

ENSURING GLOBAL ORGANIC SUPPLY CHAIN INTEGRITY

A Guide to Developing an Organic Fraud Prevention Plan



An Organic Trade Association Resource

THIS GUIDE:

- Describes a process for organic fraud prevention
- Outlines factors that increase vulnerability to organic fraud
- Recommends measures and practices that can be used to mitigate fraud
- Includes information on what to do when you suspect or detect fraud
- Provides additional resources and helpful tools for identifying and deterring fraud

I. INTRODUCTION

A. Purpose of this Guide	•										4
B. Definition of Organic Fraud										•	4
C. Structure of the Guide and Summary										•	5

II. THE ORGANIC SUPPLY CHAIN UNDER THE NATIONAL ORGANIC PROGRAM

A. Participants, Roles and Responsibilities										7
B. The Certification and Approval Process.			•							9
C. The Organic Supply Chain			•							10
D. Challenges and Gaps in the Supply Chain										11

III. DEVELOPING AND IMPLEMENTING AN ORGANIC FRAUD PREVENTION PLAN (OFPP)

A. V	/uln	erability Assessment: Identifying Gaps and Weaknesses	•	13
	i.	Definitions		15
	ii.	Vulnerability Factors		16
	iii.	Carrying out the Vulnerability Assessment Process		17
	iv.	Using the Organic Vulnerability Assessment Tool		18
	v.	Examples of Medium to High Vulnerabilities.		18
B. I	Miti	gation Measures: Designing a Mitigation Strategy	•	20
	i.	Create a Supplier Verification Approval Program	•	21
	ii.	Establish Best Practices for Receiving Organic Ingredients/ Products	•	22
	iii.	Establish Best Practices for Imports or High-Risk Products	•	23
	iv.	Establish Best Practices for Ensuring Supply Chain Traceability and Mass Balance		24
	v.	Establish Labeling Best Practices		25

A GUIDE TO DEVELOPING AN ORGANIC FRAUD PREVENTION PLAN

С.	Мо	nitoring and Verification: Effectively Implementing Mitigation Measures	27
	i.	Internal Audits	27
	ii.	Testing: A Tool For Verifying Compliance	28
	iii.	Tracking and Compliance Verification Technologies	34
	iv.	Implementing the Organic Fraud Prevention Plan	37
		1. Effective Training and Communication Strategy	37
		2. Updating the Organic System Plan	39

IV. ALERT SYSTEM – MONITORING AND REPORTING ORGANIC FRAUD

Α.	Wha	at to Do When You Suspect or D	ete	ect	Fr	au	d									41
В.	Hov	v to File a Complaint with NOP					•									41
	i.	Complaint Template									•					41

V. ACKNOWLEDGMENTS AND FURTHER READING

A. ACK	nowledgments
i.	Global Organic Supply Chain Integrity Task Force
ii.	USDA National Organic Program
iii.	Food Fraud Think Tank and GFSI Food Fraud Initiative
B. Reso	ources and Further Reading
i.	Standards
ii.	USDA Guidance Documents / Instruction / Policy
iii.	Self-Assessment Tools
iv.	Alerts and Databases.
v.	Testing
vi.	General Resources

VI. APPENDIX A

. .

Uncertified Handler Declaration	•	•					•																49
--	---	---	--	--	--	--	---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	----

VII. APPENDIX B

Organic Fraud Vulnerability Assessment Tool

VIII. APPENDIX C

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I. INTRODUCTION

The success of the organic sector relies on consumer trust of the United States Department of Agriculture's (USDA) Organic seal. The organic certification system, under the oversight of USDA's National Organic Program (NOP), is designed to deliver organic products that are uniformly certified to a single federal standard by a third-party USDA accredited certifying agent (ACA). Organic certification is also designed to create a linked system of compliance providing complete source-to-sale traceability of organic products and accountability of each operation in the global supply chain. To date, the organic label remains the only regulated eco-claim with third-party certification, federal oversight and enforcement.

Recent activities and USDA investigations have revealed products fraudulently labeled as organic and gaps in the complex organic supply chain, specifically as it relates to organic imports. Compromised supply chains due to fraud can erode consumer trust in the integrity of the organic brand. Strong action is needed to improve the effectiveness of controls throughout the organic product supply chain. In addition to the number of steps currently being taken to strengthen NOP oversight of imported organic products, further actions include oversight and training of ACAs, improved collaboration with other agencies to better oversee organic products at U.S. Ports of Entry, and encouraging the private sector to be proactive and take responsible steps for improving systems that will help mitigate and avoid the risk of fraud.

Everyone has a role in organic fraud prevention. It is critical that producers, handlers, processors, distributors, traders and holders of organic brands have systems and measures in place that adequately support the promise of providing organic food that people can trust. This Best Practices Guide, as adopted by businesses engaged in organic trade, will become the industry standard reference for achieving integrity across complex organic supply chains.

PURPOSE OF THE BEST PRACTICES GUIDE

The purpose of this Guide is to provide businesses engaged in the organic trade with a risk-based approach for developing and implementing a written Organic Fraud Prevention Plan (OFPP) to assure the authenticity of organic products by minimizing vulnerability to organic fraud and mitigating the consequences of occurrence.

By outlining systematic approaches to the organic certification process and verification procedures carried out by ACAs and certified operations, the Guide's recommended practices are intended to establish an industry standard for businesses to create continuously improving internal programs and processes for achieving organic integrity throughout their associated supply chains.

DEFINITION OF ORGANIC FRAUD

For the purposes of this Guide, organic product fraud can be defined as an intentional misleading or deceptive action carried out for illicit financial gain. Fraudulent acts may include adulteration, substitution, falsified records and the deliberate mislabeling of goods, as well as false statements made on applications, organic system plans, and during inspections. Of primary concern are intentional and economically motivated substitutions and the fraudulent mislabeling of organic products, including fabrication of fraudulent organic certificates. Such misrepresentation may occur at any point along the value chain from the product source to selling point.

STRUCTURE OF THE BEST PRACTICES GUIDE

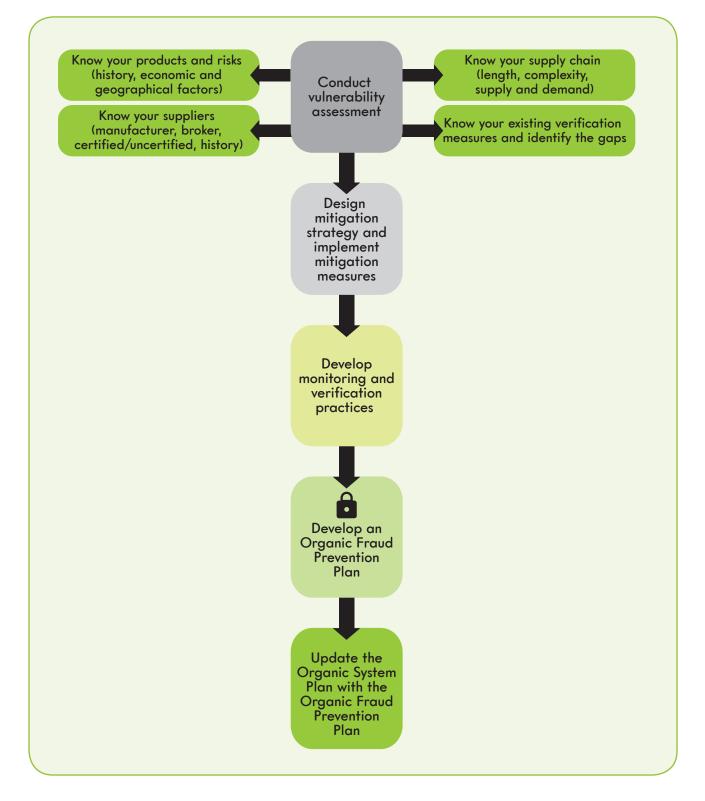
This booklet presents a systematic approach to developing and operationalizing a written organic fraud prevention plan that can be summarized by a five-step process:

- Conduct a vulnerability assessment, including
 - Know your products and risks (history, economic and geographical factors)
 - Know your suppliers (manufacturer, broker, certified/uncertified, history)
 - Know your supply chain (length, complexity, supply and demand)
 - Know your existing verification measures and identify the gaps
- Design and implement internal mitigation measures including a robust supplier approval program that involves internal audits and second-party supplier audits
- Ensure practices are effective through monitoring practices and verification tools such as internal audits and control testing
- Document the vulnerability assessment, mitigation measures and monitoring practices in an Organic Fraud Prevention Plan
- Integrate mitigation measures into the Organic System Plan (OSP)

IN SUMMARY, THIS GUIDE:

- Provides businesses engaged in organic trade with a risk-based approach for developing best practices for improving the resilience and overall integrity of global organic supply chains
- Is intended for individual businesses engaged in the selling, buying, producing, processing or packaging of certified organic products
- Provides background on the participant's responsibilities and organic requirements for a simple and complex organic supply chain
- Aims to set a standard industry practice that complements and reinforces the organic certification process and verification procedures carried out by ACAs and MROs as authorized by USDA-NOP
- Presents a process for carrying out a vulnerability assessment to design and implement appropriate mitigation practices that can be integrated into the annual organic certification system
- Provides guidance on developing and implementing a written organic fraud prevention plan to assure the authenticity of organic products by minimizing vulnerability to organic fraud and mitigating the consequences of occurrence
- Recommends monitoring procedures and verification tools that will ensure the practices and procedures are effectively implemented
- Includes detailed information on what to do when you suspect or detect fraud and the process for filing a complaint to the National Organic Program
- Provides additional resources and helpful tools for identifying and or deterring fraud.

DEVELOPING AN ORGANIC FRAUD PREVENTION PLAN



II. THE ORGANIC SUPPLY CHAIN UNDER THE NATIONAL ORGANIC PROGRAM

The global organic control system is unique in that it includes strict production and processing standards; third-party certification; accreditation of certifiers; certification of farmers, processors and handlers; and federal oversight and enforcement. USDA organic regulations include organic system plan requirements, recordkeeping requirements, comprehensive process audits, and inspections that trace organic product from farm to market. The design of this system allows a tightly regulated organic supply chain with formal mechanisms for addressing violations of organic requirements. As with any system, failures can and do occur, maintenance is a continuous process, and there is always room for improvement. Furthermore, no process can guarantee that organic products and organic supply chain are not the target of criminal activity.

The findings of organic fraud have highlighted the need to strengthen organic fraud prevention measures across the entire supply chain. The first step in understanding how the organic supply chain can be strengthened is to understand the primary participants of the National Organic Program (NOP), its roles and responsibilities, and how the organic certification system is currently structured.

A. PARTICIPANTS, ROLES AND RESPONSIBILITIES

Operators



Under USDA's National Organic Program, any product labeled "100% Organic," "Organic," or "Made with Organic (specified ingredients or food group(s))" must be produced and handled by operations certified to USDA's organic regulations. However, there are a handful of exceptions to this general rule concerning who must be certified. The organic regulations under § 205.101 provide exemptions and exclusions from certification to certain types of operations depending on the scope and activity of the operation. For example:

- Farms or handlers whose gross agricultural income from organic sales totals \$5,000 or less
- Handling operations that handle agricultural products that contain less than 70 percent organic ingredients or only identify organic ingredients on the information panel
- Retail food establishments that handle organically produced products but do not process them (e.g. grocery stores including bakeries located at grocery stores)
- A handling operation or portion of a handling operation that handles organic products in sealed containers prior to being received and does not remove or further process those products (e.g. wholesale distributors, brokers, and traders that sell boxed or otherwise sealed containers of certified organic products).

