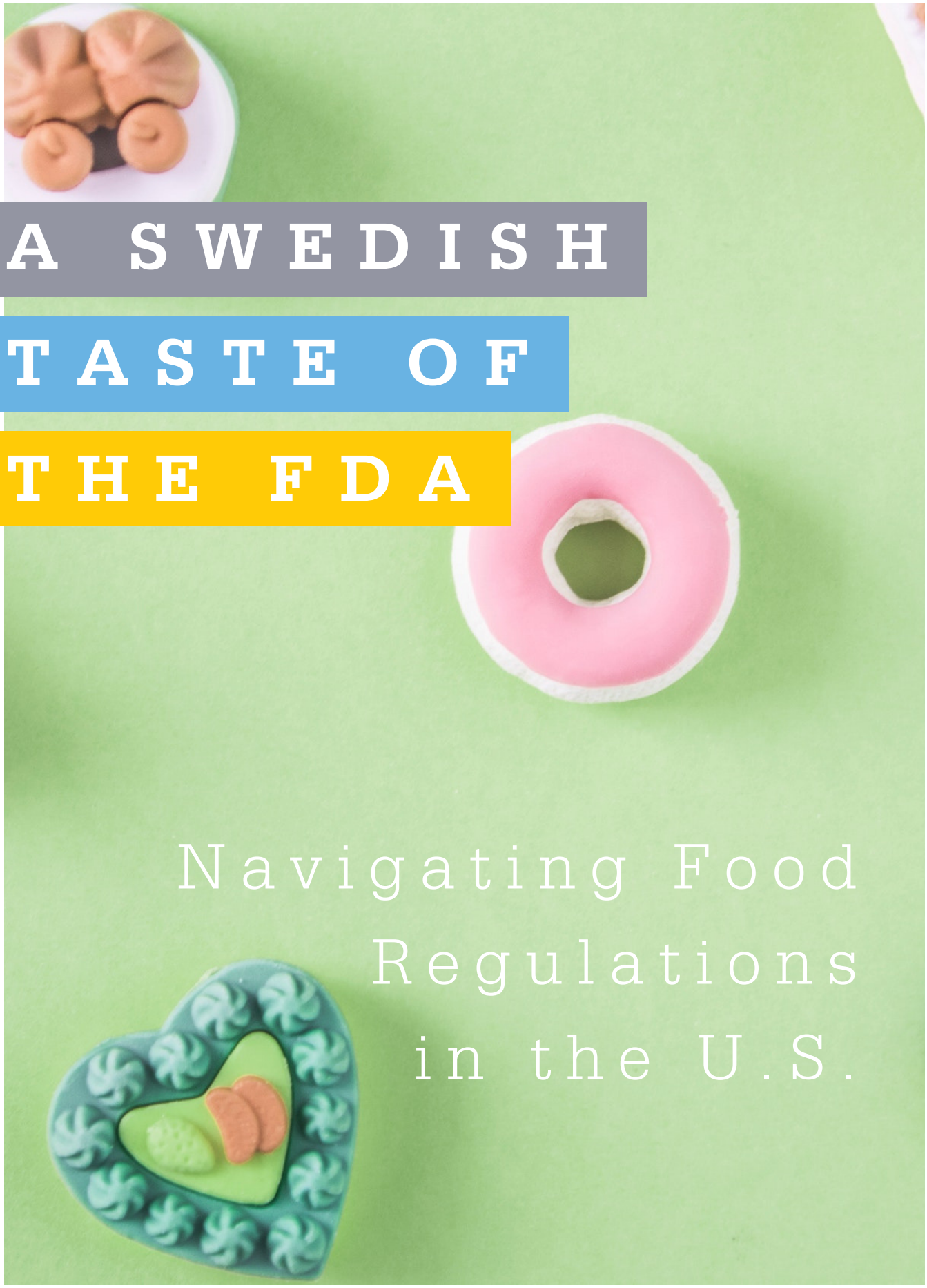


A SWEDISH TASTE OF THE FDA

Navigating Food Regulations in the U.S.

IN THIS GUIDE

IN THIS GUIDE

Try Swedish and Business Sweden are proud to present our guide to navigating the food regulatory market in the U.S.

We understand that the regulatory structure over here can be a pain to navigate. Our sincere hope is that we've pulled together the info needed to make things clearer, simpler, and more successful for you and your company.

Enjoy reading, and best of luck bringing delicious Swedish food to the American public.

The Try Swedish Team

A BIT ABOUT THE GUIDE

The Food and Drug Administration, commonly known as the FDA, is the federal regulatory body governing the safety of food and beverage consumption in the U.S. Their regulations apply to all companies selling food for consumption in U.S., including international manufacturing companies with no physical presence in the U.S. This means they likely apply to you.

Although FDA regulations are not harmonized with Europe's, similarities do exist. Understanding these similarities can give you a head start when preparing for FDA compliance. Good preparation means less waste and less worrying for you and your team. Although it can be a challenge, we think you're up to it.

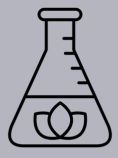
The FDA and other regulatory sources can often seem overwhelming, given the vast amount of information out there. We hope this handbook will provide both clarity and structure to your company's U.S. export strategy. This handbook aims to highlight the key areas of the regulations that your Swedish food company must adhere to, and more importantly, how.

This handbook also covers the new Food Safety Modernization Act (FSMA). These new regulations will have final implementation dates ranging between 2017-2020, depending on the scope of your operations and size of your company.

Who Is The Guide For?

Food Producers

Beverage Producers



Additive Producers

Food Lovers

FDA COMPLIANCE FLOWCHART

1. DO YOUR PRODUCTS FALL UNDER FDA REGULATIONS?

- NO → **STOP:** NO FDA REQUIRED
- YES → COMPLY WITH APPLICABLE REGULATIONS

2. DO YOU MANUFACTURE, PROCESS, PACK, OR HOLD FOOD?

- NO → ENSURE SUPPLIERS THAT DO MEET STEPS 3-5
- YES → ENSURE YOU MEET STEPS 3-8

3. DO YOU NEED TO REGISTER YOUR FACILITY WITH THE FDA?

- NO → NO ACTION REQUIRED
- YES → REGISTER FACILITY & FIND US AGENT

4. ARE THERE ANY SPECIAL PRODUCT REQUIREMENTS?

- NO → NO ACTION REQUIRED
- YES → MAKE PRODUCT CHANGES

5. DO YOUR LABELS MEET FDA REQUIREMENTS?

- NO → UPDATE LABELS
- YES → NO ACTION REQUIRED

6. ARE YOUR INGREDIENTS REGULATED BY THE FDA?

- NO → NO ACTION REQUIRED
- YES → MAKE PRODUCT CHANGES

7. IS YOUR FOOD SAFETY PLAN FDA COMPLIANT?

- NO → UPDATE PLAN
- YES → NO ACTION REQUIRED

8. HAVE YOU SUBMITTED PRIOR NOTICE?

- NO → SUBMIT NOTICE
- YES → NO ACTION REQUIRED

WHAT IS THE FDA?

THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) IS YOUR PRIMARY REGULATORY BODY

The U.S. Food and Drug Administration is responsible for "protecting public health by ensuring the safety" of products including medical drugs, cosmetics, food, and beverages. The FDA does this by, among other things, encouraging medical innovations, disseminating scientific information, and ensuring national security through food and drug safety.

