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Report Name: A Best Practices Guide for Facility Registration

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Report Highlights:

U.S. dairy and seafood export volumes to Costa Rica hit new record highs in 2021, but access to this growing Central American market requires U.S. production facility as well as product registrations. The following guide provides insight into the registration process and tips to avoid lengthy delays.

Overview

The Costa Rican Government requires registration of U.S. dairy, seafood, and ovine products and production facilities with the Costa Rican Ministry of Agriculture and Livestock (MAG) National Animal Health Service (SENASA) prior to exporting to Costa Rica.¹ The registration process does not require audits or on-site inspections, but often takes about 5 months to complete, depending the quality of information initially provided by U.S. manufacturers. MAG has 90 business days to review the questionnaires and, if needed, then ask additional questions. U.S. company responses to additional rounds of questions end up at the back of the queue of questionnaire reviews, extending the process by additional weeks or months.

U.S. companies interested in registering dairy, seafood, and ovine products and facilities <u>must</u> contact FAS/San Jose (<u>AgSanJose@usda.gov</u>) to initiate the registration process. SENASA does not permit U.S. companies to register directly, requiring registration requests to be made government-to-government. Please note that the terms "seafood products" and "ovine products" include unprocessed products (e.g., sea urchin, whole fish, fish filets, fresh/frozen lamb cuts, etc.) as well as processed products (e.g., fish sticks, octopus balls, lamb kofta, etc.).

Costa Rica's Ministry of Health requires a separate product-specific registration process for imported processed food products (e.g., cheese, smoked salmon, lamb meatballs, etc.). Processed food product registration procedures are discussed in detail in FAS/San José's <u>Food and Agricultural Import</u> <u>Regulations and Standards</u> (FAIRS) Report, and we encourage U.S. exporters to work with their Costa Rican importers to register their products before, or concurrent with, the SENASA-managed facility registration process, since the two processes are independent.

Background

In 2016, Costa Rica's Ministry of Agriculture and Livestock (MAG) implemented a facility registration regulation for animal product imports that has complicated access for U.S. dairy, seafood, and ovine products. U.S. beef, pork, and poultry exports are exempted from the regulation by a provision of the Dominican Republic – Central America Free Trade Agreement (CAFTA-DR). The legal basis for the questionnaire requirement is the September 1992 Decree #21858-MAG "Regulation on the Evaluation and Approval of Products and by-Products of Animal Origin Imported into Costa Rica." Based on this regulation, SENASA requires the competent authority of the exporting country and the individual export facilities to fill out a questionnaire, which then needs to be approved by MAG.

Registration Procedure

¹ SENASA does not require U.S. facilities that were exporting dairy, seafood, or ovine products to Costa Rica prior to 2016 to submit the questionnaire in order to register for export eligibility. Nor do these facilities have to renew their registration status every three years. This 'grandfathering' of pre-2016 exporters is effectively complete as practically all pre-2016 exporters appear on the SENASA registry of approved facilities.

SENASA has established the following procedure for new-to-market U.S. facilities manufacturing dairy, seafood, and ovine products. It is important to underscore that SENASA grants registration on an *individual facility* basis, rather than on a company-wide basis.

- 1. A U.S. company sends a message to FAS/San José indicating the name of the company, the plant number, and the specific products (e.g., milk-based beverages, wild Alaska pollock, etc.) to be exported from the processing plant to be registered.
- 2. FAS/San José submits an official request to SENASA for a facility registration questionnaire, providing the information in step #1 in an official letter.
- 3. SENASA responds to FAS/San José, attaching the most up-to-date version of the questionnaire.
- 4. FAS/San José transmits the questionnaire to the U.S. company.
- 5. The U.S. company sends the completed questionnaire (in Spanish) back to FAS/San José.
- 6. FAS/San José transmits the completed questionnaire to SENASA with an official cover letter.
- 7. SENASA has 90 business days to review the questionnaire.
 - a. If SENASA has questions regarding information or data provided, then SENASA will transmit specific questions / requests to FAS/San José.
 - b. FAS/San José relays these questions to the U.S. company.
 - c. The U.S. company provides requested information (in Spanish) to FAS/San José.
 - d. FAS/San José conveys U.S. company responses to SENASA.
- 8. Once the U.S. company has provided all requested information and supporting data and there are no further questions from SENASA, then SENASA will send FAS/San José an official letter confirming registration of the facility for a period of 3 years.
- 9. FAS/San José transmits the registration confirmation to the U.S. company.
- 10. SENASA completes the process by updating the official registry of approved facilities, which is used by customs officials at port of entry.

