農林水産省補助事業

米国食品安全強化法

総括レポート：食品安全計画のレビュー結果（2017 年度農林水産省補助事業「食品安全計画ワークショップ -FDA 査察に備えて」の報告）（英語原文）

2018 年 3 月

日本貿易振興機構（ジェトロ）

農林水産・食品部　農林水産・食品課

本報告書は、2017 年度農林水産省補助事業「米国食品安全強化法　食品安全計画ワークショップ-FDA 査察に備えて」について「総括レポート：食品安全計画のレビュー結果」としてまとめた報告（英語原文）です。ご利用にあたっては、ジェトロ仮訳もご参照ください。

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ジェトロでは、米国食品安全強化法（FSMA）への対応の参考とすることを目的に本報告書を作成しました。ぜひお役立ち度アンケートにご協力をお願いいたします。

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（https://www.jetro.go.jp/form5/pub/afa/fsma_al）

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【報告書名：米国食品安全強化法「総括レポート：食品安全計画のレビュー結果（2017 年度農林水産省補助事業「食品安全計画ワークショップ-FDA 査察に備えて」の報告）」（英語原文）】

はじめに

米国食品安全強化法（FSMA）の主要規則のひとつである「現行の適正製造規範ならびに危害分析とリスクに基づく予防管理」（PCHF）が 2016 年 9 月に適用が原則開始された。また小規模事業者への適用も 2017 年 9 月から開始された。今後 FDA による査察が施設に入った場合、同規則に対応していないと米国での流通ができなくなる。

ジェトロは、2017 年 12 月、農林水産省補助事業米国食品安全強化法（FSMA）対応支援事業の一環として、「食品安全計画ワークショップ―FDA 査察に備えて」を開催した。本ワークショップは、FSMA および食品製造にかかる危害、食品安全にかかる専門的な知見を有する米国の専門家に、FDA による査察の観点で、各社が作成した文書類（会社概要、製品説明書、フローダイアグラム、および食品安全計画（危害分析表、予防管理計画））を 1 社ずつ個別に確認してもらい、日本の食品製造業者による食品安全計画の整備と査察への対応を促すことを目的とした。米国向けに調味料、菓子、麺等の加工食品等を輸出している企業が全部で 42 社参加した。

各社が作成した食品安全計画に対しては、専門家からはほぼ全ての食品安全計画が「acceptable」と評価され、個別にアドバイスされた。42 社のワークショップ結果を振り返ると、品目や工程にかかわらず、専門家からの指摘は、概ね本報告書でまとめた内容に集約された。FDA が査察で確認するポイントが明確になったことを受け、各社が自社の食品安全計画を改善・完成させていくことが期待される。

本報告書に記載の内容をふまえ、食品安全計画の作成が必要となる日本の食品関連事業者が、各社の食品安全計画を改善していく際の一助として、本報告書をご活用いただければ幸いである。

なお、本報告書は、ジェトロ主催「米国食品安全強化法　食品安全計画ワークショップ―FDA 査察に備えて―」において、委託した米国の専門家がまとめたものである。米国食品医薬品局（FDA）による公式見解を示すものではない。内容の正確性の確認、および助言の採否は、お客様の責任と判断で行っていただきたい。また、お客様に提供した情報および助言の利用に関連して、万一お客様が不利益を被る事態が生じたとしても、ジェトロは責任を負いかねるので、ご了承いただきたい。

2018 年 3 月
日本貿易振興機構（ジェトロ）
農林水産・食品部　農林水産・食品課
シカゴ事務所

MEMORANDUM

January 16, 2018 (Revised March 2, 2018)

During the time frame of December 4 -15, 2017; I met with 43 companies from around Japan to review their Preventive Controls plans for compliance with the USA's Food and Drug Administration's (FDA) "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" regulation. All companies provided copies of their Preventive Controls plan as well as other related document pursuant to instructions from JETRO for review.

Overall, every company met with had a good start to having a preventive controls plan that met the FDA regulatory requirements.[1] There were a few overarching issues that were observed in a majority of companies. While some of these would not cause the plan to be out of regulatory compliance – they could mean that the FDA had broader regulatory authority because of what was placed in the preventive controls plan.

Following are a list of topics where concerns were identified that companies should use when reviewing their preventive controls plans.