Any organization involved in the production, packaging, labeling, storing, or distribution of food and beverages that will be consumed within the U.S. is required to ensure compliance with FDA guidelines. Compliance may look different for different organizations, however. Specific steps that must be taken by food and beverage manufacturers, such as facility registration, will be outlined further in this document.

Manufacturers do not necessarily need pre-market approval other than following the steps outlined in the rest of this guide. A specific product does not need to be "approved," so to speak, prior to sale in the U.S. market – manufacturers simply need to follow the checklist steps included above and ensure compliance with FDA regulations and guidelines.

However, failure to comply with FDA guidelines and regulations can have serious consequences including warnings, seizure of products, injunction (which may prevent you from engaging in certain activities), and criminal prosecution.

The FDA is a part of the United States Department of Health and Human Services (HHS), and is organized into four major departments. The most relevant of these departments is the Office of Foods and Veterinary Medicines. Within the Office of Foods and Veterinary Medicines, the Center for Food Safety and Applied Nutrition (CFSAN) manages food regulation. CFSAN covers, among other things: food additive safety, food product labeling, international food safety standard harmonization, compliance, regulation of dietary supplements and other medical foods, regulation of and research on food-borne and other contaminants, and biotechnology-developed food and ingredient safety.

The FDA's regulatory authority is granted by several laws enacted by the U.S. Congress.

Comparison Between U.S. and Swedish Agencies

	Food & Drug Administration	Livsmedelsverket
MANDATE	Both bodies focus on protecting national public health	
COVERAGE AREAS	In addition to food and beverages, the FDA regulates drugs and cosmetics	
AUTHORITY	Both bodies are the overarching authority for consumption of food and non-alcoholic beverages	
LEGISLATION	Although laws are determined by external lawmakers (U.S. Congress & the EU), both bodies lobby to influence legislation	
RECOMMENDATIONS	The FDA focuses on sharing important news and alerts, while Livsmedelsverket provides broader dietary guidelines	
CAN YOU COMPLY?	Yes! If you follow the guidelines and are careful about your operations, you will be in compliance with both organizations	

Livsmedelsverket





HOW DO I COMPLY?

COMPLIANCE CAN BE BROKEN DOWN INTO A 6-STEP PROCESS

Although compliance with the FDA is serious business, there is a path to follow to help stay on top of things. There are 6 essential steps you and your organization should be taking before exporting your products to the U.S.

STEP 1 - FDA REGISTRATION

Any organization that manufactures, processes, packages, or stores food destined to be consumed in the U.S. must have a valid FDA registration.

This registration process covers your food facility, ensuring it is entered into the FDA database.

The registration process can be completed online in a few minutes. You can choose to complete the application yourself, directly via the FDA website (link in the Appendix). Alternatively, you can choose to have a 3rd-party provider like Registrar Corp support you in the application process (link in the Appendix). Taking advantage of 3rd-party providers offers additional support

for some of the remaining six steps.

In order to register, you will need to provide information from three categories: Facility Information, Contact Information, and Product Information.

Facility Information requires inputting basic details such as your facility's listed name, trade name, physical address, phone number, and seasonal dates of operation. You will have the opportunity to list alternate mailing addresses or parent company addresses as needed.

Contact Information requires inputting an emergency contact person, as well as the details of your registered U.S. agent. Your emergency contact will always be your U.S. agent. You can find more information about U.S. agents in the next step.

Finally, Product Information requires inputting details about your product lines. You will first need to designate if your products are for human or animal consumption. In addition, you will need to identify the broad category into which your products fall, such as Grain Products, Alcoholic Beverages, or Candy Without Chocolate.

Facility registration must be updated every even-numbered year during the October to December registration period. Make sure to put a reminder in your calendar for each biennial autumn!

Registering Your Facility

How to Register:

- Directly through the FDA website

OR

- Through a 3rd-party agent

Information You'll Need:

- Facility information
- Contact information
- Registered U.S. agent

When to Register:

- Before exporting!

AND

- Every two years for re-registration

STEP 2 - U.S. AGENT

A U.S. agent is required for all foreign companies exporting to America - including your company. Agents act as your local representative to the FDA. They will communicate any pressing needs to you, including upcoming audits or any information the FDA may be missing from you. Picking a trustworthy agent is very important.

As mentioned above, in order to register your facility with the FDA, you must already have an agent in place. Your agent can take care of facility registration on your behalf, or you can simply note the agent's information as you complete the registration.

There are many agents available within the U.S., although some are more reputable than others. Contact us for our thoughts on a trusted partner.

Fees for an agent typically cost between 400-600 USD annually. Include this cost into your overall export budget to avoid any surprise discrepancies.

STEP 3 - LABELING

U.S. food labels differ in several ways from European labels. Nutrition facts and labeling must meet FDA regulations to avoid being denied entry into the U.S.

One of the main difference between EU and U.S. food labels is the basis used for nutrition calculations. U.S. serving sizes are based on "reference amount customarily consumed," typically referred to by the acronym RACC. This represents the average serving size the typical American will consume in one sitting, and has no relation to the 100g basis used in the EU. Note that RACC is not a recommended serving size, no matter what many Americans may assume.

Percent daily value figures are calculated using the product's RACC value. Each % figure is based on a recommended intake value for that specific ingredient. Note that these

recommended intake values are different from EU values, so be sure to adjust your calculations accordingly.

Larger packages that are likely to be consumed in one sitting should have dual labels. The first label should indicate the nutrition facts for one serving size, while the second label should list nutrition values for the entire package.

There are 8 allergens that must be declared on U.S. labels, as compared to the 14 required within the EU. These eight are: milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.

You must declare the country of origin of the product in an obvious manner. This is typically agreed to mean that it must be comparable in size and lettering to the listed distributor's information.

Unlike Europe, food additives must be listed as their common name. For example, what is called E469 in Sweden needs to labeled as Sodium Caseinate.

Finally, all labels need to be in English.

If you sell ingredients to the U.S. for further processing, you will instead need to comply with bulk labeling regulations.

Label Compliance 101

Serving Sizes

- Based on RACC
- Not a recommended serving size

% Daily Value

- Calculated using RACC
- Recommended intake differs from EU

Dual Labeling

- First label for one serving size
- Second label for entire package

Allergen Declarations

- Milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, & soybeans

Country of Origin

- Prominent, clear, and in English

STEP 4 - INGREDIENT REVIEW

Ingredients that are allowed in the EU can be prohibited in the U.S. An ingredient review must be conducted prior to shipping in order to avoid regulatory action. Although European regulations generally tend to be more restrictive compared to FDA regulations, there are certain ingredients more tightly controlled in the U.S.

Always review the status of your ingredients as early in the process as possible. Although your products may not be allowed for sale in the U.S. in their current state, you may be able to make modifications to the recipe to meet FDA regulations. If your product contains banned ingredients, ensure they do not show up on American shelves to avoid any issues.

Food additives, including flavors and colors, must either be FDA approved or listed as Generally Recognized as Safe (GRAS). Certain colors and flavors allowed in the EU are banned in the U.S.

The FDA provides a full list of regulated ingredients (link in Appendix). Note that even though an ingredient is not banned, it may still be regulated to some extent. Ensure that you are within allowed ingredient levels and meet standards for all regulated components.

STEP 5 - FOOD SAFETY PLAN

The new Food Safety Modernization Act (FSMA) is shifting the FDA's role from a "responsive" entity to a "preventative" entity.

