TRACEGAINS WEBINAR

Expediting the Process for FDA Imports

December 8th, 2022

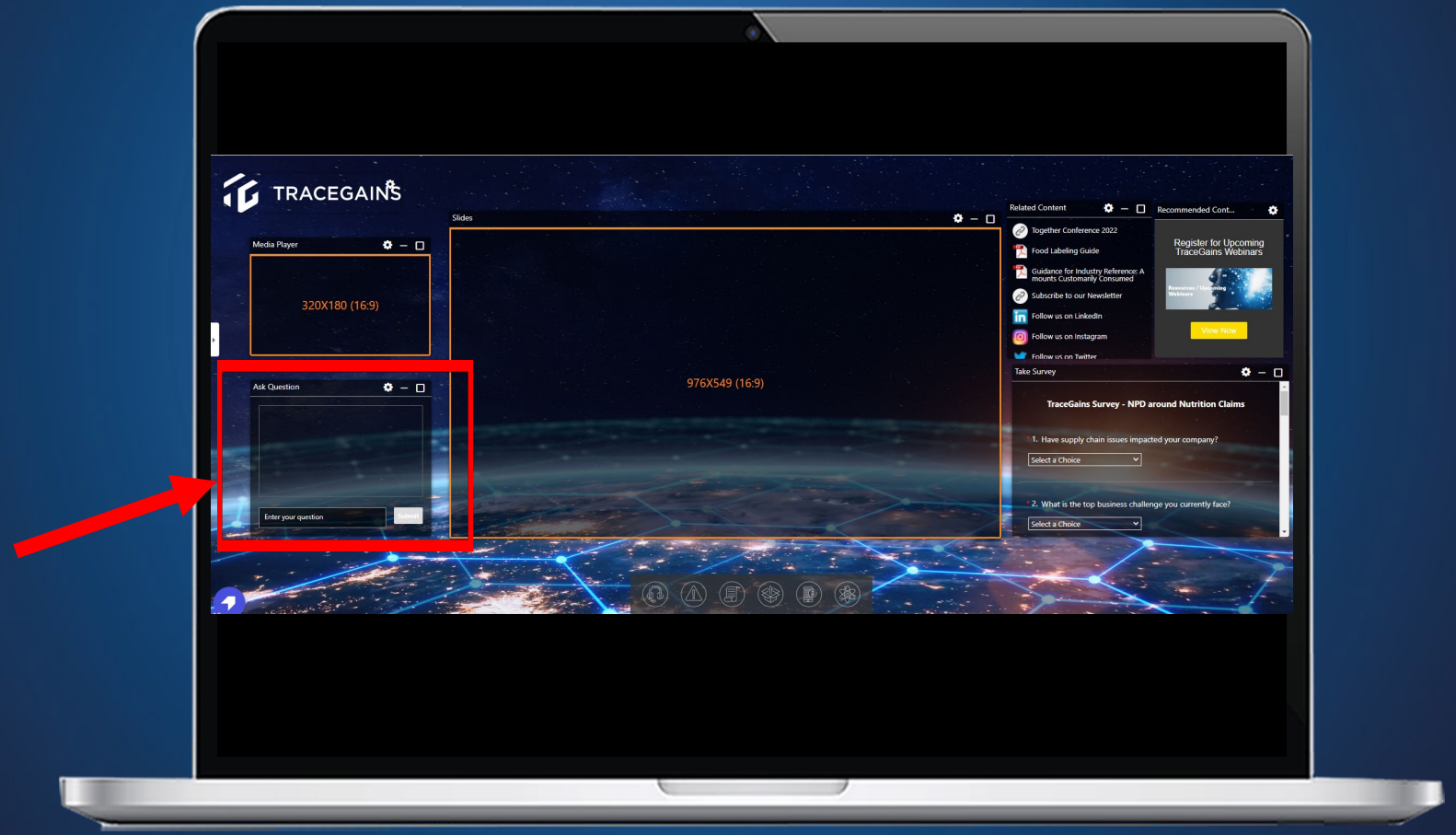
TRACEGAINS

meet

Your Moderator

Kristen Goodale
Marketing Coordinator

We want to hear from you! Please type your questions in the chat box.



About TraceGains

Together we do more

Food and Beverage ••• Dietary Supplements ••• Retail ••• Consumer Packaged Goods

What Makes TraceGains Different?