Quality Parameters

Many of the product descriptions and hazard analyses had quality parameters included. These ranged from including limits for microbial tests such as Total Plate Counts, generic E. coli and coliforms to including checking sensory characteristics. It is important that all companies keep in mind that a preventive controls plan is a food safety plan – not a quality plan. As long as the product is safe; it doesn't actually matter if it is of poor quality (e.g., misshapen, too dark or light, underweight, etc.), or that microorganisms that may be indications of spoilage or sanitation concerns are present.

Again, it is important to keep these types of parameters separate from the preventive controls plan as if they are included in the preventive controls plan – FDA can regulate on them. For example, if there is a Total Plant Count limit of 100,000 colony-forming units (CFU)/gram and the count comes out at 100,050 CFU/gram and the product is released;[2] FDA could determine that the plan was not followed and adulterated product was released. This would be true even though the 50 additional organisms are meaningless with regards to food safety.

[1] The minimum requirements for the FDA preventive controls food safety plan is detailed in 21 C.F.R. § 117.126.

[2] To even be a meaningful increase in the Total Plate Count – the number would have to be at least a log more (1 x 10^6). And this is generally looked at as an "action" level – meaning it would trigger a review of the operation to determine whether a change had occurred – not that the product was unsafe.

If quality parameters are required – keep them separate.[3] Do not put them in the product description that may be presented with the preventive controls plan. Quality parameters could, for example, be included as part of a product specification – not the product description used with the preventive controls plan. This is true for finished product information as well as parameters that may be required in an ingredient being purchased. The information needed if it is determined that a supplier is controlling a hazard are only related to a food safety hazard – not quality.

FDA Process Filings

A number of companies produce products for export to the USA that fall under the "Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" or "Acidified Foods." While compliance with the first regulation on low-acid foods can be used to support why there are no biological hazards in a preventive controls plan, and compliance with the acidified foods regulation can be used as support for why there may be no biological hazards; compliance with these regulations require that a company file process filings with the FDA prior to producing products for export to the USA.

The USA regulations require that commercial processors of shelf stable acidified foods and low-acid canned foods in a hermetically sealed container that will be sold in the USA to register each establishment and file scheduled processes with the FDA for each product, product style, container size and type and processing method.

> Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF)

The above link provides information on what is required for a process filing for low-acid canned foods (LACF) as well as acidified foods. Additional information on processing filings can be accessed here.

Differences between FSSC 22000, ISO 9001, ISO 14001, and PCHF

Many of the companies have or were close to obtaining certification under one or several private audit schemes available. One thing that all audit schemes requires is procedures and documentation to support that a company is following a procedure. Any company that understands the need for procedures and also documentation will be better-equipped to ensure compliance with the needed programs and procedures required under the PCHF.

However, audit schemes are developed to address specific areas in a company. While compliance with an audit scheme may assist a company with compliance with the PCHF – it is dependent on whether or not the audit scheme addresses PCHF requirements. It is important for

[3] Many requirements in various audit schemes (e.g., ISO, FSSC, etc.) are related to quality and not specifically food safety. While meeting the various audit schemes will meant that the majority of regulatory requirements are met – keep programs and records separate where needed so that the preventive controls plan only contains food safety concerns.

companies to understand how the various schemes relate to the Preventive Controls Human Food regulation (PCHF).

As stated above, compliance with any audit scheme will assist a company as it provides the framework necessary in understanding how to develop programs and procedures and documentation to verify a company is following those programs and procedures. However, if the audit scheme is not related to food safety, such as FSSC 22000 is, then programs and procedure developed for compliance to that audit scheme may not be relevant. Importantly – as a company only wants to include what is required under PCHF – any program not specifically related to a PCHF requirement should not be included in the preventive controls plan as FDA could regulate against it.

FSSC 22000

The FSSC 22000 Food Safety System Certification provides a framework for effectively managing a company's food safety program. It is one of the audit schemes that is fully recognized by the Global Food Safety Initiative (GFSI) and is based on existing ISO Standards. Compliance with the program indicates that a company has a robust food safety management program in place. When a comparison of the various GFSI schemes was done; FSSC 22000 was found to be the food safety audit scheme that would provide the best compliance with all aspects of the PCHF.