As part of FSMA, any facility registered with the FDA must have a written food safety plan. The U.S. has specific requirements for content and terminology within this food safety plan, which differ from other global food safety standards.

In other words, even if your food facility

Food Safety Definitions

HACCP

Hazard Analysis & Critical Control Points

- Globally recognized, but insufficient for the U.S.
- Part of ISO 22000 and BRC Global Food Safety Standard

HARPC

Hazard Analysis & Risk-Preventative Controls

- The American food safety plan mandated by the FDA
- An updated version of HACCP as a result of new FSMA regulations

FSMA

Food Safety Modernization Act

- Latest food regulation in the U.S., consisting of 7 major rules
- Shifts the FDA's role from responsive to preventative

PCQI

Preventative Controls Qualified Individual

- Person overseeing FDA compliant food safety plans (HARPC)

is following ISO 22000 or BRC global standards (and you have an HACCP plan in place), you still need to update your food safety plan to meet FDA requirements.

U.S. food safety plans are referred to as HARPC (Hazard Analysis and Risk-Based Preventive Controls). HARPCs contain several additions to Europe's food safety plan, HACCP.

This is important. Even if you have a compliant HACCP plan, you still need to develop an updated food safety plan for your U.S. sales.

The good news is that if you already have an HACCP in place, you've already come a long way towards meeting U.S. food safety regulations. In fact, you can use the same format and documentation as your HACCP plan, and even use it as the foundation towards building your U.S. food safety plan, HARPC.

Although chances are good you're familiar with HACCP, let's briefly review this system before comparing it to a HARPC food safety plan.

HACCP OVERVIEW

An HACCP plan consists of 12 parts: five preliminary steps followed by seven principles.

PRELIMINARY STEPS

1. Put together an HACCP team
2. Describe your product
3. Identify use of product
4. Create a flow diagram
5. Confirm flow diagram on site

These preliminary steps create the base on which the remainder of the HACCP is built. Actions you take follow the remaining seven principles.

PRINCIPLES

1. Conduct hazard analysis
2. Determine critical control points (CCPs)
3. Establish critical limits for all CCPs
4. Develop monitoring system for each CCP
5. Establish corrective actions
6. Develop verification procedures
7. Establish documentation and record-keeping procedures

HARPC COMPARISON

An FDA-compliant food safety plan (HARPC) is very similar to an HACCP plan. However, there are subtle differences between the two. Here is what you need to be aware of.

A major difference right away is that HARPC does not contain any separate preliminary steps. You'll notice, however, that some aspects of the HACCP's preliminary steps are included in the seven steps of the HARPC plan. We recommend still using the HACCP preliminary steps as a platform for your HARPC plan, much as you currently do in Sweden.

PRINCIPLE 1: Hazard Analysis

HARPC and HACCP both require analysis of similar hazards. Generally speaking, HARPC requires a broader analysis.

For example, HARPC includes radiological hazards and economically motivated hazards, while HACCP does not. In addition, HACCP only requires investigation of "reasonably likely" hazards, while HARPC broadens this to include "known" and "reasonably foreseeable" hazards.

PRINCIPLE 2: Critical Control Points

Although HARPC requires establishing controls at critical steps, it also requires the implementation of four preventative controls. The first three of these preventative controls are built on specific components of your food's creation: the processes of making the food (e.g. cooking, refrigerating), the identification of food allergens, and the implementation of sanitation procedures.

The fourth preventative control broadly covers any other control point not covered in previous control points, but which you identify as being necessary to minimize any additional potential hazards.

Although some of these control points may have already been covered in your HACCP plan, such as sanitation, you need to ensure that you explicitly cover these preventative elements in your HARPC plan.

PRINCIPLE 3: Critical Limits

Critical limits correspond to the control points created in the previous principle. These limits are typically numerical values like temperature or parts per million.

However, since HARPC includes preventative controls, which occur before measurement is possible, numerical values may not always be applicable. As a result, HARPC refers to these critical limits as "parameters" instead.

For example, when examining a sanitation preventative control, a parameter might be "visibly clean." This has no clear numerical value, but provides a guideline for ensuring the critical limit is met. You might also use the parameter "label correctly lists applicable allergens" for your allergen control point.

PRINCIPLE 4: Monitoring System

Under HACCP, these systems are typically summary tables describing how to handle controls and critical limits. For example, it might detail how often you monitor a CCP, what the critical limit is, and what the corrective action is.

Under HARPC, this process is essentially the same. However, they are referred to as implementation procedures.

If you identify a hazard that requires a preventative control, and the corrective action will take place in your broader supply chain (not in your facility), you must institute a supply chain program.

This program will ensure that raw materials come from compliant suppliers. If materials come from non-compliant suppliers, a separate verification procedure is required.

PRINCIPLE 5: Corrective Actions

These actions describe what to do with a product if the process gets out of control. HARPC allows for two corrective actions: simple "corrections" and more involved "corrective actions."

Corrections differ in the sense that they are things that can be taken care of immediately. An example could be the critical parameter "visibly clean." If dust is seen in a corner of a room, this can be cleaned up immediately under HARPC. Importantly, this doesn't require a formal corrective action with the related documentation.

When corrective actions occur, a recall may be required. As such, under HARPC you need to have a recall plan in place as part of your Corrective Action principle. The plan should include communication strategies for the associated parties and to the general public. It should also contain a method for properly disposing the recalled product. Finally, you'll need a method to make sure the recall was effective.

PRINCIPLE 6: Verification Procedures

Under HACCP, there is no specific timeframe for the reanalysis of your procedures. HARPC, on the other hand, requires that you check back on your processes every three years.

PRINCIPLE 7: Verification

Lucky for you! This component is the same under HARPC and HACCP.

OTHER DIFFERENCES

There are a few more differences that require your attention as you work to become HARPC compliant.

While HACCP is a voluntary standard, HARPC is mandatory. In order to be FDA compliant, you must be in alignment with HARPC principles.

The HACCP seafood and juice standards are a major exception to this, since they are not voluntary. However, within HARPC there are no particular requirements for seafood and juice - you can simply rely on your HACCP plan.

In addition, HARPC food safety plans are required even if no hazards requiring a control are identified.

Finally, while HACCP standards require a team to remain compliant, HARPC compliance only requires one individual, known as a PCQI. this person does not need to be employed by the company, but needs to have direct experience with the standards. You should ideally seek out a PCQI that is certified to avoid any issues.

We recommend having a third party, review your HACCP plan to identify what areas require adjustment in order to meet FDA regulations.

Food Safety Plans

PRELIMINARY STEPS

1. Team Creation
2. Product Description
3. Product Use ID
4. Flow Diagram Creation
5. Flow Diagram Confirmation

EU Plans Only

Some parts of these steps can be found in the US principles below

PRINCIPLES

1. Hazard Analysis	• US requires stricter analysis
2. Critical Control Points	• US requires additional preventative controls
3. Critical Limits	• EU & US share same basic processes
4. Monitoring System	• EU & US share same basic processes
5. Corrective Actions	• US allows for more flexible corrections
6. Verification Procedures	• US requires scheduled verification
7. Verification	• EU & US share same basic processes

STEP 6 - PRIOR NOTICE

The final step on your journey to compliance is an important one, but luckily, also the most straightforward.