Registered U.S. facilities and products are eligible for export from the date of the confirmation letter, rather than the date the registry is updated. In practice, Costa Rican buyers can immediately apply for an import license permit for registered products from the registered U.S. facility by contacting customs officials, rather than waiting for the registry to be updated. The official registry is available on the SENASA website <u>here</u>, by clicking on the link to the latest Excel spreadsheet titled *Establecimientos habilitado para exportar a Costa Rica*; information on registered U.S. facilities and products can be found on the "USA" tab.

If an approved U.S. dairy, seafood, or ovine product facility wants to export additional products after concluding the approval process, FAS/San José must formally request SENASA add the new product to the registry. Depending on the product to be added, SENASA may require the approved facility to submit a new questionnaire prior to adding the product to the registry.

At least 90 calendar days before the expiration of the individual facility registration (i.e., three years from the date of registration approval), U.S. companies should contact FAS/San José to request facility registration renewal. Companies seeking to renew their registration status may be asked to submit an updated questionnaire response.

Questionnaire Overview

After FAS/San José requests a questionnaire, SENASA generally provides the questionnaire to FAS/San José within 5 business days. The questionnaire is in Spanish and contains several embedded tables that must be completed, depending on the products to be registered (the questionnaire includes sections that apply to dairy products, to seafood products, etc.). The completed questionnaire must be submitted in Spanish, using the original Spanish language questionnaire version, with all requested information and responses in Spanish. SENASA will reject questionnaires not completed in Spanish. Translation of U.S. questionnaire responses, does not have to be 'official,' and FAS/San José has a list of reputable translation services that can be contracted to assist in the process. FAS/San José can share an unofficial English translation of the SENASA questionnaire upon request.

Questionnaire Guidance

FAS/San José suggests U.S. companies consider the following general points when completing the questionnaire:

- Provide <u>all</u> required information in the questionnaire itself, including the information/tables requested under each specific item in the questionnaire.
- Ensure information is provided in the correct tables within the questionnaire, such as the "Products" or "Additives" tables.
- Include specific product HACCP plan information and production flow charts in the space associated with the specific product information request (e.g., section #8).
- If possible, embed attachments with the required information under each item of the questionnaire. If the size of embedded files is too large, then ensure attached file names are clear, descriptive, and specifically reference the section of the questionnaire to which they correspond. In the appropriate section of the questionnaire, include the corresponding attached file name.
- SENASA will not accept responses such as: "the information requested is business confidential or proprietary." Such responses would result in SENASA requesting the missing information and the subsequent submission starting over at the back of the queue.

Common Errors

The following are some of SENASA's most common observations or requests for additional information after the initial review of the questionnaire is completed. These examples are provided to help U.S. companies avoid costly and lengthy delays to the approval process. FAS/San José encourages U.S.

companies to pay special attention to the related questionnaire components to improve chances for a successful registration on the first request.

- "The establishment must respond to the question asking to provide the names of the establishments that supply the raw materials (milk or cheese, for instance) for the production of the products to be exported to Costa Rica."
- "The establishment must attach a flow diagram for the products to be exported to Costa Rica."
- "The establishment must respond to item #8.3 related to the worksheet for each critical control point, indicating the following: stage, hazard, critical limit, monitoring, corrective actions, verification, and record keeping."
- "According to the table related to the establishment's internal laboratory analysis, it was determined that the establishment does not test for pathogens such as Staphylococcus aureus, Escherichia Coli, and Salmonella in the final product. Also, information regarding the number of analyses made and the number of laboratory results that were in violation was not provided."

Common observations specifically related to dairy product questionnaires include the following:

- "The establishment must indicate which additives it uses in its products, indicating the Regulatory or Bibliographic Reference for the use of the additive."
- "The establishment must respond regarding the types of microbiological analyses (total bacteria count, somatic cell count, alcohol test), and physical-chemical tests (presence of antibiotics and other veterinary drug residues) conducted on raw milk." [Note: This is applicable when the establishment processes raw milk.]
- "The establishment must respond to the item related to the capacity of the pasteurizer in liters per hour, and on the demonstration of the pressure differential between the pasteurized milk section and the non-pasteurized milk section."
- "The establishment must attach a copy of the pasteurization record demonstrating the activation of the deviation valve."
- "The establishment must provide a copy of the latest calibration of the pasteurizer."

Additional Information

For additional information please contact the Office of Agricultural Affairs at the U.S. Embassy in San José at <u>AgSanJose@usda.gov</u>

Attachments:

No Attachments.