Operations that are eligible to handle or produce organic products under one or more exception or exclusion may always voluntarily choose to obtain certification. Furthermore, while an operation may be excluded from certification, it still must comply with specified labeling, contamination prevention and recordkeeping provisions of the organic regulations.

7

Accredited Certifying Agents

The Organic Foods Production Act authorizes USDA to accredit third-party certifying agents whose responsibility it is to verify organic operations' compliance to the USDA Organic Standards. All operations not exempt or excluded from certification must be certified by one of these "Accredited Certifying Agents" (ACAs). ACAs include state agencies, non-profits, and for profit businesses, but they are all overseen, accredited, and audited by USDA to ensure consistent application of the organic standards across the globe. ACAs also enforce the organic standards through adverse actions, and, in collaboration with USDA, ensure operators implement corrective actions for minor violations or suspend or revoke certificates for major violations.

USDA's National Organic Program

Organic certification is a unique label claim in that it is enforced and maintained by the federal government. Under USDA's Agricultural Marketing Service, the National Organic Program (NOP) is responsible for developing and enforcing the organic requirements to assure consumers that products certified under NOP meet consistent uniform standards.

They do this through work in five significant areas:

- 1. Accreditation of ACAs: NOP ensures ACAs are consistently and thoroughly verifying compliance with the organic regulations and that ACAs have the staff expertise and control systems necessary to accomplish this goal.
- 2. Development of organic standards: NOP responds to changes in the organic marketplace, recommendations from the National Organic Standards Board, and input from the three branches of government through notice and comment rulemaking and issuance of guidance and policy memos. These updates and clarifications to the USDA organic standards ensure that the organic seal continues to meet consumer expectations and accommodate advances in agriculture and food processing.
- **3. Enforce the organic standards:** Compliance and enforcement is an essential component of NOP's work to ensure the integrity of organic products. Through its partnership with ACAs, NOP takes compliance action against operations that have violated the organic requirements. When violations include federal crimes like wire or mail fraud, NOP works with its Office of Inspector General (OIG) to prosecute those crimes.
- 4. Support the work of the National Organic Standards Board (NOSB): NOP facilitates the work of NOSB, which is the congressionally mandated Federal Advisory Committee that advises USDA on which materials should be allowed and prohibited in organic production and on updates to the organic standards as a whole.
- **5. Facilitate trade with international partners:** NOP works with the Foreign Agricultural Service and Office of the United States Trade Representative to establish international trade arrangements for organic products. These trade arrangements aim to promote the export of U.S.-based organic products and to ensure imported organic products are produced under the same, or equivalent, organic standard and oversight.

Certified operations produce organic products, ACAs verify these operations' compliance with the organic standards, and USDA ensures the standard is enforced consistently across the globe. Each of these unique roles plays a crucial part in sustaining the confidence of the consumer and growth in the organic industry.

8

B. CERTIFICATION AND APPROVAL PRACTICES

Despite the diversity of scale, type, and location of certified organic operations, the process to obtain approval follows a common set of structures and verification procedures. Whether an operation is growing vegetables for a farmers' market or exporting containers of packaged product, everyone starts the process with an Organic System Plan (OSP), undergoes an on-site inspection, and repeats the certification process annually.

The Organic System Plan

The "Organic System Plan" is a detailed description of the practices and procedures used by an operation to produce and handle organic goods in compliance with the USDA organic standards. It is essentially a management plan of an organic production or handling operation that has been agreed to by the producer or handler and the ACA. This includes a written plan addressing all aspects of agricultural production or handling under the organic standards. While every certified operation must develop and maintain an Organic System Plan, not all plans cover every specific organic requirement. For instance, crop producers must describe how they source seeds, rotate crops, apply fertilizers, and ensure neighbors do not drift pesticides onto their farms. These are specific to a crop producer, and do not need to be addressed in an handler's system plan, for example, which would cover issues like ingredient sourcing, organic certificate management, cleaning processing equipment before touching organic product, and ensuring all package use is compliant and labeling is accurate. The Organic System Plan is also what an inspector will use to verify compliance with the organic standards at on-site inspections.

Recordkeeping

The Organic System Plan describes how an operator will comply with the requirements of the organic standards. However, producers and handlers must also maintain records to demonstrate they have actually implemented their Organic System Plan. These records show when production input materials are applied to fields (e.g. fertilizers, pest controls), how much of a specific ingredient was purchased, and whether or not equipment was cleaned before touching organic products. An operation's recordkeeping system must also be able to track organic products from source to final market. Traceability throughout the supply chain is a critical feature of organic certification, and one that is unique to the organic product category.

Example records that must be maintained by organic producers and handlers include:

- **Crop Producer:** Input material purchase and application records; harvest yield records; sales records; soil and nutrient management records; crop rotation records.
- **Livestock Producer:** Feed purchase and feeding records; health treatment records; records that show when outdoor access is provided to livestock and poultry.
- **Handler:** Current organic certificates, ingredient and input purchase and delivery records; batch recipes; cleaning and purging records; pest management records; final product sales and shipping records.

C. THE ORGANIC SUPPLY CHAIN

Tools for Assessing Compliance

The Organic System Plan lays the foundation for an operation's compliance to the organic standards. The operation's records document that the system plan is implemented. However, review of the organic system plan and the verification of its implementation are how compliance is assessed and verified. This requires on-site inspections, audits, and testing.

Inspections



Every organic operation must be inspected annually. Some operations are inspected more frequently if new aspects to the business are added to the system plan, if violations are suspected, or as part of a routine surveillance program to ensure organic integrity. At an operation's annual inspection, all aspects of the organic system plan are reviewed and verified. Some aspects, like ensuring buffers on an organic farm are adequate to prevent drift, must be physically observed by the inspector; other

aspects, like ensuring adequate quantities of organic ingredients are sourced, must be confirmed through records review and traceability and mass-balance audits. Regardless of the scale or scope of the operation, the inspection is what confirms that the organic system plan is in place and that it is effective to ensure the integrity of organic products.

<u>Audits</u>



All inspections, regardless of scope or scale of an operation, will include audits. These audits will test operations' systems for preventing contamination and comingling as well as ensuring traceability through the supply chain. Mass balance audits examine whether an adequate supply of organic product was produced or sourced to validate the production yield of the operation. If a flourmill produces 1,000 pounds of organic flour but only purchases 500 pounds of organic wheat, the mass balance audit does

not work, which may indicate a violation of the organic requirements. Product traceability audits ensure that all organic products can be tracked throughout an operation. Farmers and ranchers must be able to track their crops and animals from planting or birth through harvest. Similarly, handling facilities must be able to track ingredients from supplier to processed product.

Residue Testing



A critical tool in the inspection and certification process is product testing. NOP requires that ACAs test a minimum of 5% of all certified operations each year – more testing may occur when violations are suspected or reported. These tests cover pesticide residues, heavy metals, GMO contamination or other prohibited substances, and can investigate contamination of crops, soil, feed or water. ACAs use positive tests as evidence that contamination prevention measures are inadequate or as

evidence that fraudulent activity has occurred. Testing alone cannot confirm or invalidate an operation's organic certification, but it can provide a critical quantitative tool for evaluating compliance to the organic standards.

D. CHALLENGES AND GAPS IN THE SUPPLY CHAIN

Despite the comprehensive and robust oversight system that is established and required under the National Organic Program, there are challenges and gaps in the organic supply chain. Acknowledging the challenges and identifying the factors in a supply chain that create weak points are critical for operations that choose to take additional measures to decrease and prevent organic fraud in a given supply chain. While there are many factors in a supply chain that create vulnerabilities and increase the risk or occurrence of organic fraud, there are three critical areas to consider that inevitably increase the risk of organic fraud: 1) length and complexity of the supply chain; 2) uncertified entities (excluded operations) in the supply chain; and 3) products crossing one or more borders.

Length and Complexity of the Supply Chain

The length and complexity of an operation's supply chain will present varying degrees of risk and challenges in ensuring integrity. When an organic producer brings their crops to a farmers' market, there is a shorter supply chain, and therefore fewer places where contamination or fraud can occur, than in the case of an organic food manufacturer sourcing multiple ingredients from across the globe. Similarly, the nature of each organic product will affect how it is transported and, in turn, affect the potential for fraud or contamination. Sealed packages of finished and labeled organic product generally are at a lower risk for contamination than bulk or non-retail shipments of grain, for example. Understanding the specific nature of each product and each operation's supply chain are necessary to evaluate where vulnerabilities to fraud may occur. In general, the potential for risk increases as the length and the complexity of the supply chain increase. In other words, the more vendors a product passes through, the more at risk it is to organic fraud. *See Simple Supply Chain and Complex Supply Chain on page 12.*

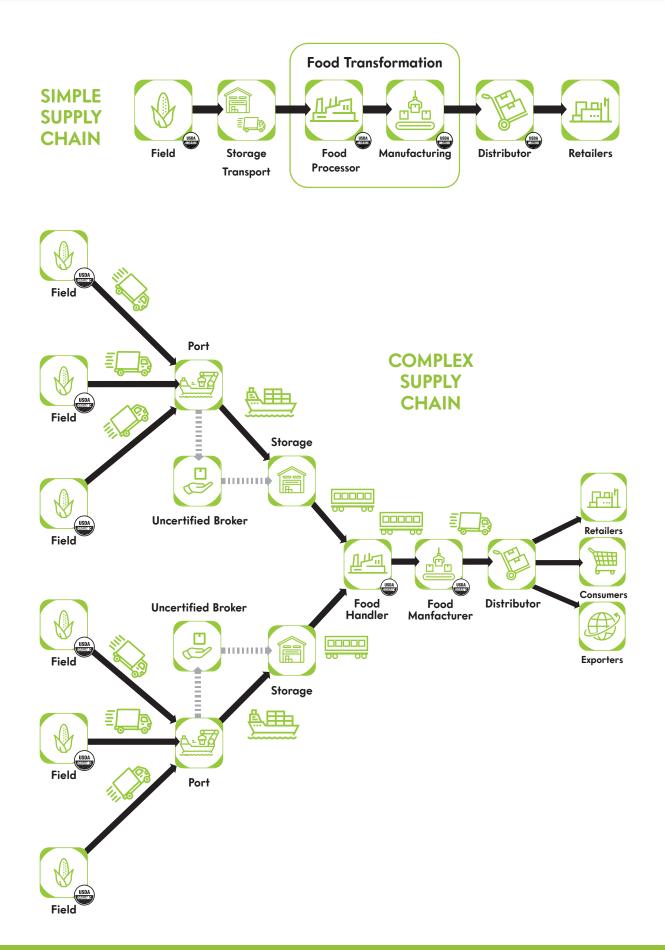
Excluded Operations

When a supply chain includes an uncertified operation, it can compound challenges pertaining to length and complexity. As described above, some activities performed in the supply chain do not require organic certification. Although legislative and regulatory efforts are underway to limit the types of operations that may be excluded from certification, as of 2018, brokers and importers may be excluded from certification, which means they are not responsible for developing and implementing an organic system plan, and they are not inspected annually. When an excluded operation is included in a certified operation's supply chain, it can pose challenges in maintaining and verifying integrity and traceability.