All food and beverages exported to the U.S. require prior notice. Different modes of transportation have different timing requirements: road requires notice at least 2 hours prior to arrival, rail and air four hours, and 8 hours by boat. Prior notice can be filed on FDA's website free of charge (link in the Appendix).

Products arriving in the U.S. without prior notice will be denied entry.

As we have hopefully demonstrated, the steps you need to take to become FDA compliant are relatively straightforward. As long as you are following the guidelines, noting major changes from European standards, and making adjustments to your labels or packaging as appropriate, you will likely be just fine.

If you have any questions or concerns about your ability to become FDA compliant, we are here for you! Please don't hesitate to reach out to our team to formulate a plan that suits your needs. We'll ensure you are on a path to success with the FDA and in the U.S.

WE ARE HERE TO HELP YOU FIND REGULATORY SUCCESS IN THE U.S.

SPECIFIC REGULATIONS

DOES YOUR PRODUCT CATEGORY HAVE SPECIFIC FDA REQUIREMENTS?

In addition to the top-level rules that are applicable to all food & beverage categories, the FDA also regulates some product categories in more specific ways.

It is important that you take the time to audit your product portfolio to ensure these fine-grained requirements don't slip through the cracks.

Acidified and Low-Acid Canned Foods

Foods in this category have a finished pH equilibrium greater than 4.6 and a water activity level greater than 0.85 (low acid), or a pH equilibrium less than 4.6 and water activity level greater than 0.85 to which acid has been added (acidified). If you manufacture products in this area, you must obtain a Food

Canning Establishment (FCE) license. In addition, FDA requires you to file documentation with their office for each of the canning or acidification processes you use. Each of these filings receives a unique SID (submission identifier) number. You will need to note your SIDs on your Affirmation of Compliance Cod) form when exporting this product category to the U.S.

Affected Items:

Canned products

Acidified products

Required Actions:

- FCE license
- FDA filings
- AofC form

Dietary Supplements

The FDA defines dietary supplements as edible products that have one or more of the following "dietary ingredients":

- Vitamins
- Minerals
- Herbs/botanicals
- Amino acids
- Products intended to increase total dietary intake
- A concentrate, metabolite, constituent, extract, or a combination of any ingredient mentioned above

You can compare dietary supplements to conventional food, which is "consumed for taste, aroma, and nutritive value."

Labeling requirements for dietary supplements differ somewhat from conventional labels. To begin with, dietary supplements may NOT be listed on standard nutrition labels. Instead, they should be listed on separate "Supplement Facts" panels.

Supplement facts panels should not list reference daily intakes (RDI), daily reference values (DRV) or any "zero amounts" of nutrients. All of these elements are required for conventional labels.

You are allowed to list the source of dietary ingredients on supplement facts panels, but make sure not to do so on standard nutrition labels - this is not allowed. If you do include an ingredient's source in the supplement facts panel, note that you do not need to also include this information in the "ingredient

statement" portion of your label.

Finally, dietary supplement information must include the part of the plant from which the supplement is derived. This should be included in the supplement notes, not the standard label.

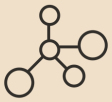
Dietary supplements must not be labeled or advertised in such a way as to suggest that the product can treat, diagnose, prevent, or cure disease. If these claims were made, the product would be classified as a drug by the FDA, requiring costly and slow drug approval.

Affected Items:


Vitamins


Minerals


Herbs / botanicals


Amino acids


Appetite accelerants


Combos of the others

Required Actions:

- Supplement Facts labels
- Identify part of plant from which supplement is derived
- Supplement source (optional)

Infant Formula

The safety procedures and regulations for the production of infant formula are stricter than those for conventional food. Along with the basic standards that other food has to meet, manufacturers of infant formulas must also meet additional requirements.

Although no prior market approval is required before selling a new infant formula, the FDA conducts annual inspections of all formula manufacturers. During these inspections, agents will . analyze product samples for safety and regulatory checks.

Infant formula requires specifically designed "good manufacturing" practices. As part of these practices, you will need to conduct tests for both Salmonella and Cronobacter.

In addition, you will need to demonstrate that the formula "supports normal physical growth." The specific details required for this demonstration can be

investigated in detail on FDA's infant formula page (link in Appendix). If you choose to adjust your formula, you must provide prior notification to the FDA and samples of the new product for testing.

Affected Items:

Infant formula

Required Actions:

- Meet FDA food standards
- Good manufacturing practice
- Proof of normal physical growth
- Prior notification for changes

Juice & Seafood

Juice and seafood producers are required to comply with HACCP (European) regulations. They are exempt from the new FSMA regulations, including the requirements for updated food plans and HARPC compliance.

Affected Items:

Juice

Seafood

Required Actions:

- Comply with HACCP regulations
- Ignore FSMA requirements

GOOD THINGS TO KNOW

FOR ALL THOSE PIECES OF INFORMATION THAT DON'T FIT NEATLY INTO A CATEGORY

WHAT ABOUT PRODUCT SAMPLES AND TRADE SHOWS?

Food and beverages that arrive to be used for trade shows in the U.S. (even as samples) must still comply with all FDA regulations. There are several regulatory steps manufacturers must take prior to entry.

Manufacturers or their customs brokers may need to appoint a Foreign Supplier Verification Program (FSVP) Agent for the entry of such samples, unless there is a U.S. purchaser/owner whose name can be used on import documentation. Several third-party regulatory consulting firms, such as Registrar Corp, offer FSVP services for trade show and sample shipments.

U.S. trade shows require companies to submit information prior to exhibiting to ensure that their labels and ingredients are in accordance with FDA regulations. If your samples are not in full compliance with FDA regulations, FDA

may still release the products on the request of the importer. Released products may only be used for the purpose of exhibition. At the end of the exhibition, they must be re-exported or destroyed under supervision by an FDA official. Requests of this nature are evaluated on a case by case basis.

DO YOU NEED TO COMPLY IF YOU ARE ONLY SENDING FOOD TO THE U.S. FOR PRODUCT TESTING?