ISO 9001

ISO 9001 is an audit scheme that details requirements for a quality management system for a company to:

- demonstrate it can consistently provide products and services that meet customer requirements as well as any applicable statutory and regulatory requirements; and
- effectively applies the system to enhance customer satisfaction including having processes to improve the system and assure conformity to customer and applicable statutory and regulatory requirements.

The requirements found in this audit scheme are generic as they are intended to be applicable to any company, regardless of what it is providing – whether it be a manufactured product or a provided service.

ISO 14001

ISO 14001 provides requirements for an environmental management system that a company can use to improve its environmental performance. It is intended for use by companies that want to use a systematic approach to managing environmental responsibilities. Its requirements are intended to enhance a company's environmental performance and regulatory compliance.

The audit scheme is applicable to any company regardless of what it produces if it determines it can control or influence some environmental aspect. It is designed so it can be used in whole or in part to improve environmental management.

Import Alerts

All products imported and regulated by the Food and Drug Administration must meet the same requirements as those produced domestically. The USA-FDA oversees the import program for these foods. Part of its program includes the issuance of Import Alerts and detention of product without physical examination (DWPE). It is important that companies understand whether or not their product may be subject to DWPE prior to beginning the export process.[4]

Companies can sign up for weekly email notifications from the FDA for its "Import Alerts Weekly Summary."

A list of all of the import alerts can be accessed here. A few key import alerts are discussed below.

> Import Alert 45-02 "Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors"

This import alert was initially issued by the FDA because of the large number of imported products found to contain illegal and undeclared food color additives. The attachment to the import alert identifies manufacturers and products, by country, which are subject to detention without physical examination and the undeclared or illegal colors found in the respective products. Products which contain illegal color additives are adulterated and cannot be reconditioned.

FDA has issued specific regulations on food and color additives. Companies can find information regarding the regulations and guidance on how these are regulated in the USA at the FDA website, "Food Additives and Ingredients." Numerous links are provided with information on approved additives and guidance on the actual approval process. A page with similar information for color additives may be accessed here.

When foods contain European Economic Community (EEC)[5] or other foreign food color designations, FDA will detain them under illegal color charge (1) below. These colors do not originate from FDA certified lots as required by U.S. regulations. When used in foods presented

[4] Import alerts inform FDA field staff as well as the public that FDA has enough evidence to allow for DWPE of products that appear to be in violation of FDA laws and regulations. These violations could be related to the product, manufacturer, shipper and/or other information.

[5] The EEC was a regional organization formed to bring about economic integration among its member states. It was created by the Treaty of Rome of 1957. However, when the European Union (EU) was formed in 1993, the EEC was incorporated and renamed as the European Community (EC). **The FDA has not updated this reference in its Import Alert as yet**.

for entry into the U.S., colors subject to certification must originate from FDA certified lots. If FDA certification lot numbers are provided, the numbers can be confirmed by FDA/CFSAN's Office of Cosmetics and Colors, Color Certification Branch.

With regards to the information:

- The Green List identifies manufacturers and products, by country, ***exempted*** from detention without physical examination of products.
- The Red List identifies firms, countries and/or products that ***are subject*** to detention without physical examination of the product identified in the alert.
- FDA districts may detain without physical examination all products that appear on the alert in the "red list." If the product is shown as containing an illegal color, it will be detained using "charge (1)." If the product is shown as containing an undeclared color additive, it will be detained using "charge (2)."

This latest update to the import alert was published January 11, 2018. It should be noted that new issues are listed upfront without accessing the "red list." Japan has several additions listed with this update:

JAPAN

(28 A - - 19) Ginger, Whole (Spice)
Desc: preserved and/or pickled ginger
Notes: All firms except those listed in Attachment B; S&J Red 106
Problems: 16255-PONCEAU 4R (C.I. ACID RED 18);45100-XYLENE RED B (C.I. ACID RED 52);COLOR NOT CONTAINED IN TABLE (ENTER NAME IN REMARKS);

(25 J - - 07) Radish (Root & Tuber Vegetable)
Desc: preserved and/or pickled radishes in pouches
Notes: all firms except those listed in attachment B
Problems: 19140-FD&C YELLOW #5 (TARTRAZINE);

All companies should review the import alert on a regular basis to determine whether or not additional products have been added. Companies need to keep in mind that they must provide positive communication to be added to the "Green List" and not be detained at import to the USA.