On average, companies find that 80% of their suppliers are already on TraceGains Network.

Meet

Your Speakers

Dean Leaman

Director of Business Development

International Import/Export

Angel Suarez

Independent Consultant

EAS Consulting Group

Justin Busch

Account Executive

EAS Consulting Group
A Certified Group Company

Certified Group
Laboratory Testing | Regulatory Consulting

Importing Food Products into the United States

Dean Leaman

Director of Business Development International Import Export

Certified Laboratories

Angel M. Suarez

Independent Consultant, EAS

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FDA Import Strategy

- Goal 1: Food Offered for Import Meets U.S. Food Safety Requirements
- Goal 2: FDA Border Surveillance Prevents Entry of Unsafe Foods
- Goal 3: Rapid and Effective Response to Unsafe Imported Food
- Goal 4: Effective and Efficient Food Import Program

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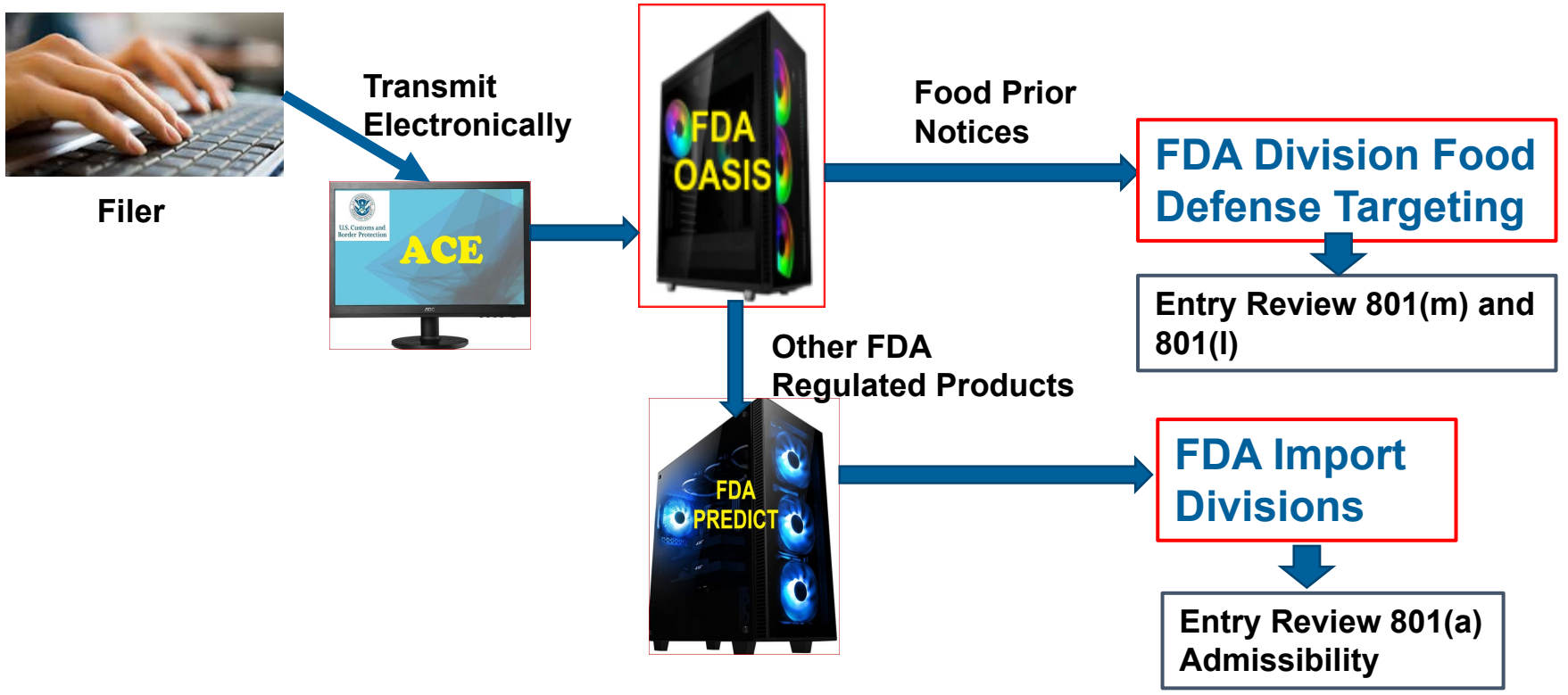
FDA Import Operations