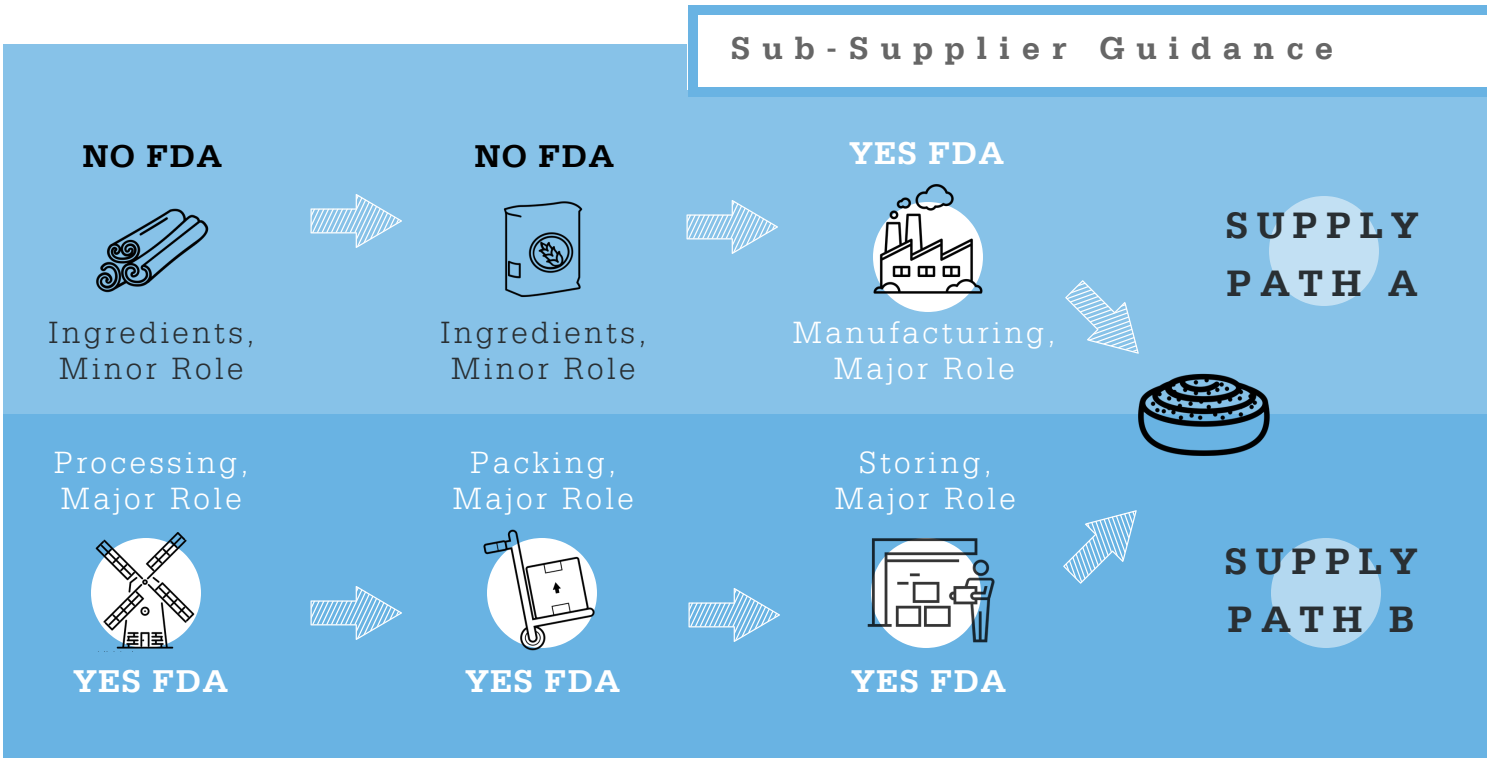
Nope! Companies that send samples to the U.S. to be tested for research only - not to be consumed within the U.S. - do not need to comply with most FDA regulations. The one exception is Prior Notice, which must be provided before the product(s) arrive at the American border. We highly recommend clearly marking all labels with text stating that the products are not intended for general consumption and that they will be used solely for lab tests in the U.S.

IF YOU HAVE AN ISO 22000 CERTIFIED FACILITY, DO YOU STILL NEED A U.S. FOOD SAFETY PLAN?

You will most likely need to add certain elements to your food safety documents and procedures in order to meet FDA's requirements, even though ISO 22000 is recognized globally and is considered to be comprehensive. For example, ISO 22000 does not require you to verify your supply chain, which is required by FDA. We recommend having your food safety documentation reviewed by a third party to map out any missing parts and to minimize non-compliance risks, should FDA decide to audit your facility.

IF YOU USE SEVERAL SUB-SUPPLIERS, DO THEY ALL NEED TO BE FDA COMPLIANT?

The answer is: it depends. If you use sub-suppliers for ingredients, but have one facility that handles the majority of the production process, typically only this final facility must be registered with with FDA. However, if there are several manufacturing facilities that all play a major role in the processing, packing, or storing of the products, they will likely all need to meet FDA regulations.



DO YOU NEED TO REGISTER YOUR FACILITY IF YOU USE A CONTRACT MANUFACTURER?

Unless you process, store, or repack food or beverages to be sold for human or animal consumption, you should not register your facility with FDA.

Although you could, since FDA can't prevent you from registering, if they were to review your company and see that you do not conduct any of the previously described activities, they would likely cancel your registration.

The correct way to handle FDA registrations in this scenario is to ensure that your contract manufacturer has a valid FDA registration and food safety documentation for their production facility, and use their registration number for your company's U.S. activities.

WHAT HAPPENS IF YOUR CONTRACT MANUFACTURER DOES NOT WANT TO COMPLY WITH FDA REQUIREMENTS?

Your option here is to either convince your contract manufacturer to change their mind, or find another manufacturer who is willing to comply with FDA

regulations. If you were to ship products to the U.S. that were manufactured in a facility that is non-compliant with FDA regulations, you could be facing serious FDA enforcement challenges. It is also important to note that the FDA reviews compliance on an ongoing basis. You may already export products to the U.S., even though you don't have all the proper documentation in place. Maybe FDA hasn't bothered you so far. However, if FDA were to review your company, you'd be in trouble. It's better to review your procedures and documentation early on to minimize non-compliance risks.

WHAT ABOUT FOOD FOR PERSONAL CONSUMPTION?

Travelers can generally bring food into the U.S. that is not for resale through a relatively simple Customs & Border Patrol (CBP; equivalent to Tullverket) process. Upon entry into the U.S., travelers must declare all food products, and certain food products may be prohibited or may require further steps for compliance.

Processed foods such as snacks and bakery items, condiments, oils, non-meat canned goods, juices, tea, spices, and candy are generally admissible. Fruits, vegetables, cheese, meat, poultry and other fresh products or products of animal origin may be prohibited, or may require further inspection due to the risk of disease spread.

It is wise to visit the CBP website to double check rules and regulations (link in the Appendix).

PRODUCT ORIGIN - DOES IT MAKE A DIFFERENCE?

A product and its manufacturer are subject to FDA guidelines (and those of other relevant agencies) if the product is sold or distributed in the U.S. for consumption - regardless of where the product originated or where it was packaged.

When ingredients are manufactured in Sweden and shipped to the U.S. for final manufacture, a U.S. agent is required. The Swedish manufacturing facility is required to meet all FDA regulations, as are all ingredients destined to enter the U.S. There are special bulk labeling regulations that apply to these ingredients.

Final products manufactured in Sweden and shipped to the U.S. must meet all of the same requirements as above. The major difference is that these products must meet consumer packaging regulations.

Finally, if all manufacturing is completed within the U.S. via a subsidiary, a local agent is no longer required. The facility must be registered with the FDA, and all ingredients and final products must meet FDA regulations.

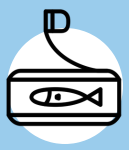
SWE

USA

Export Ingredients to U.S. for Final Manufacture

- U.S. agent and prior notice required
- Facility & ingredients meet FDA regulations
- Bulk label regulations apply

SWE



USA

Manufacture in Sweden & Export to U.S.

- U.S. agent and prior notice required
- Facility & ingredients meet FDA regulations
- Consumer packaging label regulations apply

SWE

USA

Manufacture Via U.S. Subsidiary

- U.S. agent and prior notice NOT required
- Facility & ingredients meet FDA regulations
- FDA inspections unannounced

INGREDIENT VS. PRODUCT - DOES IT MAKE A DIFFERENCE?

Regardless of whether a product is an ingredient or end-product, the manufacturer must comply with FDA regulations. For example, a sweetener being sold within the U.S. is just as subject to FDA guidelines as is a packaged product that uses the sweetener as one of its ingredients.

The FDA does regulate new food additives. Thus, if a food manufacturer is using an additive (such as a sweetener) in their product that has not been previously approved by the FDA, the food additive must go through the testing and approval petition process.

