# ATTACHMENT C

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 12420 Parklawn Dr, Rm 2037 HFC-130<br>Rockville, MD 20857<br><br>FDA483responseinternational@fda.hhs.gov | 12/4/2023-12/14/2023*<br>FEI NUMBER<br>3013416401 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Francisco Pena, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| AUSTROFOOD S.A.S. | Av. General Enriquez , Tanicuchi Lote 8 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Quito, Pichincha, 171104 Ecuador | TYPE ESTABLISHMENT INSPECTED<br>Human Food Manufacturer |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

## OBSERVATION 1

Your hazard analysis did not identify a hazard that required a preventive control.

Specifically, you conducted a hazard analysis on November 14, 2022, for all incoming raw materials, but did not identify any raw materials requiring a preventive control. In addition, cinnamon was not identified as a raw ingredient. On September 27, 2023, you conducted another hazard analysis for all raw materials ingredients including ground cinnamon. However, cinnamon was not considered a significant hazard requiring a preventive control for heavy metals including lead. In addition, you did not sample and test the raw material or the finished product for heavy metals. Furthermore, sampling conducted by FDA in the United States identified high level of lead in finished products distributed by Wanabana. FDA also conducted two sample collections of the ground cinnamon powder at Austrofood on December 05, 2023, and those samples also identified lead in the ground cinnamon.

## OBSERVATION 2

Your written process preventive control and monitoring procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control.

Specifically, your Food Safety Plan for "Fruit and Vegetable Pulp, Purees, and Compotes in Pouches M-ASC-004-C" (e.g., Appel Cinnamon Puree/Sauce) lists:

- a monitoring frequency of checking the temperatures for the (b) (4) pasteurizer ((b) (4) )

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Brant M Schroeder, Investigator<br>Israel Juarbe, Investigator<br>Rowena Trevino-Solis, Non Reporting User | X Brant M Schroeder Investigator Signed By: Brant M. Schroeder -S Date Signed: 12-14-2023 09:40:51 | 12/14/2023 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 12420 Parklawn Dr, Rm 2037 HFC-130<br>Rockville, MD 20857<br><br>FDA483responseinternational@fda.hhs.gov | 12/4/2023-12/14/2023*<br>FEI NUMBER<br>3013416401 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Francisco Pena, President | |
| FIRM NAME | STREET ADDRESS |
| AUSTROFOOD S.A.S. | Av. General Enriquez , Tanicuchi Lote 8 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Quito, Pichincha, 171104 Ecuador | Human Food Manufacturer |

and the (b) (4) pasteurizer "(b) (4) after the process starts" at the pasteurization steps. This frequency does not ensure compliance with the temperature critical limit at the pasteurization steps to control the pathogenic bacteria survival in the finished product.

- a monitoring procedure covering the temperature of the product at the (b) (4) pasteurization step; however, the monitoring procedures does not cover how the "(b) (4) " of processing time will be addressed. This procedure does not ensure compliance with the critical limit at the (b) (4) pasteurization step.

## OBSERVATION 3

You did not identify a process preventive control for a hazard when one was needed.

Specifically, your Food Safety Plan for "Fruit and Vegetable Pulp, Purees, and Compotes in Pouches M-ASC-004-C" (e.g., Appel Cinnamon Puree/Sauce) does not identify the preventive control point that is necessary to control the physical hazard. There are numerous rough edges, chipped, and pitted areas on the stainless-steel (b) (4) conveyor that leads to the (b) (4) The metal pieces from the (b) (4) conveyor can break loose and become a sources of metal inclusion that could enter food during processing.

## OBSERVATION 4

Your plant did not have adequate sanitary facilities and accommodations.

Specifically, there is no backflow protection to prevent or avert back siphonage on the water outlets with connecting hoses and threaded water faucet outlets throughout the plant.

## *DATES OF INSPECTION

12/04/2023(Mon), 12/05/2023(Tue), 12/06/2023(Wed), 12/07/2023(Thu), 12/11/2023(Mon), 12/12/2023(Tue), 12/13/2023(Wed), 12/14/2023(Thu)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Brant M Schroeder, Investigator<br>Israel Juarbe, Investigator<br>Rowena Trevino-Solis, Non Reporting User | X Brant M Schroeder Investigator Signed By: Brant M. Schroeder -S Date Signed: 12-14-2023 09:40:51 | 12/14/2023 |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 12420 Parklawn Dr, Rm 2037 HFC-130<br>Rockville, MD 20857<br><br>FDA483responseinternational@fda.hhs.gov | 12/4/2023-12/14/2023*<br>FEI NUMBER<br>3013416401 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Francisco Pena, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| AUSTROFOOD S.A.S. | Av. General Enriquez , Tanicuchi Lote 8 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Quito, Pichincha, 171104 Ecuador | Human Food Manufacturer |

X Israel Juarbe
Investigator
Signed By: Israel Juarbe Jr -S
Date Signed: 12-14-2023 09:41:23

X Rowena Trevino-Solis
Non Reporting User
Signed By: Rowena Trevino-solis -S
Date Signed: 12-14-2023 09:43:06

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Brant M Schroeder, Investigator
Israel Juarbe, Investigator
Rowena Trevino-Solis, Non Reporting User

X Brant M Schroeder
Investigator
Signed By: Brant M. Schroeder -S
Date Signed: 12-14-2023
09:40:51

DATE ISSUED
12/14/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."