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Entry Review Process

- During the **entry review process**, the imported products **must** be held and may not be distributed into U.S. commerce until the FDA has determined their admissibility.
- FDA-regulated products are refused entry if they appear to be or have been found to be:
  - adulterated, meaning the product is contaminated, is not safe, unapproved, or does not otherwise meet applicable standards,
  - misbranded, meaning the labels contain false or misleading information, or the product is not registered and listed, if required,
  - forbidden or restricted for sale.
- Products that do not comply with U.S. requirements may be refused admission. Refused products must be destroyed or exported from the United States within 90 days.

FDA Import Problems

The quality of the data submitted to the FDA will count more than ever.

- Importers need to work closely with filers to ensure data quality.
- It is important to be diligent when selecting a Customs Broker (filer). They should have experience with your particular commodity.
- Poor data quality or missing data will increase the targeting scores for your subsequent entry lines (importers and filers).

Higher risk scores increase the likelihood of physical examination by the FDA.

- Affirmations of compliance
  - Establishment registration number, unique to the facility
  - Product listing number
  - Product approval number, specific to the product
  - Radiological health product report accession number
  - Low Acid Canned Food/Acidified Foods establishment and process identifiers

FDA Import PREDICT

- Replaced the admissibility screening portion of FDA's legacy electronic system for processing import entries.
  - FDA Import Divisions
    - PREDICT
  - Division of Food Defense Targeting
    - PREDICT like application for screening bioterrorism targets

FDA Import PREDICT

- Uses automated data mining, pattern discovery, and automated queries of FDA databases to determine the potential risk of a shipment.
  - Utilize open-source intelligence
  - Provide automated queries of Center databases where relevant (i.e., registration and listing, marketing approval status, low-acid canned food scheduled processes, etc.)

FDA PREDICT Targeting

- Scoring each entry line on the basis of risk factors and surveillance requirements
- Increase the number of automated, real-time, risk-based “May Proceed” decisions, thereby giving entry reviewers more time to evaluate higher-risk lines
- For those lines not given an automated “May Proceed,¨ providing reviewers with the line scores and the reasons for those scores determine the potential risk of a shipment

FDA PREDICT Screening Rules

- Results of field exams and sample analyses of previous entries
- Results of facility inspections (foreign and domestic)
- Ratings of inherent product risks
- **Accuracy of product and facility coding by entry filers and importers**
- Compliance risk of firms associated with the imported line
- Product-related Inherent health risk
  - Incremental health risk in view of previous FDA physical examination results for products of the same manufacturer
  - Risk factors identified by the FDA or other sources that create the need to implement expert rules indicating further action by field staff

FDA PREDICT Artificial Intelligence

- In 2019 first phase of the trial demonstrating an analytical proof of concept. Expediting the review of low-risk seafood shipments, while identifying those with a higher risk of abuse or rejection.
- Second phase February 2021 through July 2021 at 328 ports of entries in the United States proved to be successful.
- Third phase will enable the FDA to reach its goal to protect consumers from unsafe foods by enhancing the FDA's ability to identify potential risks. Expectation screening other FDA-regulated products and risk-based monitoring products enhancing the ability to identify potential risks and protect consumers.
- PREDICT future on the use of artificial intelligence and machine learning (ML) will consist of its ability to enhance import screening and ensure the safety of foods entering the United States.
- Combination of the use of artificial intelligence and machine learning will make possible to rapidly analyze data, automatically identifying connections and patterns in data that people or even the agency's current rules-based screening system cannot be seen.

FDA Import Holds

- **DFDT Holds – Prior Notice – Bioterrorism Act**
  - **Must be held within the port of entry for the article unless directed by CBP or FDA**
- **FDA Imports Admissibility**
  - Hold status while FDA performs entry review to determine whether the product comply with U.S. law
  - Importer must hold the article and not distribute FDA Notice of Action
    - Line Hold or Hold All
    - Failure to hold will lead into a bond action – which could include a recall
  - Examination and Sample Collection
  - Detention and Hearing
    - Import Refusal
    - Must be redelivered to Customs custody within 90 days

FDA Notice of Action

Advises that the entry is to be held for an FDA examination or sampling;

Specifies the items (lines) in the entry that need be held.