Imported Product

USDA enforces the organic regulations across the globe to ensure that all organic products, whether produced domestically or internationally, meet the same or equivalent organic standard. USDA, however, remains a U.S. authority, and when enforcing standards across international borders, there are inherent challenges. While USDA does have the capacity to take adverse actions against foreign organic operations, a U.S. government agency cannot levy civil penalties against a foreign company, which inherently limits USDA's enforcement capacity overseas. An Office of Inspector General report from September 2017 found that NOP was unable to provide reasonable assurance that organic documents are reviewed at U.S. Ports of Entry to verify organic integrity of imported products and that NOP had not established and implemented controls at U.S. Ports of Entry to identify, track, and ensure treated organic products are not sold, labeled, or represented as organic. Limited enforcement capacity, document control, and tracking of products that had been fumigated or otherwise treated to prevent prohibited pests from entering the U.S. all pose challenges to ensuring the integrity of imported organic products.

11



III. DEVELOPING AND IMPLEMENTING AN ORGANIC FRAUD PREVENTION PLAN

A. VULNERABILITY ASSESSMENT — IDENTIFYING GAPS AND WEAKNESSES

Identifying the weak points in a supply chain that increase exposure to fraud is critical for any operation that chooses to take additional measures to decrease and prevent organic fraud. In this Guide, we acknowledge the tremendous amount of activity already underway in and around food fraud prevention, and accordingly utilize the work of the GFSI Food Fraud Think Tank¹ that recommended two fundamental steps to aid in the mitigation of food fraud.

- Carry out a "food fraud vulnerability assessment" in which information is collected at the appropriate points along the supply chain (including raw materials, ingredients, products, packaging) and evaluated to identify and prioritize significant vulnerabilities for food fraud.
- Put in place appropriate control measures to reduce the risks from these vulnerabilities. These control measures can include developing a more robust supplier verification program, monitoring strategy, a testing strategy, origin verification, specification management, and supplier audits. A clearly documented control plan outlines when, where and how to mitigate fraudulent activities.

FOOD FRAUD PREVENTION



13

¹ The Food Fraud Think Tank was convened to further advance the food fraud topic; it brought together experts in analytical testing, certification, supply chain security and criminology as well as manufacturing and retailing companies.

Based on the approach adopted into the GFSI Guidance Document (Version 7) and the Food Safety System Certification (FSSC) 22000 requirements for food fraud prevention, a general approach to **preventing organic fraud** can be summarized as follows²:

- Establish a multi-disciplinary Organic Fraud Mitigation Team
- Conduct and document a vulnerability assessment including:
 - Know your materials and risks (history, economic factors, geographical origins, physical state, pest/disease risks, emerging issues)
 - Know your suppliers (manufacturer, distributor, broker, history)
 - Know your supply chain (length, complexity, non-certified entities, supply and demand arrangements, ease of access)
 - Know your existing control measures
- Communicate findings to the top levels of management of your business
- Identify and select proportionate mitigation measures and design a mitigation strategy based on the outcomes of the vulnerability assessment
- Document the vulnerability assessment, mitigation measures and verification and incident management procedures in an **Organic Fraud Prevention Plan**
- Develop an **effective training and communication strategy** to implement the Organic Fraud Prevention Plan
- Validate and verify mitigation measures and continually review and monitor the organic fraud prevention plan on at least an annual basis

- Nestle, "Food Fraud Prevention, Economically Motivated Adulteration"
 https://www.nestle.com/asset-library/documents/library/documents/suppliers/food-fraud-prevention.pdf
- GFSI position on mitigating the public health risk of food fraud
 <u>http://www.mygfsi.com/files/Technical_Documents/Food_Fraud_Position_Paper.pdf</u>
- PWC, "Food Fraud Vulnerability Assessment and Mitigation Are you doing enough to prevent food fraud?"

• <u>https://www.pwc.com/gx/en/services/food-supply-integrity-services/assets/pwc-food-fraud-vulnerability-assess-ment-and-mitigation-november.pdf</u>

FSSC 22000, "Tackling Food Fraud – Results of the FSSC 22000 Pilot audits on Food Fraud Prevention"
 http://www.fssc22000.com/documents/pdf/article-ff-201702-final.pdf

² References used to inform this section of the best practice guide:

I. DEFINITIONS

Mitigation Measure:

Measure taken to decrease vulnerability to organic fraud in a given supply chain.

Mitigation Strategy:

Selected set of mitigation measures aimed at preventing food fraud in a given supply chain that are incorporated into the Organic Fraud Prevention Plan.

Organic Critical Control Points (OCCP):

A step or procedure at which controls can be applied to prevent the organic integrity of an organic ingredient or product being compromised. Control points are essential components of an Organic System Plan, and identify the places in a product process flow or in the supply chain where the organic integrity of a product could be compromised.

Organic Fraud:

For the purposes of this Guide, organic product fraud can be defined as an intentional misleading or deceptive action carried out for illicit financial gain. Fraudulent acts may include adulteration, substitution, falsified records and the deliberate mislabeling of goods, as well as false statements made on applications, organic system plans, and during inspections. Of primary concern are intentional and economically motivated substitutions and the fraudulent mislabeling of organic products, including fabrication of fraudulent organic certificates. Such misrepresentation may occur at any point along the value chain from the product source to selling point.

Organic Fraud Prevention Plan:

A company plan that documents the vulnerability assessment, mitigation measures and verification procedures that will be performed and maintained to verify that the plan is effectively implemented.

Organic System Plan:

A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent, and that includes written plans concerning all aspects of agricultural production or handling described in Title 7 CFR 205 (National Organic Program Regulations.)

Vulnerability Assessment (or Vulnerability Characterization):

Within a food fraud management system, the step aimed at reviewing and assessing various factors that create vulnerabilities in a supply chain (i.e. weak points where fraud has greater chances to occur).

• Note: A *vulnerability* is a weakness or gap in protection efforts. *Risk* – The potential for loss, damage or destruction of an asset as a result of a threat exploiting a *vulnerability*. *Risk* is the intersection of assets, threats, and *vulnerabilities*.

II. VULNERABILITY FACTORS

To characterize the vulnerability of an ingredient, product or input to organic fraud, the following three aspects must be assessed:

Vulnerability driven by factors inherent to the ingredient



Factors such as the ingredient market price, its fraud history, composition and physical state are entirely independent of the actions taken by the buyer to mitigate the risk of organic fraud. This is defined as the inherent vulnerability of an organic ingredient or material. For example, fraud history is a good source of information. It is an indicator of the raw material potential vulnerability, and an important source of possible factors for which mitigation measures are needed.

Vulnerability driven by factors impacting the business (business pressure)

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Factors such as the demand for a specific ingredient (volume), the extent of its use (ingredient used in several products and businesses), or the market price fluctuation may contribute to an increased level of vulnerability to fraud.

Any anomaly in the economics of particular raw material sources is an indicator of the raw material potential vulnerability. Drastic increases in market price and scarce supplies of a

raw material in combination with high demand are strong indicators of increased raw material vulnerability based on economic anomalies.

Geopolitical considerations are also important to characterize vulnerability to food fraud. A sudden fluctuation in market price or country-specific low price compared with the rest of the market may indicate a lack of food control and/or regulatory/enforcement framework in the country of origin (or any other country through which the ingredient may transit).

Vulnerability driven by factors under the control of the buyer (i.e. supply chain)



Perhaps the greatest control a company has in preventing organic fraud is through knowledge and control of its supply chain. Vulnerability to organic fraud increases with the complexity of the supply chain, therefore supply chain transparency, traceability and simplification (fewer suppliers) are all key factors to minimizing and preventing organic fraud. Supplier relationships supported by supplier audits are also critical to protecting the organic supply chain. Full visibility of the supply chain, full traceability,

adequate purchasing specifications, availability of analytical methods, and robustness of surveillance programs all reflect the strength or weakness of a company's mitigation strategy.

III. CARRYING OUT THE VULNERABILITY ASSESSMENT PROCESS

Assessing the risk of fraud for an organic ingredient requires the understanding of the inherent raw material vulnerabilities, the business vulnerabilities, supply chain vulnerabilities and the existing controls in place. This will allow a company to define which preventive actions are needed (and where) to mitigate the risk of organic fraud. When conducting the vulnerability assessment, it is allowed to group materials to start with (e.g. similar raw materials or similar finished products). When significant risks are identified within a group, a more in-depth analysis may be required³.

Conducting an organic fraud vulnerability assessment can be compared to the hazard assessment used for developing a Hazard Analysis and Risk-Based Preventive Control (HARPC) plan. The major difference is that HARPC addresses food safety risks whereas the risk with organic fraud is primarily loss of consumer trust and the value of the USDA Organic seal. The similarity, however, is that both require a systematic approach to assessing risk and developing a preventive plan. Additionally, unlike the traditional Hazard Analysis and Critical Control Points (HACCP) analysis, several of the questions and factors considered to prevent organic fraud need to be addressed on subjective information or insights because companies may not have fact-based insights into specific fraud issues as the information is simply not available.

Unlike quality management systems that focus on preventing unintentional contamination with prohibited substances, organic fraud prevention must take into account economic incentives and deceptive criminal behavior. From this perspective, organic fraud prevention requires multi-competence support collecting as many insights on the unknown as possible to ensure that subjective opinions and insights are identified by thorough internal discussion and review. Accordingly, conducting a vulnerability assessment will require involvement from multidisciplinary teams depending on the size and scope of a company. Quality departments are best positioned to take the lead in conducting an assessment, but will be best supported by procurement, legal, and Human Resources (HR). Furthermore, the process for the on-going management of a vulnerability assessment should be clearly described in the Organic Fraud Prevention Plan.

It is important to note that every vulnerability identified will not automatically be determined to be significant and will not automatically be required to be addressed by a mitigation measure. It is important to identify as many vulnerabilities as possible, so they can be assessed. It is also important to note that such a vulnerability assessment is not a one-time activity but a dynamic process, which needs to be maintained regarding new information and external pressures.

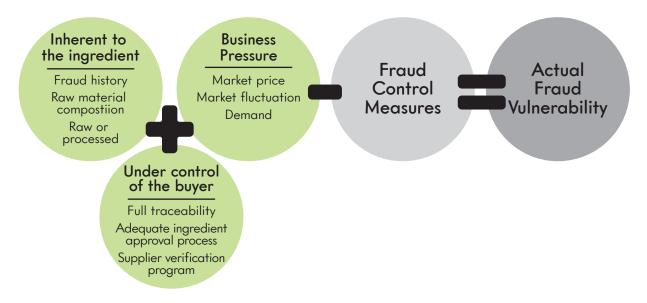
Finally, the initial implementation of an ingredient-by-ingredient organic fraud management system as described in this Guidance may be operationally challenging for organizations with large portfolios of ingredients and/or numerous ingredient-supplier combinations. A possible strategy for implementation in such situations is the addition of a pre-screening step to target use of this Guidance to a smaller subset of ingredients posing the greatest vulnerability to fraud to the organization. Ingredients found to be the most vulnerable in a pre-screening evaluation could then be more carefully evaluated by the supplier by carrying out the complete assessment in the Guidance.