The Food Additive Status List on the FDA website provides information for additives that have been proven safe for use; the information can also be found in Title 21 of the U.S. Code of Federal Regulations (link in the Appendix).

During the petition process, the FDA evaluates all scientific evidence about the ingredient, its proposed use, and other characteristics. The process can take several months to a few years.

Once a final rule is written for an additive, the agreed upon safe level of use is permanently added into CFR Title 21. Anyone who wishes to add that ingredient in compliance with that regulation is able to do so.

FOUR QUESTIONS FOR:

Mike Messersmith
General Manager,
Oatly USA

A SWEDISH ORIGINAL

What has it been like working with the FDA?

The FDA can certainly be overwhelming for small companies, considering the breadth of standards and how to apply those regulations. Since the regulatory environment in the U.S. is fluid - things change - the idea that we would be able to manage that on our own would be setting ourselves up for failure. So ensure that you're consulting with experienced partners who can help you navigate the process.

What misconceptions do Swedes have about the U.S. market?

One misconception is that the threat of a robust regulatory environment is an insurmountable obstacle. If you're operating out of that fear, then you need to do the diligence to understand the risk factors before coming to that conclusion. Dismissing the U.S. and pursuing a market that doesn't have this scope of opportunity because of concerns about compliance would be doing a disservice to your business.

In addition, not all regulations have to be black and white. The government leaves areas open for interpretation on purpose.

Do you have any pointers for new entrants?

When it comes to language and packaging for example, you can't assume that how it works in your home market will be acceptable in the U.S. This is a very fluid regulatory environment, with identity and claims on packaging for example, so it's important to have partners regularly check things - to have a fresh set of eyes.

Also, understand that if you are making health, nutritional, or efficacy claims on your products, the releated standards are different in the U.S. than in the EU. You need to really understand the nuances of how this relates specifically to your business - but this can also be a tremendous opportunity for your company.

What do you recommend for Swedish food manufacturers?

It's best to find partners who specialize in understanding the landscape to help you assess risk - to help you adapt your strategy to ensure you are on the right side of compliance. So, find great partners who can take a holistic approach.

FIND PARTNERS WHO SPECIALIZE IN UNDERSTANDING THE LANDSCAPE

RISKS OF NON-COMPLIANCE

IN CASE YOU EVER SLIP UP, THIS IS WHAT YOU CAN EXPECT FROM THE FDA

Although we're certain that you'll take every precaution necessary to ensure you remain compliant with FDA regulations, there are naturally instances where companies slip up. The FDA uses five primary tools of enforcement in case regulations are not followed.

1. FACILITY INSPECTIONS

The FDA may make unannounced facility inspections based on food safety concerns or alerts, but the agency is also increasing routine inspections for foreign food facilities as a part of the Food Safety Modernization Act. The purpose of inspection is to ensure facility compliance and prevent food safety issues prior to consumption in the U.S.

All manufacturing facilities may be inspected - even yours in Sweden. For international facilities, the FDA will always inform your U.S. agent about the visit beforehand. This is a great reason to have a dependable agent on your

side! U.S.-based facilities do not benefit from advance warning for their inspection visits.

2. IMPORT REFUSAL

The FDA may also refuse entry into the U.S. for products that don't meet regulatory requirements.

Import refusals at the border are considered a final decision from the FDA that a shipment is not in compliance and must be destroyed or exported. Import refusals typically occur after the FDA has notified a manufacturer that their product is not in compliance, or because a manufacturer failed to demonstrate a useful remedy to a violation.

3. FACILITY SUSPENSION

In cases where the FDA believes a product has a reasonable probability of causing harmful health effects, the facility in which the product was manufactured is at risk of having its registration suspended. In addition to the suspension of facilities involved in the manufacturing of unsafe products, the FDA may also suspend facilities that knew about adverse health effects or that stored/packaged the food.

Facilities may have some recourse, however. They may be able to participate in a hearing and submit a corrective action plan to eventually have their facility registration reinstated. This process is at the discretion of the FDA.

4. ALERTS & WARNINGS

Import alerts create a trigger so that products may be detained without physical examination. They are triggered when the FDA has evidence that a product is not in compliance with regulations and guidance, either through investigation, tips, or other means.

Import alerts are maintained publicly on the FDA website, so that consumers and individuals throughout the supply chain can remain informed. Alerts can vary in size, and they may pertain to a specific

manufacturer or products from an entire product, country, or region. Manufacturers subject to import alerts or detention are able to petition the FDA through a hearing process and by providing evidence of food safety and regulatory compliance.

If all else fails, warning letters may be sent to the manufacturer. These letters are the last caution before legal actions are undertaken.

5. CIVIL & CRIMINAL PENALTY

In cases of continued non-compliance, despite attempts by the FDA to improve the situation through the previous four steps, the manufacturer will become susceptible to legal action.

Such penalties often involve either fines or prison sentences, which can vary depending on the manufacturer's intent to commit fraud and the nature of the food safety issues. Criminal and civil penalties are less common than other penalties because they generally require repeated offenses with intent to break the law, despite FDA warnings.

You should alway avoid violating FDA regulations. If you accidentally become non-compliant, make sure to seek quick remedies and let the FDA know.

STAKEHOLDER OVERVIEW

WHO ARE THE STAKEHOLDERS YOU NEED TO BE AWARE OF IN THE U.S.?

The FDA

As we have already discussed above, the FDA is a broadly focused regulatory agency covering food, beverages, medical drugs, and cosmetics. If your products fit into one of these categories, you can be assured that there are FDA regulations that apply to you.

FDA Affected Items:

The U. S. Department of Agriculture (USDA)

The USDA is an agency that oversees activities within agricultural, food, and rural categories. It's closest Swedish equivalent is Jordbruksverket. Within its mission, USDA has a strategic goal to "provide all Americans access to a safe, nutritious, and secure food supply." The FDA and the USDA have a formal agreement that clearly distinguishes which agency is responsible for specific products. They work in tandem to cover food holistically.

In general, the USDA oversees poultry (any domesticated bird), red meat (such as cattle, sheep, swine, and equines), and some egg products (such as dried, frozen, or liquid), as well as egg product plants.

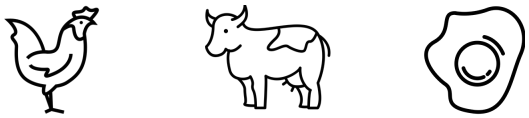
To fill in the gaps within these categories, the FDA is generally responsible for non-specified poultry (such as wild turkeys), non-specified red meat (such as bison, rabbits, moose, and zoo animals), and shell eggs (of chicken, turkey, geese, etc.).

Deciding whether the FDA or the USDA is more appropriate for your product lines can be confusing. The specific jurisdictions are as follows:

FDA: products with less than 2% cooked poultry meat and less than 10% cooked poultry skins, giblets, fat, and poultry meat; products with less than 3% raw meat, less than 2% cooked meat or other portions of the carcass, or less than 30% fat, tallow, or meat extract.

USDA: products 2% or more cooked poultry and more than 10% cooked poultry skins, giblets, fat, and poultry meat; products with more than 3% raw meat, 2% or more cooked meat or other portions of the carcass, or 30% or more fat, tallow, or meat extract.