If the product appears to be in violation, the product is subject to refusal

- specify the nature of the violation and provide the importer an opportunity to present supporting evidence to overcome the violation, **within a specified time period – referred to as "respond by date"**
- request an extension if additional time is needed to collect or present the information
  - If you choose to "provide testimony" from a private lab, the CO will typically request that the "sample collection report" be uploaded to ITACS which is provided by the private lab.

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United States Food and Drug Administration

Division of West Coast Imports

Notice of FDA Action

Entry Number: DP6-[redacted]-3

Notice Number: 5
December 3, 2020

Filer:
[redacted]
Burlingame, CA 94010-1312

Attention: S[redacted] K[redacted]

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Port of Entry: 2809, San Francisco, CA
Carrier: OCEAN NETWORK EXPRESS PTE LTD;
Date Received: October 14, 2020
Arrival Date: October 18, 2020

Importer Of Record: [redacted], Newark, CA 94560-3021
Consignee: [redacted] Hayward, CA 94545-3206

HOLD DESIGNATED

Notify FDA of Availability

Summary of Current Status of Individual Lines

	Line	ACS/ACE/FDA Product Description	Quantity	Current Status
	12/1	FROZEN ASTER INDICUS	100 CT	Released 10-30-2020
	22/1	BAMBOO SHOOT	200 CT	Released 10-30-2020
	32/1	FROZEN GARLIC SHOOT	100 CT	Released 10-30-2020
*	42/1	FROZEN STEAMED FLOUR BUN (MUSHROOM & GREEN VEGETABLE)	430 CT	Detained 12-02-2020
*	52/1	FROZEN STEAMED FLOUR BUN (DRIED CABBAGE)	100 CT	Detained 12-02-2020
*	62/1	FROZEN STEAMED FLOUR BUN (CHINESE SPINACH)	100 CT	Detained 12-02-2020

FDA Notice of Action

– Specify the nature of the violation.

- Example - FD&CA Section 403(w) 801(a)(3); Misbranding

– the label fails to declare all major food allergens present in the product, as required by section 403(w)(1). Your product ingredients list does not identify major food allergens. Allergen declaration is required per 403(w)(1) of the FD&C Act. You may provide your testimony within the detention timeframe.

FDA Notice of Action - Detention and Hearing

– Product appears to be in violation.

- Specify the nature of the violation and provide the importer an opportunity to present supporting evidence to overcome the violation, within a specified time period.
- Importer can request an extension if additional time is needed to collect or present the information.

FDA Notice of Action - Detention and Hearing

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA),or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/ACE/FDA	Product Description	Respond By
42/1	FROZEN STEAMED FLOUR BUN (MUSHROOM & GREEN VEGETABLE)	December 22, 2020

FD&CA Section 403(w) 801(a)(3); Misbranding
the label fails to declare all major food allergens present in the product, as required by section 403(w)(1). Your product ingredients list does not identify major food allergens. Allergen declaration is required per 403(w)(1) of the FD&C Act. You may provide your testimony within the detention timeframe.

FDA Import Detentions

Product may be detained because it appears to be:

- adulterated, meaning the product is contaminated, is not safe, or does not otherwise meet applicable standards;
- misbranded, meaning the labels contain false or misleading information;
- an unapproved new drug, medical device, biological product;
- manufactured, processed, or packed under insanitary conditions;
- forbidden or restricted for sale in the country in which it was produced or from which it was exported.

FDA Notice of Action - Detention and Hearing

Importer has the following options:

- Entitled to an informal hearing in order to provide testimony regarding the admissibility of the product.
- Submit evidence that the product is in compliance.
- Failure to submit evidence or a plan to bring the product into compliance.
  - Destroy the product under FDA and CBP supervision.
  - Export the product under FDA and CBP supervision.

FDA Import Detentions

Notice of Detention and Hearing

– "respond by" date

– provide the sections of the laws and regulations that appear to be violated; these are referred to as charges.

Options include

- Submitting evidence (also called testimony) to overcome the appearance of a violation.
- Submitting a request to recondition (FDA-766) the product to correct the violation.