³ Guidance on Food Fraud Mitigation:

http://www.fssc22000.com/documents/graphics/version-4-1-downloads/fssc-22000-guidance-on-foodfraud-final-100418.pdf

Another approach is to group ingredients by class (e.g. grain, produce, dairy) and evaluate them according to the vulnerabilities inherent to both the ingredient/product and the business (see Organic Vulnerability Assessment Tool). Ingredient classes found to be the most vulnerable in a pre-screening evaluation would then be more carefully evaluated ingredient-by-ingredient using the complete assessment (including supplier-specific factors).

ADEQUATE MITIGATION MEASURES REDUCE VULNERABILITY TO FRAUD



IV. ORGANIC FRAUD VULNERABILITY ASSESSMENT TOOL

Recent food fraud events in all sectors of industry have highlighted the need to reinforce companies' ability to combat fraud – within their own organization, and across the entire food value chain. With respect to food fraud prevention, several guidance and self-assessment tools have been developed by a number of organizations to help companies undertake their own vulnerability assessments and implement appropriate prevention plans. See Helpful Tools and Resources.

The self-assessment tool presented in this Best Practices Guide is specific to organic fraud prevention, and focuses on the vulnerabilities inherent to both the ingredient/product and the business (general, geographic, economic, and agronomic) as well as the vulnerabilities under the control of the buyer (supply chain assessment). Each factor in the assessment tool requires a response or answer that should be assigned to a vulnerability level. For each assessment factor, the company must also evaluate whether there is an existing mitigation measure in place to address the vulnerability. Any factor assigned to medium- or high-vulnerability that does not have a mitigation measure in place requires company action.

See Organic Fraud Vulnerability Assessment Tool in Appendix B

(beginning on page 52).

V. EXAMPLES OF MEDIUM- TO HIGH-VULNERABILITY WHAT ARE YOUR MITIGATION MEASURES?

- No formalized supplier approval process
- New supplier/short history
- Use of uncertified handlers (brokers, traders) in the supply chain
- Supplier handles both conventional and organic
- Long and/or complex supply chain
- Imported from areas of known risk (history of fraud)
- Ingredient/product comes from multiple suppliers
- Ingredient/product has crossed multiple borders
- Ingredient/product is sourced from multiple sources in an open market with limited knowledge about the supplier
- Supplier will <u>not</u> disclose sources and/or provide certificates for those sources
- Compliance documents submitted are not verifiable

- Violations of fraud found by NOP from product type and/or region
- Sudden change in volume or market price
- Certified company or certifier is not listed on the NOP Organic Integrity Database
- Supplier company operates under multiple names
- Bulk product with a valid organic certificate but not identified as organic on paperwork
- Missing certificate from originating farm or intermediate handler
- Evidence of falsification changed operation name on certificate to protect proprietary information
- Known production challenges and need for use of pesticides
- Lack of clarity about whether product was fumigated
- Lack of documentation verifying that the product was not fumigated.

B. MITIGATION MEASURES — DESIGNING A MITIGATION STRATEGY

Once the vulnerability assessment is complete and the findings have been documented and communicated to the top levels of management of your business, the next step is to design an appropriate mitigation strategy. The control and mitigation measures will be developed directly in response to the weaknesses or gaps identified by the vulnerability assessment; the objective is to move any of the medium or high contributions to vulnerability to the low contribution level.

MITIGATION MEASURES

When defining a Mitigation strategy, the potential vulnerabilities identified in the Vulnerability Assessment Tool should be assessed for their significance. A risk matrix similar to HACCP can be used (e.g. Likelihood of occurrence x Consequences). Profitability is an important factor of likelihood of occurrence. It is extremely helpful if a mitigation strategy for the significant risks is developed and documented.

In accordance with the results of your vulnerability assessment, below are examples of best practices and critical actions that can reduce your vulnerability to organic fraud:

BEST PRACTICES I.

CREATE A SUPPLIER VERIFICATION APPROVAL PROGRAM

One of the most effective actions that you can take is to increase supply chain transparency by implementing a formal supplier approval program, or by improving your existing program. The program should include a process that will improve transparency, traceability and the management of ingredients and products and an assessment to create "confidence" that each supplier will provide an authentic/compliant product.

- Identify who in your company is responsible for the various aspects of the supplier approval program including regular monitoring
- Determine whether you have full visibility of your supply chain. Who are your immediate suppliers? Who supplies them? What is your process for changing suppliers?
- Map and simplify (if possible) your supply chain:
 - Gather information to determine who is most at risk
 - Simplify your supply chain as much as possible to eliminate sources of risk
- Develop a Supplier/Vendor Approval Questionnaire and Checklist.
- Elements include but are not limited to:
 - Purpose and Scope
 - Supplier information and product information
 - Identify supplier activities
 - New/Existing/Trusted
 - Required documents, specifications, etc.

BEST PRACTICES I.

CREATE A SUPPLIER VERIFICATION APPROVAL PROGRAM (Cont.)

- Verify that the supplier (if certified) is listed in the NOP Integrity Database
- Verify that supplier's certifying agent is listed on the NOP website
- Ensure ingredient specifications are agreed upon and they include organic authenticity requirements
- Letters of guarantee
- Supplier audits
- Entity, if uncertified, has filled out "Uncertified Handler Affidavit"
- Other third-party audits such as GFSI or SQF
- Full visibility from supplier back to the farm
- Supplier has an Organic Fraud Prevention Plan
- Supplier's Organic Fraud Prevention plan is verified by a third party
- Establish and Maintain a Supplier Approval List
 - Clearly indicate the suppliers that are certified and the ones that are not
 - Develop a policy for receiving and verifying high risk ingredients
 - Develop a policy to only to source from NOP or equivalent certified entities
 - Ask suppliers of vulnerable ingredients or materials to undertake a mass balance exercise at their facility or further upstream in the supply chain
 - Implement more stringent requirements for suppliers that provide vulnerable products or materials
 - Make a business case for switching suppliers of ingredients or materials that prove to be consistently problematic, and present it to your purchasing department
- Establish a Supplier and Supplier Documentation Monitoring Process
 - Establish process for ensuring supplier is meeting expectations. This includes a formal annual monitoring process for all verification documents to ensure they are valid and up-to-date
 - Establish a six-month "compliance check" for new suppliers/new certificates
 - Develop a policy for procedure in case of non-conformance
 - Develop a process for communicating changes from supplier to buyer and vice versa
 - Develop a process for maintaining the supplier approval list
 - Reference to all related records (supplier list, vulnerability assessment, etc.)
 - Establish supplier audits

BEST PRACTICES II.

ESTABLISH BEST PRACTICES FOR RECEIVING ORGANIC INPUTS, INGREDIENTS AND PRODUCTS

Examples of records and practices to document and verify compliance:

In addition to a current valid organic certificate, the following practices or documents should be carried out and/or required and maintained:

- Cross-reference valid certificate to receiving documents to product labels. Ensure that "organic" is designated on all labels and associated paperwork, and cross-check to verify that product, paperwork and labels line-up
- Cross-check incoming product and paperwork with approved supplier list
- As applicable, verify that the following documents are available in order to verify certified organic status:
 - Transaction certificates for the shipment and sales to intermediate handlers, including brokers, traders, wholesalers, and transporters
 - Shipping manifest
 - Packing list
 - Bill(s) of Lading and invoice(s) from all vendor(s)
 - Certificate of origin
 - Clean truck affidavits, records of cleaning and sanitizing materials, and procedures used to clean trucks
 - Records documenting the audit trail, chain of custody, tanker seals, wash tags, truck and trailer numbers
 - Documents to demonstrate residue, GMO, quality, or other analytical testing performed on the product or in the supply chain
- Ensure that lot numbers are assigned to all products/ingredients, and organic designation is clearly maintained on label and storage areas.

BEST PRACTICES III.

ESTABLISH BEST PRACTICES FOR IMPORTS OR HIGH-RISK PRODUCTS

Require the following records to verify organic compliance of imported products:

- Organic certificates for each product or ingredient received
- Certificate of origin
- Transaction certificates for the shipment and sales to intermediate handlers, including brokers, traders, wholesalers, and transporters
- NOP Import Certificates
- Receiving records showing organic status, quantity of organic product received, and source of product
- Transaction documents including lot number or production code that links each document to the next and to the organic product
- Invoices and purchase orders with information identifying the specific product(s), such as lot numbers, quantities, and supply chain entities. The product should be designated as "organic" on all associated paperwork
- Shipping documents, such as booking sheets or bills of lading, with information such as lot numbers, product volume, handling instructions and the name of the last certified organic operation
- Phytosanitary certificate for each vessel used to move the product in the supply chain check for record of any fumigation activity
- Weigh tickets, receipts, and tags cross-check to organic ingredient/product
- Clean truck/container affidavit for bulk product verifying that truck/container was thoroughly cleaned and poses no risk of contact with prohibited substances
- Certificates of Analyses or Product Specification Sheets
- Product inventory and storage records
- TraceNet certificates (Applies to products certified in India to the USDA organic standards)
- Attestation statements (Applies to products certified to the Canadian organic standards)

BEST PRACTICES IV.

ESTABLISH BEST PRACTICES FOR ENSURING SUPPLY CHAIN TRACEABILITY AND MASS BALANCE

- Simplify your supply chain as much as possible
- Perform internal traceability exercises from finished product back to all raw ingredients.
 - Randomly choose a final/finished product
 - Determine if the final product can be traced back to all ingredients, processing aids and inputs used to produce the product
- Perform internal mass balance exercises
 - Randomly choose a final/finished product
 - Randomly choose a finished product
 - Can a mass balance be successfully performed? Does product in (all ingredients used to make a batch of product) account for product out?
 - Perform on batch production as well as monthly and annual production
- High Risk Product: Carry out verification of the volumes and full traceability for all at-risk (high) product in the shipment back to the growers. Verification should include the following, at a minimum, and be in sufficient detail to be readily understood and audited:
 - Identification of all growers and suppliers, their acreage, certifier, certificate, certificate number, NOP ID (if applicable), and expected production volume.
 - Volume of each grower's product (i.e. grain) represented in the shipment.
 - Identification of each intermediate handler in the shipment's supply chain, the name of its organic certification agency, certificate, certificate number, and NOP ID (if applicable). This includes all brokers, traders, wholesalers, and transporters.
 - For trace-back, ensure that clear links are established and documented
 - Verification of mass balance for the shipment from the organic certification agency of each intermediate handler.

BEST PRACTICES V.