Import Alert 99-33 "Detention Without Physical Examination of Products from Japan Due to Radionuclide Contamination"

On March 11, 2011, an 8.9 magnitude earthquake triggering a 30 ft. tsunami struck the Pacific Coast of Japan. The most notable damage from the tsunami affected the Fukushima Daiichi nuclear plant. The following prefectures are in the closest proximity to the Fukushima Daiichi nuclear plant: Fukushima, Gunma Ibaraki, and Tochigi. After the damage occurred, on March 19, 2011, the Japanese Ministry of Health, Labour and Welfare confirmed the presence of radioactive iodine contamination in dairy, fresh produce, and infant formula products. Japanese data analyses revealed that the food products measured from March 16-18, 2011, indicated the presence of radioactive iodine was five times the acceptable levels.

The import alert, 99-33 (initially issued after the issue was confirmed in 2011), provides that FDA districts may detain, without physical examination, the specified products from firms in the Fukushima, Aomori, Chiba, Gumna, Ibaraki, Iwate, Miyagi, Nagano, Niigata, Saitama Shizuoka, Tochigig, Yamagata and Yamanashi prefectures. The latest revisions to this import alert was issued on November 20, 2017 and ***removes*** additional products from the list of products restricted by the Government of Japan.

FDA and the Japanese government are continuing to collaborate to ensure products from the affected prefectures do not pose a health risk to Japanese or U.S. consumers. FDA has indicated it will continue monitoring the public health risks due to radionuclide contamination, and when appropriate will deactivate the import alert and resume routine coverage of entries.

All companies exporting or considering exporting product to the USA should review the import alert and ensure that they are not using any of the identified products still on the import alert as an ingredient. If using an ingredient produced in an ***unaffected*** area; it would be expected that the company would have the producer's information showing radiological issues are not a concern due to the source of the product.

> Import Alert 28-07 "Detention Without Physical Examination of Coumarin in Vanilla Products Extracts Flavorings Imitations"

The import alert on the use of Coumarin in Vanilla extracts and flavorings has been included in this report as a number of the companies produce various baked goods that could be using vanilla extract or flavoring. Companies should review the import alert to determine whether or not vanilla extract or flavoring used in product destined for the USA is included.

Product Rework

When producing products, rework can be generated when not all the product is packaged by the end of the production day. Rework could also result if there are equipment breakdowns or packaged products that have packaging defects whereby the product needs to be opened and re-packaged into an acceptable container.

It is important to understand that traceability of product is generally based on when the product was initially produced. If product is carried over to another day and used in that day's production – it must be accounted for. Moreover, the opportunity to "carry forward" any issues from one day into the next must be recognized. For example, if an issue with the unapproved use or cross-contact from an allergen occurred on one day and product was then mixed into the next day's production – there would now be two days of production at risk.

When dealing with environmental contamination for Listeria or Salmonella, if finished product is packaged on a line one day and some of that is opened and re-packaged the following day – there is also the risk that now the second day is included if there is an issue with one of these organisms identified on the production line on the first day as by repackaging the product down the production line on the second day – it is now potentially contaminated.

Companies should carefully consider how any rework is added back to the system so that they can account for it for traceability as well as to ensure if there is an issue – any concerns are identified prior to use. Depending on the company – if can be a business decision as to how many production days it may want to have tied together by carrying over recork to the next production day.

Flow Chart

The regulation does not actually require that a flow chart be developed. However, best practice is that one be made as it is very difficult to actually develop a hazard analysis without one. The flow chart should list each step in the process where location, fit, form, or function, changes. The steps should match those identified in the hazard analysis. Best practice is that someone takes the flow chart onto the production floor on a periodic basis, or whenever the hazard analysis and/or preventive controls plan is reanalyzed, and check that it is accurate. It there is more than one shift of operations – this check should be done on each shift.

Hazard Analysis (*See* 21 C.F.R. § 117.130)

Receiving Step

Companies should review their hazard analysis at the receiving steps to determine whether or not they have either addressed all potential hazards for a particular ingredient that FDA has identified or that they can support why it does not apply in their case. FDA has provided a Preventive Controls guidance document, Appendix 1, with many of the ingredients used to produce various types of foods as well as the food with what FDA considers to be potential hazards. Companies should use this document to review each of their ingredients.