FDA ITACS – Notice of Action

Import Refusal Filer, importer, owner and/or consignee

- Online communication system for submitting entry documentation
- Checking entry status for FDA entries
    - only for lines that have been selected for physical examination or sampling

FDA Notice of Action - Refusal

Appeal the refusal decision

- Refusal is a final decision.
- Unless the refusal was issued by FDA in error, consideration is not given to a request to rescind the refusal.

Extension beyond the 90 days to FDA

- FDA has no authority to grant such extensions.
- Local CBP office for questions related to extending the 90-day period.

FDA Import Alerts

- Inform the FDA's field staff and the public there is enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of the FDA's laws and regulations.
- Prevent potentially violative products from being distributed in US
- Free-up agency resources to examine other shipments
- Provide uniform coverage across the country
- Place the responsibility back on the importer to ensure that the products being imported into the United States are in compliance with the FDA's laws and regulations.

Detention Without Physical Examination

- FDA Import Districts recommendation whenever there is information that would cause future shipments of a product or products offered for entry to appear violative within the meaning of Section 801(a).
- Evidence that a product from a specific geographical area or country could pose a health hazard appearance standard after discovering a violation based on multiple samples showing violations of the Act
  - Example: Cantaloupe from Mexico – countrywide IA 22-01 Salmonella
- Importation of violative articles that has resulted in the issuance of a Warning Letter to the importer with no subsequent response (FSVP)

Detention Without Physical Examination

Inform the agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of the FDA's laws and regulations.

Detention Without Physical Examination

- FDA Import Districts recommendation whenever there is information that would cause future shipments of a product or products offered for entry to appear violative within the meaning of Section 801(a).
- Evidence that a product from a specific geographical area or country could pose a health hazard appearance standard after discovering a violation based on multiple samples showing violations of the Act
- Importation of violative articles that has resulted in the issuance of a Warning Letter to the importer with no subsequent response (FSVP)

Detention Without Physical Examination

- Information received from other government agencies (e.g. U.S. CBP)
- Verifiable information in the form of consumer or trade complaints, or otherwise, that has the effect of causing the articles offered for import to appear adulterated,
misbranded, or otherwise in violation of the FD&C Act as specified in Section 801(a).
- Establishment inspections of foreign manufacturers of FDA regulated products that reveal significant deviations
    - IA 99-41 references compliance of FSVP
- if there is a reason to believe, and evidence to support, that future shipments of a product or class of products will appear violative within the scope of Section 801(a).

Removal DWPE – Import Alert

Have its products removed from the Red List of an Import Alert, **the company must submit a petition to FDA**, detailing how the company has identified the source of the problem and is implementing specific, corrective actions that will prevent future violations.

There are several requirements that must be included in the petition – a consultant with experience is highly recommended.

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Certified Group
Laboratory Testing | Regulatory Consulting

Dean Leaman
Certified Laboratories
Email – dleaman@certified-laboratories.com
516-317-2775
www.certified-laboratories.com

EAS Consulting Group
A Certified Group Company

Angel M Suarez
EAS Consulting Group
Email – asuarez@easconsultinggroup.com
571-447-5500
www.easconsultinggroup.com

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Justin Busch

Account Executive

What did we talk about today?

- The layers and processes of import refusal and detention and what to expect at every stage.
- Overview of foreign and domestic food safety, importing food and understanding the automated customs environment (ACE), and the PREDICT program.
- Insights into the FDA import trade auxiliary communications system (ITACS).
- The many moving parts of FDA Alerts that include number, import alert name, the reason for alert, guidance, and more.

How can TraceGains Help?

TraceGains Network

Freedom from tracking down suppliers and requesting information or documents

56K+
Supplier Locations

425K+
Items & Ingredients

3M+
Supplier, Item & Ingredient Documents

717k
Completed Standard Online Forms

146+
Supplier Countries

53+
Countries with Customer Presence

TraceGains Product Suite

R&D / NPD TEAMS

QUALITY and REGULATORY COMPLIANCE TEAMS

Intelligence: Horizon Scanning Global

Marketplace

Supplier Management

Formula Management

Spec Management– Raw Materials / Spec Management – Finished Goods

Audit Management

Supplier Compliance

Quality Management

Customer Manager

Explore Concept

Validate Product

Build/Manage Product

CONCEPT

TRACEGAINS C TO C SUITE

CONSUMPTION

Live Q&A

Type your questions into the chat box!

TRACEGAINS

Thank You

Together we do more