ESTABLISH LABELING BEST PRACTICES

- Develop a policy that all incoming and outgoing certified organic product must be identified as "organic" on all accompanying/associated documentation (receiving documents, invoices, BOLs, etc.)
- Develop a policy that identification of certified organic status is clearly marked on all product labels (retail and non-retail) for incoming and outgoing products.
- Develop a policy that all incoming certified organic product (retail and non-retail) be labeled with the following information:
 - Identification of the product as organic
 - The last certified organic operation that handled the product
 - Name and contact information for the certifier of the last handler that handled the product
 - Handling instructions to maintain organic integrity of the product
 - Lot number
- Clearly designate products and product storage areas as "ORGANIC" in writing on the product label. Include statements such as "DO NOT FUMIGATE OR TREAT WITH IRRADIATION" on the label and on associated shipping documents.
 - Reference NOP Instruction 4013 Maintaining the Integrity of Organic Imports
 - Reference NOP Policy Memo PM18-1 Impact of Fumigation and Irradiation Requirements on Organic Imports
 - Reference NOP Guidance 5025 Commingling and Contamination Prevention in Organic Production and Handling. <u>https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf</u>

CRITICAL ACTIONS THAT CAN REDUCE VULNERABILITY. GOAL: INCREASE SUPPLY CHAIN TRANSPARENCY AS MUCH AS POSSIBLE.

- Create a robust Supplier Verification Approval Program
 - Map and simplify your supply chain
 - Make sure you have full traceability back to the raw material source
 - Make sure all suppliers have current and valid organic certificates
- Establish heightened scrutiny and surveillance for high-risk ingredients
- Establish best practices for receiving and

verifying organic status of ingredients

- Cross-reference (link) incoming product with organic certificates, approved supplier lists and all receiving documents and associated records (invoices, BOLs, shipping manifest, lot numbers, etc.)
- Require product labels include organic status, lot number and certification agent.
- Require record of any fumigation activity (phytosanitary certificates)

C. MONITORING AND VERIFICATION: EFFECTIVELY IMPLEMENTING MITIGATION MEASURES

ENSURING MITIGATION MEASURES ARE ADEQUATE AND EFFECTIVELY IMPLEMENTED

To ensure that organic fraud mitigations measures are adequate and effectively implemented, a monitoring program, including verification activities and incident management procedures, must be documented and formally built into the Organic Fraud Prevention Plan and a company's quality control systems. For the purposes of ensuring organic integrity, monitoring can be defined as a planned sequence of measurements and observations taken in real-time that reflect the proper functioning of the Organic Fraud Prevention Plan. Such measurements are typically assigned to the Organic Critical Control Points (OCCP) where organic fraud or loss of organic integrity is most likely to occur and/or to the key mitigation measures that have been implemented to prevent or deter the occurrence of organic fraud. On the other hand, verification describes activities other than monitoring, such as tests and other evaluations, that determine the validity of an OCCP and that the system is operating according to the plan.

There are a number of practices a company may perform that will not only allow for ongoing evaluation and maintenance of the overall organic fraud mitigation strategy but will also allow for the detection of organic fraud issues. Key monitoring and verification practices include internal audits, supplier audits, analytical surveillance or testing, and use of traceability tools and technology such as block chain.

I. INTERNAL AUDITS

While the organic certification process for any particular product is verified by an accredited certifying agent, all companies that trade, buy, grow, process or sell certified organic products and use the USDA Certified Organic seal on any of its products shall have an internal audit and verification process. This should be documented in writing as an Organic Integrity Quality Management System (QMS) that assures that the Organic Fraud Prevention Plan and all associated mitigation measures (including those beyond requirements for certification) will be used to verify the authenticity of all of the organic certificates issued during the production, handling and transportation of any and all USDA certified organic products.

27

The top management of the company, including the CEO, COO, President and all others in senior management, guarantee to commit the necessary resources and requisite training to:

- Establish and document an internal Organic Integrity Quality Management System (QMS) that ensures that all ingredients and products bought, processed or sold as certified organic conform to the requirements of the National Organic Program and to the specified mitigation measures established in the Organic Fraud Prevention Plan that ensure their authenticity and integrity
- Acquire, maintain, review and verify all organic certificates and accompanying documentation issued in the course of production, handling and transportation of certified organic products
- Provide those responsible for purchasing and auditing the authenticity of organic ingredients and products with adequate training, support and resources to perform all necessary tasks for verification in a timely fashion
- Develop a program of corrective action and reporting to appropriate authorities that will be implemented in any and all cases of potential fraud in the certification of organic products
- Maintain a program of continuous improvement that works towards improving the quality of the verification audit and timeliness of the organic fraud prevention process
- Audit all approved programs at least once per year. However, more frequent audits may be conducted (1) if either numerous minor non-conformances or a major non-conformance are identified during the audit;
 (2) if customer complaints indicate an ongoing problem; or (3) as suggested or directed by the National Organic Program of USDA or other regulatory agencies or trade groups monitoring the organic industry and trade.

In addition:

- The company must have an organizational chart or similar document listing all personnel assigned to managerial positions and responsibilities as described by the Organic Integrity QMS. This document will be updated at least once per year, or as needed to ensure accuracy and adequacy
- Top management must designate a management representative who, irrespective of other responsibilities, must have responsibility and authority that includes:
 - Ensuring that processes needed for the Organic Fraud Prevention Plan and the QMS are established, implemented, and maintained;
 - Reporting to top management on the performance of the QMS and any need for improvement; and
 - Ensuring the promotion of awareness of customer requirements and specified process verified points throughout the company.
- Each year, the Organic Fraud Prevention Plan and the Organic Integrity QMS will be reviewed and signed by the CEO, president (or equivalent) and management representative responsible for the implementation and proper execution of the QMS.

II. TESTING - A TOOL FOR VERIFYING COMPLIANCE

Testing under USDA's National Organic Program has a dual role in organic certification. It provides a means for monitoring compliance with the USDA organic regulations and discouraging the mislabeling of agricultural products. Testing also provides State Organic Program and certifying agents with a tool for ensuring compliance. Testing is a critical tool that can be used to verify that there was no intentional application of prohibited substances and also to measure the effectiveness of your contamination and commingling prevention measures. Examples of contamination events include but are not limited to overspray of pesticides from adjacent conventional fields, fraudulent manufacturing of organic fertilizers using prohibited substances, fumigation using prohibited substances at Ports of Entry and GE contamination of crops, ingredients or products.

Once you have completed your vulnerability assessment and designed your mitigation strategy, you can begin to set up your testing program that will ultimately be described in the Organic Fraud Prevention Plan. The following is a guideline on how to set up a testing program. Your involvement with the supply chain will dictate the type of testing you will be performing.

Key considerations that any company developing a testing program should consider include:

- Defining the parameters and responsibilities for a testing program
- Identifying a laboratory
- Sampling
- Testing frequency
- Test results and corrective actions.

DEFINING THE PARAMETERS AND RESPONSIBILITIES FOR A TESTING PROGRAM

As with any quality assurance program, the first important step is to identify the person who will be responsible for developing a testing plan along with the tests, method, and procedures to be used and a corrective action plan as needed. Typically, a testing program falls under the responsibility of the QA Manager who works with the QA department to collect and submit raw material samples, review all lab results to assure compliance and release product for usage, document all corrective action taken when a test is out of tolerance, and places the documentation of the rejection or other corrective actions on file in a lab testing log.

IDENTIFYING A LABORATORY

Identify a laboratory that can perform the tests that you are interested in. The laboratory should be certified or accredited to an industry standard. To ensure consistency in the analytical approach and quality assurance of the data by parties conducting residue testing, the National Organic Program issued instruction on laboratory criteria that should be used as part of meeting the residue testing requirements under 206.670 of the NOP regulations. The instruction includes helpful information to be followed when selecting a laboratory. Although not essential, greater credibility can be gained by the laboratory participation in proficiency testing. Ask your lab what certifications they hold and if they participate in proficiency testing. ISO 17025 and ELAP are examples of testing competency.

SAMPLING

Sampling your material is an integral part of your testing plan and is sometimes overlooked. It is critical to identify what risk mitigation measure your sampling program is aiming to validate. When using sampling as a tool to validate fraud prevention measures, the goal is a representative sample. That is, obtaining a sample that can accurately represent the size of your lot or the amount of material that you want the resulting test to apply to. There is a balance here, where you must determine the frequency and the size of each sub-sample compared to the overall amount. If the sample is not representative, one risks a loss of credibility in the test results. Excessive sampling can exaggerate the costs of testing without providing any additional assurance. Typically, once accredited laboratories have been chosen for testing, their guidelines regarding quantity and collection procedures should be followed to obtain a representative sample.

Sampling plans are available online and can form the basis of your own sampling plan (See NIST Mil Spec 105D or equivalent in your segment of the supply chain). Alternatively, your quality team may already have a food safety sampling plan in place that evaluates the effectiveness of reducing foodborne pathogens. These types of plans can be used as a template for organic fraud prevention sampling.

TESTING FREQUENCY

The testing frequency will be determined through your vulnerability assessment. Increased exposure or potential to loss of integrity will be identified. Frequency of testing based on the findings can increase confidence in results.

The actual test that you perform will vary with what your testing plan is trying to accomplish. The tests may range from pesticide testing, isotope ratio testing and GMO testing. Choose the tests that would best address your product or commodity and the risks that have been identified in your vulnerability assessment. To choose the right test, you must first understand the fraud risks endemic in your supply chain (e.g. GE testing on imported wheat would not make sense, as GE wheat has not been released onto the market), and the capacity for any given test to actually detect fraud (e.g. pesticide residues can volatilize when exposed to heat, so testing roasted soybeans for pesticides may not be the best use of testing resources).

Establish the actions taken for each set of test results that you receive. Similar to the actions taken for food safety purposes, you may consider a Hold and Release program, or diversion to another market (i.e. conventional). Results should be reviewed to determine if corrective action is needed, and if there are any trends.

TEST RESULTS AND CORRECTIVE ACTIONS

Test results provide documentation about the integrity of your products and can verify that your organic fraud prevention plan is or is not working. The following considerations are critical to interpreting results and identifying corrective actions.

- 1. Lot number designation
- 2. Available tests
- 3. Which test is right for you
- 4. Interpreting and reacting to the results.

1. Lot number designation

Regardless of the product that you sell, it is important to define the lot that your testing represents. This is referred to as a lot definition. This goes hand in hand with the representative sampling plan discussed previously. A "lot" can be defined in many ways and depends entirely on your process. Some examples can be as follows:

- a) One day of production
- b) One block of land
- c) A single shipment.

The concept would be to provide a unique number that will never be duplicated or repeated and can be traced back to an amount that you designated. In the event of a quality issue, this amount or "lot" can be traced throughout your supply chain, isolated, and diverted or recalled.

You may already have lot numbers that have been designated depending on what segment of the supply chain that you are on. Any lot numbers that are supplied to you should be recorded to move back a step if requested.

