with elevated numbers of non-pathogenic bacteria and the presence of pathogenic bacteria, and/or parasites due to unsanitary practices, use of abnormal milk, and from environment during milking.
- Biological contamination of the in-process and finished mozzarella due to the survival of pathogenic bacteria if the following processing steps are not properly controlled: pasteurization, fermentation, coagulation, cooling, salting, and labeling/storage.
- Chemical contamination of raw milk with antibiotic residues due to improper treatment of sick buffalos.
- Chemical contamination of raw milk due to economically motivated adulteration.
- Chemical contamination of raw milk due to mycotoxins from the buffalo's diet.
- Chemical contamination due to undeclared allergens (milk).
- Physical contamination of raw milk due to the presence of foreign materials from the milking environment.
- Physical contamination with foreign materials such as metal fragments caused by metal-to-metal contact (e.g., blending operations) and equipment with metal parts that can break loose (e.g., portion control equipment, product sampling equipment, etc.) during processing.

Bufalinda USA LLC agrees with the supplier's hazard analysis and the control measures that have been implemented.

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#### 4. ENTITIES REPOSNSIBLE FOR MINIMIZING OR PREVENTING THE HAZARDS

Identified Hazard Requiring Control	Entity Controlling the Hazard	Type of Control Measure Applied
Biological contaminants in received raw product	Foreign Supplier's (Hato El Oso C.A.) raw material supplier	Supply-Chain Control
Biological contaminants potentially introduced (e.g., not controlled) during processing	Foreign Supplier (Hato El Oso C.A.)	Process Control
Chemical contaminants (e.g. antibiotic residues, mycotoxins and economically motivated adulteration) in received raw material	Foreign Supplier's (Hato El Oso C.A.) raw material supplier	Supply-Chain Control
Chemical contaminants (undeclared allergens)	Foreign Supplier (Hato El Oso C.A.)	Food Allergen Control
Physical contaminants in received raw product or introduced during processing	Foreign Supplier (Hato El Oso C.A.)	Process Control

#### 5. EVALUATION OF FOREIGN SUPPLIER'S PERFORMANCE

Foreign supplier procedures, processes and practices related to the safety of the food

<b>Supplier Name:</b>	HATO EL OSO C.A.
<b>Date of evaluation:</b>	April 18, 2018
<b>Food Safety Plan provided and reviewed:</b>	Yes. Document: Hato El Oso C.A. Food Safety Plan
<b>Process records provided and reviewed:</b>	Yes. Mildred Perez de Zerpa will review the processed records prior to importing and on a consistent basis moving forward.

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*QUXS*





Foreign supplier compliance with applicable FDA regulations

<b>Supplier Name:</b>	HATO EL OSO C.A.
<b>Date of evaluation:</b>	April 18, 2018
<b>Applicable FDA Regulations:</b>	21 CFR Part 117 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods 21 CFR Part 133 – Cheeses and Related Cheese Products Grade A Pasterized Milk Ordinance (Public Health Service/Food and Drug Administration)
<b>FDA Warning Letter issued:</b>	As of April 15, 2018 the company appears to be compliant with FDA. Debbie Shlesinger will monitor Hato El Oso's compliance status with the FDA to maintain awareness of the firm's regulatory standings.
<b>Import Alerts issued:</b>	As of April 15, 2018 the company appears to be compliant with FDA. Debbie Shlesinger will monitor Hato El Oso's compliance status with the FDA to maintain awareness of the firm's regulatory standings.
<b>Import Refusals issued:</b>	As of April 15, 2018 the company appears to be compliant with FDA. Debbie Shlesinger will monitor Hato El Oso's compliance status with the FDA to maintain awareness of the firm's regulatory standings.
<b>Product Recalls issued:</b>	As of April 15, 2018 the company appears to be compliant with FDA. Debbie Shlesinger will monitor Hato El Oso's compliance status with the FDA to maintain awareness of the firm's regulatory standings.
<b>Suspension of Facility Registration:</b>	As of April 15, 2018 the company appears to be compliant with FDA. Debbie Shlesinger will monitor Hato El Oso's compliance status with the FDA to maintain awareness of the firm's regulatory standings.

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(Qualified Individual)

*Mildred Perez de Zerpa*  
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*ALLS*

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#### Foreign supplier food safety history

<b>Supplier Name:</b>	HATO EL OSO C.A.
<b>Date of evaluation:</b>	April 18, 2018
<b>Food Testing Results:</b>	Food tests were reviewed and approved. Please see attached the detailed audit results.
<b>Audit Results relating to the safety of the food :</b>	Food Safety Plan was reviewed and approved. Please see attached the detailed audit results.
<b>Responsiveness in Correcting Problems:</b>	Detailed outline has been provided for small modifications that Hato El Oso should make moving forward. Their plan is to implement the changes as soon as possible.