USDA Affected Items:



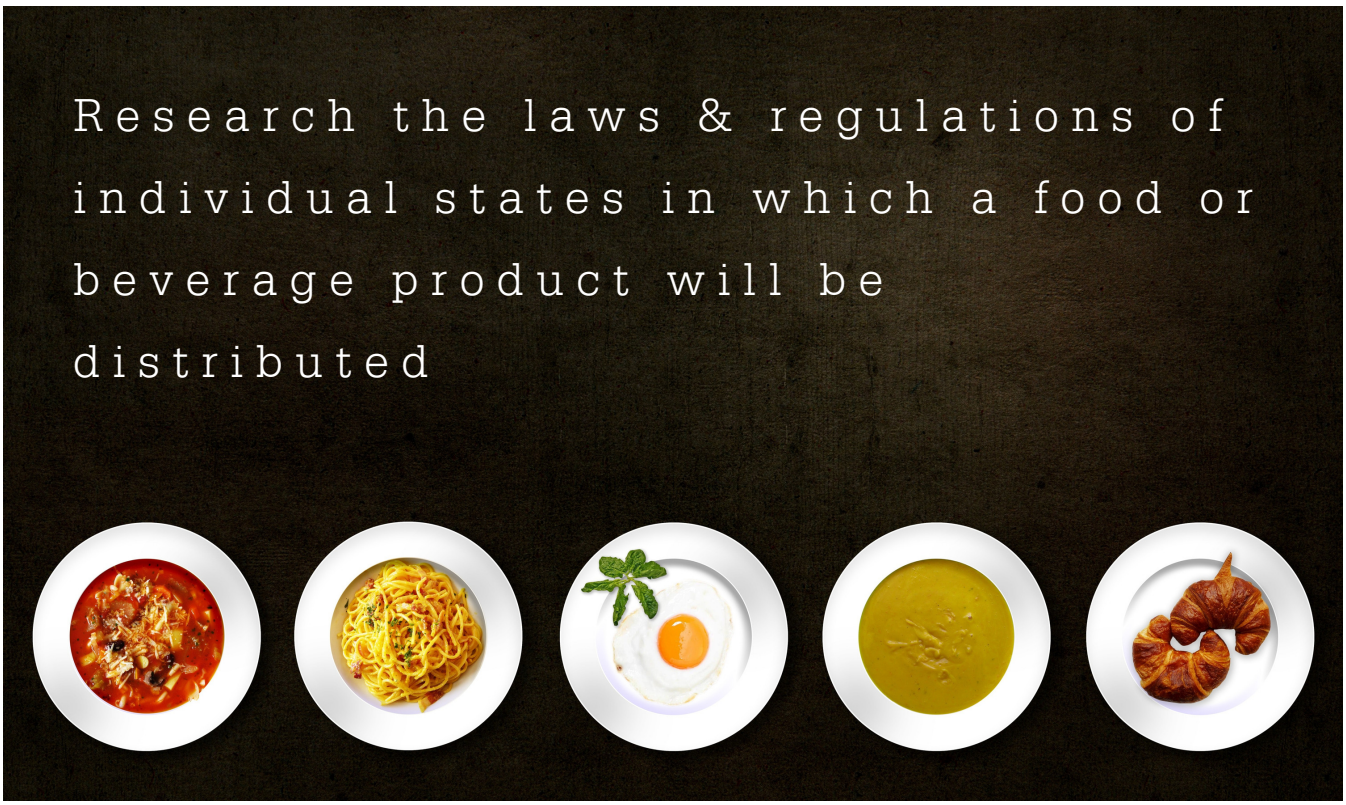
U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB)

The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) falls under the U.S. Department of Treasury. The Bureau has a mission to both collect excise tax on alcohol, tobacco, and firearms and to oversee compliance with, among other things, regulations for alcohol labeling, marketing, and permitting.

TTB and the FDA have a formal agreement clarifying roles; the FDA determines which ingredients are allowed in food and beverage products, while TTB's Beverage Alcohol Laboratory analyzes products for prohibited ingredients, enforcing FDA guidance.

Producers of wine, spirits, and malt beverages should look to TTB's Federal Alcohol Administration Act, which sets guidelines for alcohol advertising, labeling, and packaging. It is also important to look to individual state alcoholic beverage laws, which can be found by researching guidance set by the state's alcohol beverage control board or department.

TTB Affected Items:



U.S Customs & Border Patrol (CBP)

U.S. Customs and Border Protection is a law-enforcement agency responsible for "facilitating lawful international travel and trade." It is similar to Tullverket in Sweden. CBP has a number of guidelines for import processes, in addition to suggestions for compliance (including required documentation).

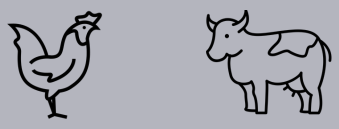
All imports must comply with CBP processes and regulations, and a basic introduction can be found on the CBP website (link in the Appendix).

It is sometimes useful to contact the port of entry through which a shipment will pass to discuss specific documentation and other requirements. Contact information for ports of entry can be found on the CBP website (link in the Appendix).

Affected Items:

Which U.S. Stakeholder Is Right for Me?

FDA



USDA

TTB

CBP

WHAT ARE YOUR NEXT STEPS?

HOW CAN WE HELP YOU GET YOUR FOOD/ BEVERAGE ONTO AMERICAN SHELVES?

Business Sweden is happy to offer turnkey FDA compliance support for Swedish food and beverage companies exporting to the U.S.

By providing overviews, trainings, and complete compliance checks, we help minimize your company's American regulatory risk. We identify regulatory areas that must be covered while providing full compliance along each and every step. Our goal is to shorten your path to this lucrative market while increasing your revenue.

Business Sweden can help support you in every aspect of your FDA journey. Whether you are starting from scratch, trying to identify the regulatory steps required for your organization, or if you simply need help reviewing your current labels and food safety plan, we are here to help.

Our services start at the FDA registration stage. We'll ensure your facility is

Business Sweden's Turnkey FDA Offering

Regulatory Analysis

- Evaluation of key stakeholders
- Overview of regulations

Regulatory Compliance Support

- Comprehensive compliance support
- Ranges from small projects to full service

Regulatory Staff Training

- Day of training led by expert
- Targeted to your company's needs

properly registered, and you'll be informed of any next steps you need to take. As part of this process, we are excited to offer the services of our FDA partner as your registered U.S. agent. Their expert handling of all your local FDA needs will ensure you can focus on your local operations.

In addition, we offer labeling compliance and ingredient review. Each of these tasks will ensure none of those little details fall through the cracks.

We are very happy to offer full Food Safety Plan writing and review services by a certified PCQI professional.

As a final step, we'll make sure all prior notice filings are made to the FDA. With all of the red tape taken care of, you have a green light for success in the U.S.

Reach out to our team today to set up an advisory meeting. Together we can pinpoint the next steps you need to take on your U.S. expansion journey.