FRAUDULENT ACTIVITY	TEST	APPLICABLE CROP	TYPE OF RESULTS (QUALITATIVE OR QUANTITATIVE)
USE OF PROHIBITED PESTICIDES IN THE PRODUCTION OF CROPS	Multi- Residue Pesticide Screens (QuEChERS)	MOST CROPS CAN BE ANALYZED FOR PESTICIDE RESIDUES	QUANTITATIVE – MOST LABS WILL PROVIDE CONCENTRATIONS DOWN TO 0.01 PPM
USE OF PROHIBITED HERBICIDES LIKE GLYPHOSATE OR 2,4-D	Individual compound tests must be ordered to detect glypho- sate or 2,4-D	MOST CROPS CAN BE ANALYZED FOR PESTICIDE RESIDUES	QUANTITATIVE – MOST LABS WILL PROVIDE CONCENTRATIONS DOWN TO 0.01 PPM
FUMIGATION OF CROPS POST-HARVEST WITH PROHIBITED SUBSTANCES	No Reliable Tests for Methyl Bromide, Magnesium Phosphide or Calcium Phosphide available	N/A	N/A
	Strip test	CORN, SOY, ALFALFA,	QUALITATIVE (POS/NEG)
COMINGLING, BLENDING, OR SUBSTITUTION OF ORGANIC CROPS WITH	ELISA	SUGAR BEET, CANOLA, COTTON, RICE, PAPAYA, SUMMER SQUASH,	QUANTITATIVE – CAN DETECT 0.01 – 0.1% GMO PROTEINS
GMO CROPS	PCR	TOBACCO	QUANTITATIVE – CAN DETECT 0.01% GMO DNA
USE OF PROHIBITED SYNTHETIC FERTILIZERS IN THE PRODUCTION OF CROPS	Nitrogen 15 / Nitrogen 14 Isotope Ratio Testing	PRODUCE	QUALITATIVE – A LOWER RATIO OF N14/N15 CAN INDICATE THE USE OF SYNTHETIC FERTILIZERS, BUT TESTING METHODOLOGY IS NOT ALWAYS CONCLUSIVE
	Metabolomics (ref)		QUALITATIVE (POS/NEG)

2. Available Tests

Ideally, the tests that you have identified as relevant for demonstrating organic integrity will be applied to this lot. Testing resources and frequency will need to be allocated based on how much risk your company has identified exists within the supply chain.

Below is a list of types of fraud, tests that can be performed to detect this fraud, the possible crops they may apply to, and limitations of the testing methodologies.

3. Which test is right for you?

At this point, you must decide which tests are right for you. Ask yourself (but not limited to) the following questions:

1. Does my product have a potential for coming into contact with prohibited material like pesticides or fumigants?

- 2. Does my product have a risk for GMO contamination, either through pollen drift or comingling?
- 3. Do my ingredients or inputs have a history in the industry of being tainted? With what?

Based on your answers, you can then decide which tests are applicable for your supply chain. Based on each test's limitations, you can determine how valuable it will be for detecting fraud or validating that risk mitigation measures are successful.

4. Interpreting and reacting to the results

Understand the appropriate levels of testing for each test. Technology continues to improve and detection levels continue to get increasingly more sensitive. For example, QuEChERS results can be accurate to parts per billion where the industry standard acceptance criteria may be higher, perhaps parts per million. Industry standards are generally available for each quantitative testing method.

At this point, you have completed the following:

- 1. Risk assessment
- 2. Identified your lot
- 3. Obtained a representative sample
- 4. Identified the appropriate tests to demonstrate organic integrity
- 5. Performed the appropriate supporting tests.

Ideally, all the results came back in support and compliance with your organic systems plan. That is, no pesticides were detected, your product tested free of GMOs, and the isotope ratio tests showed that it was unlikely your product was grown using synthetic fertilizers.

What happens if all the tests didn't come back quite as planned? The results showed some pesticide residues or there were GMOs detected at levels higher than the acceptance criteria allows. You must address this through corrective action. In some cases, the product must be diverted from the organic market.

Following a positive sample, an investigation can help to identify the source of the contamination. Refer back to your organic systems plan and your process to identify the possible places that contamination or comingling could have occurred. Trace back samples and test at each potential critical control point. Identifying the potential points along the supply chain where contamination or fraud can occur and establishing appropriate and consistent testing protocols at each of these points will ensure you are using residue testing to its maximum capacity as a tool for validating fraud prevention measures.

HELPFUL RESOURCES

To assist certifiers and industry in matters of testing residues, UDSA's National Organic Program has created extensive guidance that can be found in its Certification Handbook. The guidance includes sampling procedures for residue testing (NOP 2610), laboratory selection criteria (NOP 2611), a target list of prohibited pesticides that includes approximately 188 analytes (NOP 2611-1), and step-by-step instructions for responding to test results (NOP 2613).

All of the guidance documents may be viewed electronically and/or be downloaded through NOP's website at <u>https://www.ams.usda.gov/rules-regulations/organic/handbook</u>.

Pesticide Residue Testing

- Sampling Procedures for Residue Testing: NOP2610
- Laboratory Selection Criteria for Pesticide Residue Testing: NOP2611
- Prohibited Pesticides for NOP Residue Testing: NOP 2611-1
- Responding to Results from Pesticide Residue Testing 2613

GMO Testing

- NOP Policy Memo 11-13 (Clarification of Existing Regulations Regarding the Use of Genetically Modified Organisms in Organic Agriculture)
- See Resources for laboratory suggestions

III. TRACKING AND COMPLIANCE VERIFICATION TECHNOLOGIES

Supply chain transparency, a rigorous supplier approval process, and monitoring supplier compliance and performance are critical to ensuring organic integrity. Each company will have their own systems for monitoring and tracking suppliers, inputs, orders, production, fulfillment, and sales. General concepts such as blockchain and SaaS tools are described below to help companies determine which type of technology solutions if any, might be incorporated as an organic fraud prevention tool. Questions to consider before utilizing any mitigation tool are summarized at the end of this section.

A. SUPPLY CHAIN TRACKING AND TRANSPARENCY

CONCEPT: Blockchain

A blockchain is a digital ledger of identifying information, transactions, and smart contracts that creates a digital history or lifecycle of an asset. Entries on an asset become permanent and unchangeable. Assets can be digital or physical. Blockchain was co-created cryptocurrency to provide a distributed consensus on the history of a particular asset. Now, blockchain is being used by myriad industries for transparency in complex supply chains. The blockchain of any particular item can be extremely specific and 100% transparent, or can be a complete record but portions of the record are only available to authorized users. Since

blockchain creates the product history as it moves, information is available 24/7 in real-time rather than relying on compilation and investigation of past records. One key requirement is that participants relying on a blockchain are part of the same platform or system.



USES FOR PROMOTING ORGANIC SUPPLY CHAIN INTEGRITY

- creating a many to one data solution for clear identification and traceability of a product
- track produce from seeds used to product condition at time of harvest to delivery
- collect and organize documentation gathered from various sources
- develop smart contracts that will trigger an action if a requirement is met. For example, if a supplier uploads testing evidence for a particular lot, that particular transaction can pass to the next phase of the buyer's procurement process.
- protect confidential business information also using smart contracts while maintaining full supply chain history
- automate data collection from sensors (in-field, during transport, or on the shelf)
- automate notices for action required such as document review of certificates and test results added to a product ledger
- institute member-approved rules and condition for advancement of an asset transacted through the chain.

CASE STUDIES

- IBM and Walmart use blockchain to trace mangos back to the source involving 16 farms, two packing houses, three brokers, two import warehouses, and one processing facility ¹
- Dole, Driscoll's, Kroger, McCormick and Company, Nestle, Unilever, and Walmart formed a food safety coalition focusing on blockchain as a method to increase supply chain transparency²
- Taiwan is using blockchain technology to screen and track the health status of milk imports.³

CONCEPT: SENSORS

Precision agriculture is revolutionizing the way food is planted, grown, and harvested. Thanks to the Internet of Things (IoT), more information is available than ever before. This data-driven approach is moving beyond the field and into the supply chain to monitor for product freshness, freight conditions, contaminants, and more, thanks to rapid innovation in sensors. A sensor is a device that obtains information about a particular condition. The sensor then reports that condition either at a predetermined standardized reporting period, in the event an alert is triggered, or both. Sensors can be programmed to report directly into a blockchain. Sensors are available for a range of reports, come in all sizes and price points.

USES FOR PROMOTING ORGANIC SUPPLY CHAIN INTEGRITY

- Tracking field conditions where products are produced such as nitrogen content
- Tracking product conditions such as chemical changes due to a fumigation occurrences; originally developed as a food defense tool
- Tracking location details so the journey from field to factory is detailed and automated.

CASE STUDIES

- The European Union commissioned a report demonstrating that sensors and the Internet of things will revolutionize supply chain management from small niche operations to large-scale industrial operations. The report indicated more funds would be spent on expanding the knowledge base and applications of this technology for the benefit of farmers and consumers. ⁴
- Food sensors and RFID tagging have been demonstrated to increase supply chain traceability and safety.⁵
- Zest Labs helps food retailers monitor best-by dates and product conditions on arrival to reduce food waste in transit and stores. ⁶

² <u>http://www.sustainablebrands.com/news_and_views/startups/sustainable_brands/ibm_harnesses_blockchain_technolo-gy_improve_supply_chain_</u>

- ⁴ <u>https://ec.europa.eu/eip/agriculture/sites/agri-eip/files/eip-agri_focus_group_on_precision_farming_final_report_2015.pdf</u>
- ⁵ RFID and Sensor Network Automation in the Food Industry: Ensuring Quality and Safety through Supply Chain Visibility,

First Edition. Selwyn Piramuthu and Wei Zhou

⁶ https://www.fastcompany.com/40424163/these-high-tech-sensors-track-exactly-how-fresh-our-produce-is-so-we-stopwasting-food

¹ Galvin, David, "IBM and Walmart: Blockchain for Food Safety"; <u>https://www-01.ibm.com/events/wwe/grp/grp308.nsf/vLookup-</u> PDFs/6%20Using%20Blockchain%20for%20Food%20Safe%202/%24file/6%20Using%20Blockchain%20for%20Food%20Safe%202.pdf

³ <u>https://www.ccn.com/taiwans-owlting-launches-ethereum-based-blockchain-for-food-safety/</u>

CONCEPT: SOFTWARE AS A SERVICE (SAAS)

There are several Software As A Service (SaaS) solutions that have been created to strengthen supply chain integrity. While this is not an endorsement of a particular provider, the 'best in class' solutions providers support: 1) easy integration of suppliers into their buyers' systems; 2) support of 'real time' monitoring/ updating; and 3) recognition of common safety and integrity systems (i.e., HACCP, ISO, etc.). Most SaaS offerings are cloud based and can be accessed anywhere with an Internet connection.

USES FOR PROMOTING ORGANIC SUPPLY CHAIN INTEGRITY

- Customer relationship management
- Increased visibility across teams for enterprise resource planning
- eCommerce can be used to track products out
- batch recipe management and inventory trackbacks.

CASE STUDIES

- Olam Farmer Information System (OFIS) is an SaaS platform aiming to provide smallholder farmers with a variety of resources to help sustain and grow their operations, as well as give Olam the information it needs to assure its customers about the provenance of their products. OFIS now has 100,000 farmers signed up. OFIS offers registrants a variety of features, including data management, geotagging for traceability, and ways to reduce supply chain risk in a variety of crops like coffee, cocoa, cashews, hazels, palm, pepper, rice, and rubber.⁷
- Purchasing verified organic supplies from online SaaS such as Mercaris or Ekowarehouse
- Utilizing SaaS like Compliance Cops to help with supplier verification and document maintenance.