#### 6. APPROVAL OF FOREIGN SUPPLIER(S)

The approval process is based on the evaluation of the foreign supplier's performance and risk posed by the foods, which considered the following factors in accordance with 21 CFR 1.505(b):

- The hazard analysis of the food
- The entities that will be responsible for controlling or minimizing the hazards
- Food safety performance history including their procedures, processes, and practices related to the safety of the food and their compliance status with the applicable FDA regulations (import alerts, recalls, warning letters, etc.).

<b>Foreign Supplier:</b>	<b>Approved Food Products:</b>	<b>Approval Date</b>
HATO EL OSO C.A.	mozzarella cheese (made with buffalo milk)	April 23, 2018

#### Procedures To Ensure Food Are Obtained From Approved Suppliers:

Responsible Individual: Debbie Shlesinger

Procedure:

1. Verify that each shipment of Mozzarella di Bufala Bocconcini, Mozzarella di Bufala Ciliegine, Mozzarella di Bufala Large Size, and Buffalo Milk Burrata was produced by Hato El Oso C.A. located in Maturin, Monagas, Venezuela by checking the bill of lading and/or the manufacturer's name on the product received.
2. Document foreign supplier's approved status on receiving documents.

Corrections: If we determine that any of the matters addressed in the evaluation have changed (such as the emergence of a new hazard or a significant supplier

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*[Signature]*





compliance problem), we will promptly determine and document whether we should continue to import the food from the foreign supplier and whether the verification activities need to be changed.

Records: Receiving records (e.g., bill of lading) of all imported foods

Verification: Receiving records reviewed within 7 working days. Document the review.

## 7. FOREIGN SUPPLIER VERIFICATION ACTIVITIES

Bufalinda USA LLC has determined that an onsite audit will provide adequate assurances that the hazards requiring a control have been significantly minimized or prevented. The determination was based on the evaluation of the food and foreign supplier's performance in accordance with 21 CFR 1.506.

### Verification Procedures for Imported Foods

Imported Food	Hazards Requiring Control	Appropriate Verification Activity	Justification	Frequency of verification
Mozzarella cheese (made with buffalo milk)	Biological contaminants (e.g., pathogenic bacteria associated with raw milk)	Onsite audit	Foodborne illness outbreaks and recalls have been associated with contaminated milk-based products. The onsite audit provides a comprehensive assessment of the food safety systems implemented by the foreign supplier.	Annually
	Chemical contaminants (e.g., antibiotic residues, mycotoxins and economically motivated adulteration)			
	Physical contaminants (e.g., foreign material)			

### Procedures To Conduct The Selected Foreign Supplier Verification Activity:

To ensure that appropriate foreign supplier verification activities are conducted for each foreign supplier and food(s), the following factors were considered:

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- The hazard analysis of the food, including the nature of the hazard(s) requiring a control
- The entity or entities that will be significantly minimizing or preventing the hazards requiring a control
- Foreign supplier performance, including:
  - The foreign supplier's procedures, processes, and practices related to the safety of the food.
  - Applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of food and other FDA compliance actions related to food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations).
  - The supplier's food safety history relevant to the food imported from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems.
  - Any other factors as appropriate and necessary, such as storage and transportation practices.

Appropriate supplier verification activities include:

- Onsite audits
- Sampling and testing of a food
- Review of the foreign supplier's relevant food safety records

When a hazard is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA) the appropriate supplier verification activity will be an onsite audit of the foreign supplier.

Based on the above factors, we have determined that an onsite audit of the food is the appropriate verification activity for the food products imported from Hato El Oso C.A. The importer can choose to perform the testing, require such testing from the foreign supplier, or rely on another entity's test results.

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(Qualified Individual)

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*Mildred Perez de Zerpa*  
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# On-site Audit

Supplier Name and location:	HATO EL OSO C.A. Km 32 Carretera Maturin Barrancas, Maturin, Monagas, Venezuela
Audit Procedures:	A complete company audit has been performed of Hato El Oso's Food Safety Plan and Good Manufacturing Practices
Audit dates:	April 16 – April 19, 2018
Audit conclusions:	Hato El Oso has been approved to export: Buffalo Milk Burrata, Mozzarella di Bufala Large Size, Mozzarella di Bufala Ciliegine, Mozzarella de Bufala Bocconcini
Corrective action taken in response to significant deficiencies:	Hato El Oso will implement minor modifications as soon as possible to meet GFSI (SQF) requirements. No significant deficiencies were observed.
Qualifications of the auditor:	Please refer to attached resume of Mildred Perez de Zerpa

**Mildred de Zerpa**

RIF.: V-05145639-0

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Sercamer N° de Consultor Registro Nacional 3802

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Auditor Lider IRCA en OHSAS 18001 (SEGURIDAD Y SALUD LABORAL) N° OHS/12/VE/8779

Auditor Lider IRCA en ISO 14001 (AMBIENTE) N° 11/7/17/28-09-12

**Reviewed by: Mildred Perez de Zerpa**  
(Qualified Individual)

*Mildred Perez de Zerpa*

**Approved by:**

*[Signature]*

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