A company should either address the FDA-identified potential hazard or have information to support why it is not a hazard in their particular situation. All ingredients' hazards should be addressed at receiving. If there is a hazard that is controlled by the supplier – a company needs to have a supply chain program in place (*see* below). The majority of hazards that a supplier controls are chemical hazards (e.g., heavy metals, pesticides, mycotoxins, etc.) including radiological as these are generally related to where the ingredient originates (e.g., where it is grown or extracted (well water[6]).

When listing potential biological hazards;[7] ensure that the specific pathogenic organism is named. Do not state, for example, "vegetative pathogens" as all vegetative pathogens known would need to be addressed. Moreover, ensure that microorganisms that are not related to food safety are not listed (e.g., Total Plate Count, generic E. coli, Coliforms).

[6] FDA expects when well water is used that radiological be addressed. FDA is looking at whether or not the well could be located in an area where geologically there could be deposits of radiological materials. This can be easily addressed with the use of information on the geology of location. In addition, the company would need to address biological hazards to ensure potabiity.

[7] This applies to the listing of biological hazards at any step in the process.

Historical information a company has in its files can be used to support what verification activities are needed as well as their frequency. This can be a summary document of historical information on a particular ingredient from a particular supplier or it could be a scientific document that supports the hazard decision. If a new supplier is added; the supplier must be approved initially and then verification activities will likely be much more frequent until enough evidence of control is gathered.

If a company has the incoming inspection of an ingredient as a preventive control step (e.g., inspection to confirm no foreign material); the inspection procedure must be extremely detailed so that any employee performing the inspection does it exactly the same. Moreover, the inspection parameters must have validation to support that the sampling scheme (e.g., how samples are chosen, number of samples, etc.) will actually represent the entire lot of product.

Supply Chain Programs (*See* 21 C.F.R. Part 117, Subpart G)

The only time a supply chain program is needed is if a supplier is controlling an identified hazard that cannot be controlled in-house.[8] Because a company must detail how it will verify the supplier controlling the hazard – including verification of information on Certificates of Analyses (COA) or Certificates of Conformance (COC) – it is suggested that a company control hazards in-house if it can. Keep in mind that verification is much more than inspecting the product at receiving in most cases.

Moreover, if a supplier controls what is considered a significant hazard (e.g., a lethality step such as pasteurization of milk or cooking of a product to make it ready-to-eat and there is not control step in-house); verification of the supplier must include an onsite audit of the supplier prior to the initial receipt of product and an annual audit of the supplier thereafter unless the Preventive Controls Qualified Individual (PCQI) determines that something else will substitute for that audit. (*See* 21 C.F.R. § 117.430(b)(1)). The onsite audit must be performed by a qualified auditor and meet the requirements detailed in 21 C.F.R. § 117.135.

Allergens

The allergens that must be addressed in product exported to the USA are milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. The product label must identify any of these allergens in compliance with the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). FALCPA requires that with tree nuts, the specific type of nut must be declared (e.g., almonds, pecans, or walnuts). Likewise, the species must be declared for fish (e.g., bass, flounder, or cod) and Crustacean shellfish (crab, lobster, or shrimp).[9]

[8] A company can make the decision that it wants a supplier to be responsible for a hazard even if there is a step later in its process that would control the identified hazard. However – this will require the implementation of a supply chain program. If the hazard is significant (e.g., the application of a lethality step); the supply chain program will need to include how the supplier will be audited.

[9] Additional information on labeling may be found in the FDA guidance document, "Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance."

While there are many more food items that cause allergic reactions – the eight listed above account for 90% of reactions in the USA. Under the preventive controls regulation, a company must ensure product is labeled in compliance with FALCPA and also ensure it prevents cross-contact with a food containing an allergen not present in the product being produced, or with equipment that could have an allergen present that is not in the product.

If a product is produced that contains one of the identified allergens above, a company will have a preventive control in place to ensure that the finished product label correctly identifies the allergen. Moreover, if there is an opportunity that the product may be produced where allergen cross-contact can occur; the company will have in place an allergen sanitation preventive control for cross-contact at each step in the process where cross-contact may occur. The regulation only requires that after an allergen sanitation cleaning – that equipment be visually clean. Best practices would include that the sanitation procedure is verified using an allergen test kit.

