CHEESE IMPORTERS ASSOCIATION OF AMERICA

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CIAA Bulletin **An Exclusive CIAA Member Update**

FDA Announces Re-inspection and VQIP FY 2020 Fees

The Food and Drug Administration announced its Fiscal Year (FY) 2020 fee rates for several food safety and FSMA related programs. FDA is authorized to collect these fees under the Food Safety Modernization Act (FSMA) and the fees were first implemented by FDA in October 2011 for FY 2012.

Voluntary Qualified Importer Program Fees

The Voluntary Qualified Importer Program (VQIP) is a voluntary, fee-based program that provides participating importers expedited review and import entry for human and animal foods. The FY 2020 user fee paid by each VQIP participant is $16,681. Additionally, FDA can charge fees related to inspections of foreign facilities at the following hourly rates:

- $240 if no travel is required;
- $258 if domestic travel is required; and
- $301 if foreign travel is required.

At this time, FDA does not have a mechanism for small business to receive a fee reduction.

These fees are effective August 1, 2019 and will remain in effect until December 31, 2019 because the VQIP participation portal for participation in FY 2020 is only open until July 31, 2019. The portal will remain closed until January 2020 when FDA will accept applications for FY 2021. To be eligible to participate in VQIP, VQIP participants must pay any invoices that have been issued prior to October 1, 2019. In subsequent years, if the user fee is not paid prior to October 1, FDA will send a "Notice of Intent to Revoke" participation in VQIP. If the user fee is not paid within 30 days of that notice, FDA will revoke participation in VQIP.

How to Participate in VQIP and It's Benefits

To qualify for participation in VQIP, an importer must meet the following requirements:

- Show at least a three-year history of importing food into the United States;
  - This import history may be based on the shared importation history of previous or parent companies, such as those that have been involved in a merger. Note that if

applicants have imported food for more than three years, the FDA may review additional years as necessary to adequately evaluate compliance history.

· Have a Dun & Bradstreet Data Universal Numbering System (DUNS) number;
  - To obtain a DUNS number, contact Dun & Bradstreet at 866-705-5711 or via e-mail to govt@dnb.com. All entities doing business with the U.S. government can receive a DUNS number free of charge.

· Use of paperless filers/brokers who received a passing rating during their last FDA Filer Evaluation;
  - Note that if the filer/broker has not been evaluated by FDA when making the application, the applicant or the filer/broker may request FDA to conduct a filer evaluation. The results of the evaluation will be included in the list of FDA Filer Evaluation Outcomes after FDA completes the evaluation. The filer/broker may be used for VQIP entries if it receives acceptable results for its FDA Filer Evaluation.

· Do not import any food that is subject to an Import Alert or Class I recall (including a food the applicant does not intend to include under VQIP) at the time the application is submitted;

· Neither the importer nor any non-applicant entities associated with a VQIP food is subject to any ongoing FDA administrative or judicial action (e.g., Import Alert, injunction, or debarment) or have a history of significant non-compliance's relating to food safety (e.g., an FDA inspection classified as "Official Action Indicated" with no documentation of appropriate corrective actions, one or more Class I recalls relating to food safety);
  - Non-applicant entities are those entities associated with a VQIP food that conduct activities throughout the supply chain necessary for ensuring that the eligibility requirements of VQIP are met. Non-applicant entities include the FSVP or HACCP importer of the food (if other than the applicant), the foreign supplier of the food, and the filer/broker.

· The FSVP or HACCP importer for a VQIP food must be in compliance with the supplier verification and other importer requirements under the applicable FSVP, juice HACCP, or seafood HACCP regulations;
  - Note that if the applicant is not the FSVP or HACCP importer of a VQIP food, the applicant must identify the FSVP or HACCP importer and ensure that the FSVP or HACCP importer is in compliance with the applicable FSVP or HACCP regulations.

· Have a current food facility certification issued by an FDA-accredited third-party auditor or certification body for each foreign supplier of food the applicant intends to import under VQIP;
  - Refer to FDA's third-party certification program for more details regarding this requirement.

· Develop and implement a VQIP Quality Assurance Program (QAP) and submit documentation of the QAP with the application;
  - A VQIP QAP is a compilation of the written policies and procedures an importer uses to ensure adequate control over the safety and security of the foods it imports. Any format may be used to organize a QAP to include all foods and all of the written policies and procedures under VQIP.

· Not be the subject of any U.S. Customs and Border Protection (CBP) penalties, forfeitures, or sanctions related to the safety and security of any FDA-regulated products imported during the past 3 years; and
  - FDA may elect to review more than three years, as noted above.

· Pay the annual VQIP user fee before October 1 of the year in which the applicant intends to participate in VQIP.
  - As provided above, the FY 2020 user fee paid by each VQIP participant is $16,681.

There are a wide variety of benefits for an importer that participates in VQIP, including:

- Expedited entry into the U.S. for all human and animal foods included in the approved VQIP application;
- Limited examination or sampling of VQIP food entries to (1) "for cause" situations, (2) obtain statistically necessary risk-based microbiological samples, and (3) audit to verify an importer's compliance with VQIP;
- Examination of the entry and sample collection at the VQIP food's destination or other location preferred by the VQIP importer;
- Prioritized testing of VQIP samples at FDA laboratories; and
- Access to a VQIP Importers Help Desk that will respond to questions and resolve issues raised by VQIP importers.

Facility and Importer Re-inspections and Recall Fees

FDA can assess fees for re-inspection when FDA needs to return to a facility or an importer to determine whether corrective actions have been implemented and are effective, and compliance has been achieved. Recall fees are assessed when (1) a facility fails to initiate a recall as ordered by FDA, (2) a recall is not conducted in the manner specified by FDA in a recall order, or (3) a facility does not provide FDA with information requested by FDA regarding the recall. These fees are effective on October 1, 2020 and remain in effect through September 20, 2020.

The FY 2020 fee rates, as discussed above, are as follows:
- $240 if no travel is required
- $258 if domestic travel is required
- $301 if foreign travel is required

These rates are slightly higher than the rates provided in FY 2019, as these rates are adjusted for inflation by FDA each year.

The Federal Register notice announcing these fees notes that FDA is refraining from issuing any invoices for re-inspection or recall order fees because the agency has not yet published a guidance document outlining the process through which small businesses can request a fee reduction. Even though these fees are currently in effect, food companies of all sizes should not expect to receive an invoice until FDA issues this guidance.

Best regards,
Phil Marfuggi
President
CIAA

Dates to Remember

August 31, 2019
Last day to enter dairy products into U.S. Customs territory that may be used to qualify and establish eligibility for a calendar year 2020 license.

September 3, 2019
First day of 2020 license applications
Last day to request a globalization of a calendar year 2019 license

September 16, 2019
Last day of licensees applying for reallocated license amounts for 2019

October 1, 2019
Last day to surrender 2019 license amounts

October 15, 2019
Last day of 2020 license applications

November 7, 2019
Member Meeting
9:30 am - 11:30 am
Saddle Brook Marriott
Saddle Brook, NJ

***** If a deadline date falls on a Saturday, Sunday, or Federal holiday, the deadline will be the next business day (Section 6.36(a) of the Dairy Tariff-Rate Import Quota Licensing Regulation). This does not apply to dates of entry for eligibility.

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