EVALUATING A TECHNOLOGY BEFORE INTEGRATION INTO COMPANY PROTOCOLS AND THE ORGANIC FRAUD PREVENTION PLAN

There are countless technology solutions, providers, and promises in the marketplace today. Individual companies will rely on different tools depending on their footprint, supply chain complexity, and available resources. Before investing in any particular tool, be sure to get answers to the following questions first.

- read out of information we already collect?
- Does the program or service streamline an existing process, create a new one, or both?
- How will this tool integrate with existing critical systems?
- What resources will be needed to utilize and maintain the tool?
- How will this tool improve the organization or
 What support is available from the vendor after programs are installed and implemented?
 - How easy will it be to add / change/ update users and permissions?
 - Which other companies are already using the tool? Request a conversation with an existing client.

⁷ https://aqfundernews.com/olam-creates-aqtech-platform.html

IV. IMPLEMENTING THE ORGANIC FRAUD PREVENTION PLAN

At this point in the program, a food fraud mitigation team has been established, a vulnerability assessment is complete, appropriate mitigation measures have been identified and selected, and a monitoring program, including verification activities and incident management procedures, are documented in the Organic Fraud Prevention Plan. This should all be supported by the Organic Integrity Quality Management System that assures that the Plan and all associated mitigation measures will be used to verify the authenticity of the organic ingredients and products that are purchased by your company. Central to this process is the internal audit and verification process described earlier. Additional key activities that will help ensure the Organic Fraud Prevention Plan is fully implemented include developing an effective **employee training and communication strategy** and integrating the **Organic Fraud Prevention** Plan into the Organic System Plan via an Organic System Plan Update.

1. EFFECTIVE TRAINING AND COMMUNICATION STRATEGY

Training and good communication systems are essential to every element in an organic fraud prevention program. As described earlier, a vulnerability assessment will likely require a multidisciplinary team with a wide range of expertise, depending on the size and scope of a company. The composition of a fraud prevention team is likely going to be different than the team that is assembled for the development of a HACCP Plan. Furthermore, the team will likely evolve over time as the understanding of food fraud develops and/or a company grows or diversifies its product offerings. Training of the team will be required, and external education and expertise may be necessary.

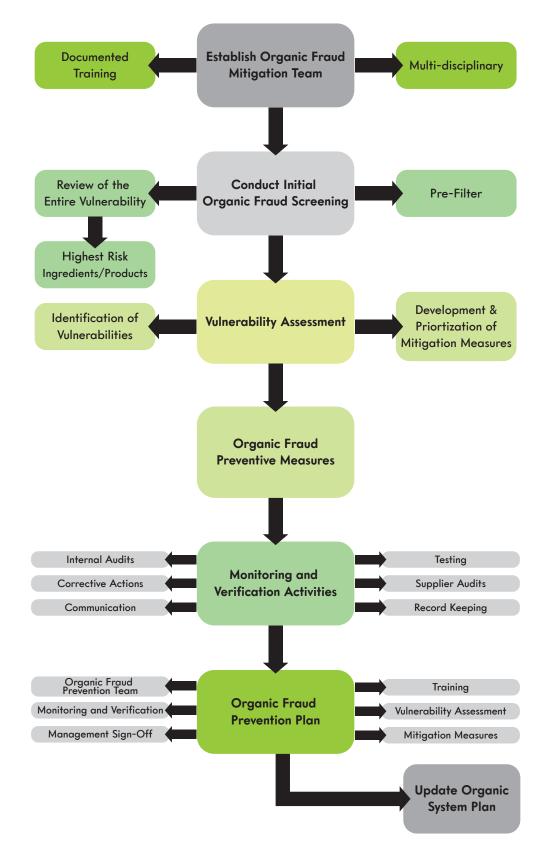
Several related training options also exist for food fraud prevention as it relates to the requirements of major food safety and company standards¹, an example being Michigan State University which provides free web-based courses (MOOC Food Fraud audit guide – MOOC = massive open online course): <u>http://foodfraud.msu.edu/mooc</u>. Additional resources are found in Section V. (Acknowledgements and Further Reading) of this Guide.

In addition to personnel training and education, communication is a critical element in developing, implementing and maintaining effective fraud mitigation measures. It will be necessary to describe, in the Organic Fraud Prevention Plan, how internal and external communication will be carried out. Examples within a company include employee trainings, team meetings, educational programs, bulletin boards and of course well-documented procedures that are managed and maintained under document control protocols. Examples of communications outside the company include correspondence with regulators, auditors, suppliers, customers, and contractors. A quality assurance document control protocol that includes managing how procedures, work instructions and forms are developed, implemented and modified will be key. Leaders of the organic fraud prevention team must ensure that employees in their respective areas have been trained on these protocols, including how communication must be managed to maintain the system. The training must, of course, be documented.

¹ Food fraud mitigation is a requirement of different food legislation and customer standards. Here are a few examples: FSMA – §117.130 and §117.135 states that you must identify hazards that may be intentionally introduced for purposes of economic gain and to subsequently identify and implement suitable preventive controls; BRC – 5.4 Product Authenticity, Claims and Chain of Custody; GFSI FSSC22000 – 2.1.4.6 Food Fraud Prevention; Freshcare – F12 Food Defence and food fraud; HARPS – 17.0 Food Fraud; Woolworths Supplier Excellence Program, Manufacturing – 1. Company Commitment and Food Fraud; SQF Edition 8 – Fundamentals – 2.7.2 Food Fraud



DEVELOPING AN ORGANIC FRAUD PREVENTION PLAN



2. UPDATING THE ORGANIC SYSTEM PLAN

In Section II of this Guide, we introduced the Organic System Plan (OSP) which is the cornerstone for organic certification. The OSP is the primary document that describes how a certified operation will comply with the requirements of USDA's organic regulations. Every USDA organic certified operation is required to develop and maintain an OSP and it functions as a legally binding contract between the certifier and the certified operation. The OSP is comprehensive and defines how an operation will remain in compliance with the organic standards and it explains, in detail, how this will be done. Furthermore, the OSP is not stagnant – it evolves and is updated as an operation may change and develop or revise its practices. At an operation's annual inspection, all aspects of the OSP are reviewed and verified.

COMPONENTS OF AN ORGANIC SYSTEM PLAN

- Practices and procedures to be performed and maintained;
- A list of each substance to be used as a production or handling input;
 Practices and physical barriers established to prevent commining input;
- Monitoring practices and procedures to be performed and maintained;
- A description of the record keeping system;
- Practices and physical barriers established to prevent commingling with conventional food and contact with prohibited substances; and
- Any additional information needed to document NOP compliance.

Accordingly, organic fraud mitigation measures that are established as a result of the vulnerability assessment exercise, will need to be added to the Organic System Plan. For example, any new or revised practice related to organic product purchasing, receiving, labeling, supplier approval, ingredient/input verification, document control (e.g. organic certificates), record keeping, monitoring practices and procedures, storage, etc. would require an update to the OSP. This makes sense, since the mitigation measures that were developed in response to identified gaps or weaknesses in the organic management system, presumably did not exist prior. Furthermore, the mitigation measures developed for organic fraud prevention purposes are, in fact, practices that are used to verify NOP compliance of organic ingredients and products.

Adding either individual organic fraud mitigation measures into the OSP, or preferably attaching the Organic Fraud Prevention Plan as an addendum or update to the OSP has multiple benefits:

- 1. Updating the OSP will be required if a certified organic operation is making changes to its organic management program as a result of the vulnerability assessment. To do otherwise may result in non-compliances.
- 2. Integrating the Organic Fraud Prevention Plan into the OSP by way of an OSP update will by default integrate the practices and procedures into the annual certification cycle, thereby creating an annual 3rd party verification mechanism. A 3rd party company audit in addition to the internal audit and supplier audits will create a very robust system for ensuring organic product authenticity.
- 3. Integrating the Organic Fraud Prevention Plan into the OSP will only strengthen a company's existing OSP and the overall organic certification process and it will add to the collective effort by the organic industry to achieve organic integrity across complex organic supply chains.

COMPONENTS OF THE ORGANIC FRAUD PREVENTION PLAN

- Names and Roles of the Organic Fraud Prevention Team (including designated lead)
- Vulnerability Assessment
- Organic Mitigation Measures
- Monitoring Procedures
- Verification Activities (testing, supplier audits, specification management, block chain)

- Internal Audits
- Incident Management Procedures
- Communication and Training Strategy
- Description of Record Keeping
- Management Review and Sign Off
- Integration into the Organic System
 Plan (or attach as an addendum)

IV. ALERT SYSTEM: MONITORING AND REPORTING ORGANIC FRAUD

It is essential to maintain a routine watch of USDA National Organic Program (NOP) announcements regarding fraudulent certificates, investigations, suspensions, and revocations as well as monitoring other official and industry publications, which may give early warning of information or changes that may trigger new threats of organic fraud, or change the priority of existing threats.

This section provides guidance on what to do when a business engaged in organic trade suspects or detects fraud. It includes a template that will help businesses collect and organize the necessary information to be shared in order to submit an actionable complaint.

A. WHAT DO YOU DO WHEN YOU SUSPECT OR DETECT FRAUD.

In short, reject the product, return it to the vendor/supplier/producer and report it to your own ACA, the ACA of your supplier and the competent authority (e.g. USDA-NOP, State Organic Program). Please note that it is most effective to file the complaint to BOTH your certifier and the USDA-NOP. **For other com-plaints within California**, both the <u>California State Organic Program</u> and the <u>National Organic Program</u> should be contacted as they can levy fines and embargo products.

B. HOW TO FILE A COMPLAINT WITH NOP

Anyone who suspects a violation of the USDA organic regulations can and should file a complaint. When you report an alleged violation, you must provide as much information as possible to help ensure a thorough investigation. Provide your contact information, and the NOP will contact you if necessary for clarification or when the case is closed. It is recommended practice to check in with NOP on a regular basis to see if they need any additional information.

I. COMPLAINT TEMPLATE

Follow this suggested template to organize your complaint: If you are willing to discuss the issue further or wish to be notified when the case is closed, please include your name and contact information with your complaint. If you would like to remain **CONFIDENTIAL**, clearly state this with your submission and mark all documents accordingly.

CONTACT INFORMATION

- Company
- Name of person filing the complaint, title
- Contact email/phone
- Date Submitted
- Your certifier (if applicable)
- State whether you wish to remain confidential

FILING A COMPLAINT

EMAIL: NOPCompliance@ams.usda.gov

PHONE: (202) 720-3252

MAILING ADDRESS:

NOP Compliance and Enforcement Branch Agricultural Marketing Service United States Department of Agriculture 1400 Independence Avenue, S.W. Mail Stop 0268, Room 2648-S Washington, D.C. 20250-0268

Reports should be written, verifiable, and accompanied with evidence documenting the suspected fraud. Evidence should be first-hand. We recommend sending a copy of the complaint to any organic certifiers involved and your certifier as well.