Foreign Material

Depending on the products produced, various types of foreign material may need to be addressed. The hazard normally addressed is metal. This can be through the use of magnets, filters or screens, or metal detectors and x-rays. Whether or not any of these are a preventive control or CCP; all should be monitored, at minimum, at the beginning and end of production. Best practice is that systems are monitored numerous times throughout the production day so that if an issue is identified – all product back to the last acceptable check can be re-run through a functioning system.

If packing products in glass containers; there is usually a good manufacturing practice (GMP) in place where the glass containers are inverted, and washed or blown out. Sometimes there are also visual inspections to ensure there are no inclusions in the bottles that could break loose.

Storage Areas

All storage areas should have GMPs in place to ensure that products are stored properly, not damaged, and used appropriately. If various allergens are stored – they should have designated areas. If areas are refrigerated, ensure that there are calibrated monitoring devices in place and a procedure that details corrective actions to take if an issue occurs with refrigeration. The procedure should detail when action will need to be taken regarding the product. Generally, it will take some time for the product to rise to too high a temperature as compared to the area temperature, but a plan should be available if this occurs.

Post-lethality Exposed Ready-To-Eat Product (*See* 21 C.F.R. §117.165(a) &(b))

If product is ready-to-eat (RTE) and exposed to the environment after receiving its lethality treatment; a company will need to have a sanitation preventive control in place at each step in the process where product is exposed. In addition, there will need to be an environmental monitoring program to verify the effectiveness of the sanitation process. Depending on whether the environment is dry-cleaned or maintained dry versus wet-cleaned, the program will need to

monitor for *Salmonella* or *Listeria monocytogenes* respectively. This can be done by monitoring for the actual organism or an indicator organism.

Moreover, the regulation also discusses product testing as an additional verification step. The frequency of testing can be based on historical testing information if available. Otherwise, the frequency of testing of finished product can be validated within the first 90 days that the plan or the testing procedure is implemented. When testing product – best practice is that it be tested directly for the pathogen – not the indicator organism.[10]

Preventive Controls or CCPs (*See* 21 C.F.R. Part 117, Subpart C)

When documenting critical limits, ensure there is a monitoring parameter for each component of the critical limit, and that all key components that would affect the control of the hazard are included. For example, if a product temperature must reach ≥100°C for ≥2 minutes; the temperature must be measured and documented to show it has reached ≥100°C and the time must also be monitored to show that the temperature remains at or over100°C for at least 2 minutes. If humidity is important in meeting the temperature – it must also be monitored. All parameters of a critical limit must be measurable, monitored, and verified.

Ensure there is documentation to support the critical limits. This should consist of peer-reviewed scientific information that meeting the critical limits will provide control of the hazard. In addition, there should be validation information that the equipment will consistently provide the parameters needed so that all product reaches the critical limits. For example, if using an oven, all areas of the oven should provide the same temperature so that all product in the oven reaches the critical limit. If not, the product going though the coldest part of the oven should be monitored or the variance addressed.

When documenting the verification activities for a preventive control or CCP; ensure that any equipment or instrumentation used in the monitoring step is calibrated appropriately. Also ensure that all records related to the preventive controls or CCPs are verified within seven (7) working days of the time the record is produced. However, best practice would be that records would be verified prior to the product being released into commerce.

Records

The need to maintain records is addressed in various parts of the regulation. Initially, in 21 C.F.R. § 117.4, records are required that document that:

> Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:
>
> (1) Be a **qualified individual** as that term is defined in § 117.3—i.e., have the education, training, or experience (or a combination thereof) necessary

[10] Companies should keep in mind that the FDA considers seasonings such as salt and pepper or chili mixes, etc., to be RTE as consumers add these to many foods after cooking or to foods such as salads.

> to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and
> (2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, **as appropriate to the food, the facility and the individual's assigned duties**.
> (emphasis added)

A "qualified individual" is one "who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment." (*See* 21 C.F.R. § 117.3). So the first set of records needed is that everyone working in a facility has had the appropriate documented training to perform their job – including appropriate food safety training.[11]

In FDA inspections that have occurred under the preventive controls regulation, FDA has specifically asked to see the written training documents for individuals performing certain jobs in a facility. For example, when FDA was present when an allergen sanitation preventive control to prevent cross-contact was occurring, FDA asked to see the documentation that the individuals performing the sanitation of the equipment had been specifically training in the allergen sanitation changeover procedure. If the documents did not exist showing individuals had been specifically trained on the procedure – the company was written up on the FDA Form 483, Inspectional Observations.