Therése Dalebrant
Food & Beverage Lead,
Business Sweden USA
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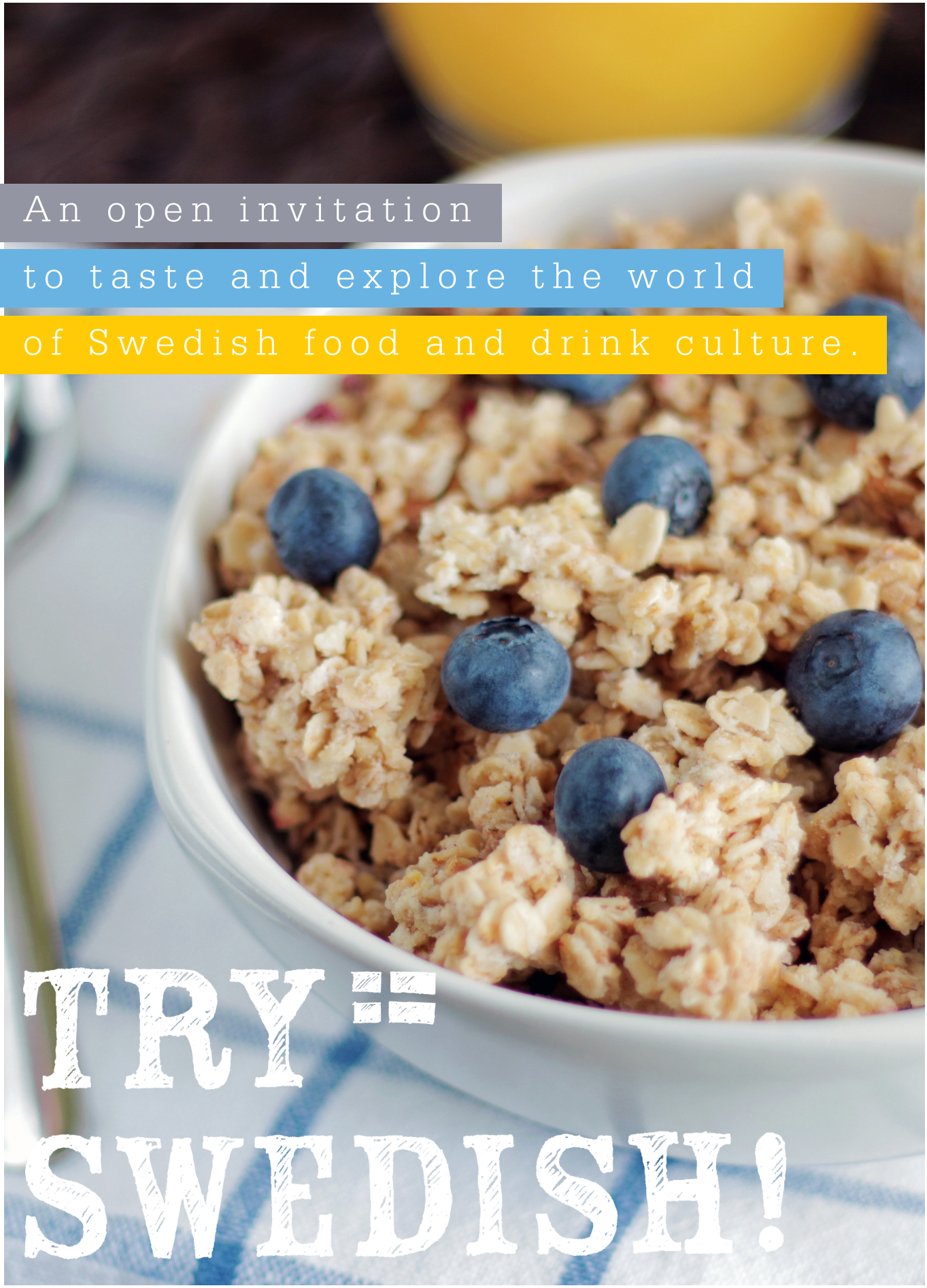
An open invitation
to taste and explore the world
of Swedish food and drink culture.
TRY =
SWEDISH!

GLOSSARY AND APPENDIX

THE LINKS AND ADDITIONAL RESOURCES YOU NEED TO ROUND OUT YOUR KNOWLEDGE

Glossary of Terms and Acronyms

Business Sweden

Shortens time to market and maximizes international revenue for Swedish companies.

CBP

U.S. Customs and Border Protection

U.S. governmental department that regulates international trade.

CFSAN

Center for Food Safety and Applied Nutrition

Branch of the FDA that regulates food, beverages, dietary supplements, and cosmetics.

FDA

U.S. Food and Drug Administration

U.S. governmental department that regulates food, beverages, pharmaceuticals, and cosmetics.

FSMA

Food Safety Modernization Act

Legislation that awards the FDA increased preventative regulatory power to the FDA.

FSVP

Foreign Supplier Verification Program

Rule that requires importers to verify FDA compliance for all foreign suppliers of food. Required for FSMA compliance.

GRAS

Generally Recognized as Safe

Acronym used by the FDA to designate chemicals or substances that are considered safe to add to food or beverages.

HACCP

Hazard Analysis Critical Control Point

Guidelines for EU-based food safety plans

HARPC

Hazard Analysis and Risk-Based Preventative Controls

Guidelines for U.S.-based food safety plans compliant with FSMA.

HHS

U.S Department of Health and Human Services

Also known as the Health Department. U.S. governmental department that protects public health.

NFA

National Food Agency

AKA Livesmedelsverket. Swedish Governmental agency that regulates food and drinking water, as well as providing guidelines for healthy living.

PCQI

Preventative Controls Qualified Individual

Trained professional that reviews all HARPC-compliant food safety plans.

RACC

Reference Amount Customarily Consumed

The unit of food used for nutrition labeling within the U.S. Differs from EU measurement baselines.

Registrar Corp

FDA compliance organization.

Try Swedish

Trade organization that facilitates the spread of Swedish food across the globe.

TTB

U.S. Alcohol and Tobacco Tax and Trade Bureau

U.S. governmental department that regulates taxation of alcohol and tobacco.

U.S. Congress

Legislative branch of the U.S. government responsible for most food-related laws.

USDA

U.S. Department of Agriculture

U.S. governmental department that regulates meat, dairy, and egg products.

%DV

Percent Daily Value

Calculation based on RACC to determine nutrient content for labels.

Appendix

CLICK THE HEADER TO VISIT LINK

CBP

Food For Personal Consumption

https://help.cbp.gov/app/answers/detail/a_id/3619/~/travelers-bringing-food-into-the-u.s.-for-personal-use

EU

Food Labels

https://ec.europa.eu/food/safety/labelling_nutrition_en

FDA

Acidified and Low-Acid Canned Foods

https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/acidifiedlacf/default.htm

FDA

Allergens

https://www.fda.gov/food/ingredientspackaginglabeling/foodallergens/default.htm

FDA

Bottled Water and Carbonated Soft Drinks

https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/bottledwatercarbonatedsoftdrinks/default.htm

FDA

Dietary Supplements

https://www.fda.gov/food/dietarysupplements/default.htm

FDA

Food Additive Status List

https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm091048.htm

FDA

FSMA

https://www.fda.gov/food/guidanceregulation/fsma/

FDA

FSVP

https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf

FDA

Infant Formula

https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/infantformula/default.htm

FDA

Juice

https://www.fda.gov/food/guidanceregulation/haccp/ucm2006803.htm

FDA

Nutrition Labels

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

FDA

Prior Notice

https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm

FDA

Product Categories

https://www.fda.gov/iceci/inspections/inspectionguides/ucm114704.htm

FDA

Registration

https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/default.htm

FDA

Seafood

https://www.fda.gov/food/guidanceregulation/haccp/ucm2006764.htm

FDA

Title 21

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Registrar Corp

FDA Registration

https://www.registrarcorp.com/fdaregistration/

THANKS FOR READING!

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