The need for various records is discussed in a number of other sections in the regulation. Records are also needed to document:

- monitoring of all preventive controls/CCPs (21 C.F.R. § 117.140(c));
- corrective action (21 C.F.R. § 117.150(d));
- verification (21 C.F.R. § 117.155(d));
- requirements applicable to a preventive controls qualified individual and a qualified auditor (21 C.F.R. § 117.180(d));
- implementation (21 C.F.R. § 117.190);
- qualified facility status (21 C.F.R. § 117.201(f));
- modified requirements applying to a facility solely engaged in storage of unexposed packaged food (21 C.F.R. §177.206(a)(5)); and
- supply chain program (21 C.F.R. § 117.475);

Requirements for required records are addressed in 21 C.F.R. Part 117, Subpart F. The majority of these records must meet the parameters detailed in 21 C.F.R. § 117.305, "General

[11] It should be noted that records verifying training are the only ones required as they relate to 21 C.F.R. Part 117, Subpart B (Current Good Manufacturing Practice). However, best practice is that a company documents compliance with GMPs and has written procedures, and verifies its compliance with its procedures.

Requirements Applying to Records." This section discusses the information that must be on every record, how records can be maintained and what is needed if the record is electronic.

Of note is the section on records retention – all records required must be retained for two years after the record was produced and/or two years after the record was last used. This last part applies, for example, to records that would document validation of an oven. If you re-validate an oven, the original validation records must be maintained for two years after the re-validation.

Recall Procedure (*See* 21 C.F.R. § 117.139)

The regulation requires that if a hazard analysis identifies the need for a preventive control – then a written recall plan is needed. At minimum, the written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

> (1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
> (2) Notify the public about any hazard presented by the food when appropriate to protect public health;
> (3) Conduct effectiveness checks to verify that the recall is carried out; and
> (4) Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

Companies are responsible (as stated in (1) above) to notify their direct consignees. In the notification, they should detail what steps the consignee is to take. This should include whether or not the consignee should notify whomever they sold the product to and what steps should be taken by their consignees. This notification also needs to include how any remaining product should be handled.

It is important to also ask consignees to provide documentation on whether or not product remained as well as documentation as to its disposal of product. This documentation supports a company's effectivity checks in accounting for what happened to all product originally produced. FDA would expect a manufacturer to contact (with documentation of that contact) its consignees a number of times if it has not received any information from the consignee on affected product it received.[12]

The FDA classifies recalls as Class I – III. The classifications are as follows:

> *Class I recall*: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

[12] The FDA has published guidance to assist industry in conducting a recall, "Industry Guidance for Recalls."

Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

While FDA will classify recalls; it is important that companies understand that if they determine a product was produced and intended for consumption in the USA that would meet the definition of a Class I recall – that once that is determined – there is 24 hours to file a Reportable Food Report (RFR) using the FDA portal. Issues that would be classified as Class I include, but are not limited to:

- Identifying a pathogen such as *Listeria monocytogenes* or *Salmonella* in a ready-to-eat food;
- Undeclared allergens;[13] and
- Certain hard and/or sharp foreign material of a certain size.

While not required by the regulation to be a part of the recall plan; it would be a best practice to detail how it will be determined when a RFR is needed and the steps to ensuring it is filed in the recall plan so this regulatory requirement is not missed.

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The above provides a summary of opportunities to review preventive controls plans and strengthen their compliance to the FDAs preventive controls regulation. It does not however discuss all parameters necessary for regulatory compliance. Companies should be very familiar with the regulation as it relates to their specific operation.

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[13] The presence of certain undeclared allergens such as peanuts is always a Class I recall. A company may be able to support that the presence of soy in a product in small amounts is not a Class I recall, but this determination would need scientific support that would need to be provided to FDA.

米国食品安全強化法
総括レポート：食品安全計画のレビュー結果（2017 年度農林水産省補助事業「食品安全計画ワークショップ-FDA 査察に備えて」の報告）（英語原文）

2018 年 3 月作成

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