COMPLAINT INFORMATION

1. Nature of complaint - detailed explanation of the identified regulatory violation

- a. Use of fraudulent organic certificates to market or sell agricultural products
- b. Misrepresentation of conventional as organic (not fraudulent certificates)
- c. Labeling violation
- d. Excess volume (evidence that volume exceeds organic supply)
- e. Lack of documentation
- f. Evidence of contamination by a prohibited substance (pesticide use, fumigation, treated seed, etc.)
- g. Changing identity
- h. Inability to follow an audit Documentation not in alignment with product (not matched, excessive documents, wrong documentation type, etc.
- i. Use of uncertified co-packers or other handlers in the processing of agricultural products to be sold, labeled or represented as organic
- j. Distribution by an uncertified/readily confirmed entity
- k. Below market value
- I. Other: Please explain

2. Severity of the complaint – indicate the severity of the complaint and explain why

- a. Minor The violation is un-willful, correctable and is not a result of a systemic failure in OSP
- b. Major The violation is un-willful but is a systemic failure of OSP and inability to comply with the regulation; warrants a proposed suspension
- c. Severe The violation is a willful violation of the organic regulations and warrants revocation

3. Reference the section of the rule(s) you think the complaint violates

- a. 7 CFR XXX
- b. Explain why it violates this section of the rule

4. The source of the product, list:

- a. Full Business name (s)
- b. Brand name of the product
- c. Contact name
- d. Address
- e. Phone number
- f. Certification agency of that source

5. Other parties involved in transactions, list:

- a. Reference certificate documents information offered as proof of compliance (list operator name, certifier, certificate number)
- 6. The type (including variety, if applicable) of contaminated/fraudulent product

- 7. The lot number or other identifying mark, if any, of the product ("best by")
- 8. The quantity of product, if known
 - a. Is this entire lot or just contaminated product?
 - b. E.g., 1 lot, etc.
- 9. If the complaint involves a contaminated product
 - a. The name of the prohibited contaminant, if known
 - b. The amount of the prohibited material, if known
- 10. The length of time that the violation has been occurring, if known
- 11. The basis of knowledge of the fraud (food safety testing, observation, phone call, etc.)
- 12. If testing was performed, the test results themselves and any information about the sampling protocol and chain of custody
- 13. Any information about the likely source or reason for the contamination/fraud
- 14. Who the product has already been sold to (if applicable)
- 15. Any additional information relevant to the situation (images of labels, attachments and additional documentation accepted)
- 16. What action has complainant already completed?
- 17. Has there been any industry action? If so, what?
- 18. Nature of the supply chain (who is selling the product? Who else is buying? Market saturation level?)

Remember, filling a complaint should follow the big 5 W's: Who, What, When, Where, and Why.

43

WHAT HAPPENS AFTER THE COMPLAINT IS FILED?

The National Organic Program (NOP)* will review your complaint and determine how best to proceed. This may include coordinating a thorough investigation with the operation's certifying agent. If the suspected violation is confirmed, the operation could be subject to financial penalties up to \$11,000 per violation or suspension or revocation of its organic certificate. If you provided your contact information, the NOP will contact you when the case is closed.

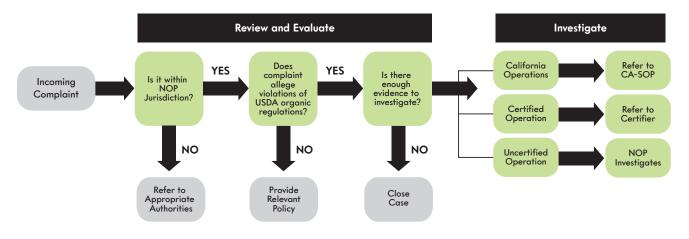
*Complaints involving operations in California are referred to the California Department of Food and Agriculture and follow a similar process. Why are these handled differently?

WHAT SHOULD I DO IF I USE AN INGREDIENT OR PRODUCT SHOWN TO **BE FRAUDULENT?**

Do not sell it as organic. Knowingly selling fraudulent product is unethical and may also make your operation subject to criminal prosecution or civil penalties. It may be marketable without any organic claims, but in some cases, the product may need to be written off as a complete loss.

HOW DOES THE COMPLAINT PROCESS WORK?

As the flow chart shows, there are several steps the NOP follows once receiving a complaint. It is important to note that if sufficient evidence is not available, NOP is unable to move forward with further review and investigation and the case closes.



Resources

- How to File a Complaint on Organic Regulations https://www.ams.usda.gov/services/enforcement/ organic/file-complaint
- NOP Integrity Database (includes list of suspended
 Fraudulent Organic Certificates and revoked organic operations) https://organic.ams.usda.gov/integrity/
- Joint Organic Compliance Committee https://www.ams.usda.gov/services/enforcement/ organic/joint-committee
- https://www.ams.usda.gov/services/enforcement/ organic/fraudulent-certificates
 - Receive email updates on topics of organic interest: Get E-mail Updates

V. ACKNOWLEDGEMENTS, RESOURCES AND FURTHER READING

A. ACKNOWLEDGMENTS

The Organic Trade Association would like to thank the members of the Global Organic Supply Chain Task Force, convened in May 2017. The mandate of this task force is to develop a best practices guide to use in managing and verifying global organic supply chain integrity to help brands and traders manage and mitigate the risk and occurrence of organic fraud. The Organic Trade Association would also like to thank the USDA National Organic Program for providing valuable feedback on the complaint template included in this guide and the Accredited Certifiers Association for its collaboration on this project. Finally, the Organic Trade Association would like to recognize the GFSI Food Fraud Think Tank and the MSU Food Fraud Initiative for their ongoing and valuable work on vulnerability assessment and mitigation strategy. The food fraud prevention model and associated guidance adopted by GFSI significantly shaped the process we adopted in this guide for developing and implementing a written organic fraud prevention plan.

B. RESOURCES AND FURTHER READING

Below are additional resources that the users of this guide will find helpful. Links and contact info are provide where appropriate.

NOTE: This is not intended to be a comprehensive list nor an endorsement of any particular product or service.

I. STANDARDS

- Title 7 Code of Federal Regulations, Part 205-National Organic Program **USDA** organic regulations
- Access to international standards Global Organic Trade Resource Guide http://www.globalorganictrade.com/

II. USDA GUIDANCE DOCUMENTS/INSTRUCTIONS/POLICY

- NOP 5031: Certification Requirements for Handling NOP 2609: Unannounced Inspections **Unpackaged Organic Products** https://www.ams.usda.gov/sites/default/files/media/5031.pdf
- NOP 4013 Interim Instruction: Maintaining the Integrity of Organic Imports https://www.ams.usda.gov/sites/default/files/media/NOP4013IntegrityOrganicImports.pdf
- NOP 2602: Recordkeeping for Certified Operations https://www.ams.usda.gov/sites/default/files/media/2602.pdf
- https://www.ams.usda.gov/sites/default/files/media/2609.pdf
- NOP 4009: Who Needs to be Certified https://www.ams.usda.gov/sites/default/files/media/4009.pdf
- APHIS Fruit and Vegetable Import Requirement (FAVIR) Database: https://epermits.aphis.usda.gov/manual/index. cfm?CFID=227701andCFTOKEN=9b59dc120fc5103f-0102C510-9977-5744-AC3D60FA1941AAC-BandACTION=pubHome

III. SELF-ASSESSMENT TOOLS

- SSAFE Food Fraud Assessment Tool <u>https://ffv.pwc.com</u>
- Food and Drug Administration (FDA) Vulnerability Assessment Software <u>http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295900.htm</u>
- IV. ALERTS AND DATABASES
- California State Organic Program
 <u>https://www.cdfa.ca.gov/is/i_and_c/organic.html</u>
- FAO Early Warning Bulletin http://www.fao.org/food-chain-crisis/early-warning-bulletin/en/
- Ports of Entry websites

 (e.g. <u>http://www.portofstockton.com/project/view-log</u>)
- U S Food and Drug Administration (FDA) Import Alerts and Refusals <u>http://www.fda.gov/ForIndustry/ImportProgram/</u> <u>default.htm</u>
- Fraud History USP Food Fraud Database <u>http://www.foodfraud.org/</u>
- Fraud History NCFPD EMA Incidents Database <u>https://www.foodshield.org/</u>
- Fraud History European Union Rapid Alert System

http://ec.europa.eu/food/safety/rasff/index_ en.htm

- USDA AMS Market and price information: <u>https://www.ams.usda.gov/market-news/organic</u>
- Canadian Trade Data <u>http://strategis.gc.ca/eic/site/tdo-dcd.nsf/eng/</u> <u>Home</u>

- Food Fraud Prevention Training https://www.foodfraudadvisors.com/ food-fraud-prevention-training-online/?gclid=CjwKCAiAuMTfBRAcEiwAV4SDkaPrHImzDIcX-WO78t4PTxqe3hHHBvs8f0HMaLmlj66UR-JAHgzDpvCBoChoUQAvD_BwE
- USDA FAS GATS Import/export data for organic <u>https://apps.fas.usda.gov/gats/default.aspx</u>
- Transparency International's Corruption Perception Indices <u>http://ec.europa.eu/food/safety/rasff/index</u> en.htm
- USDA National Agricultural Statistics Service <u>https://www.nass.usda.gov/Surveys/Guide_to_</u> <u>NASS_Surveys/Organic_Production/index.php</u>
- USDA NOP Fraudulent Certificates List of fraudulent organic certificates
- USDA NOP Industry Alerts
 <u>https://www.ams.usda.gov/reports/organic-insider</u>
- USDA NOP Organic Enforcement Webpage <u>https://www.ams.usda.gov/services/enforcement/</u> organic_
- USDA NOP Organic Integrity Database <u>https://organic.ams.usda.gov/integrity/</u>
- Vessel Finder <u>https://www.vesselfinder.com</u>

V. TESTING

NITROGEN ISOTOPE RATIO TESTING LABS

- Aquatech Enviroscience Laboratories, Inc. <u>http://www.aquatechenvirolabs.com/</u>
- Agroisolab United Kingdom
 <u>http://www.agroisolab.com/</u>

PESTICIDE RESIDUE TESTING LABS

- Pacific Ag Lab <u>http://www.pacaglab.com</u>
- Medallion Labs
 <u>https://www.medallionlabs.com</u>
- Eurofins
 <u>https://www.eurofinsus.com/food-testing/test-</u> ing-services/contaminants/pesticide-residue/
- Primus Labs <u>http://www.primuslabs.com/services/Pesticide-</u> <u>Analysis.aspx</u>

GMO TESTING LABS AND SERVICES

- Eurofins GeneScan, Inc. www.eurofinsus.com/gmotesting/
- Genetic ID NA, Inc. www.genetic-id.com
- Genista Biosciences
 <u>www.genistabio.com/</u>
- ICIA
 <u>www.indianacrop.org</u>

- Isotech Laboratories Inc. <u>http://www.isotechlabs.com/index.html</u>
- IEH Laboratories and Consulting G <u>http://www.iehinc.com/food-testing-services-au-</u> thenticity-of-organic-vs-conventional-products/
- EMA Inc Environmental Micro Analysis <u>http://www.emalab.com/</u>
- Analytical Bio-Chemistry Laboratories <u>http://www.eag.com/locations/north-america/</u> <u>columbia-mo</u>
- Midwest Laboratories <u>https://www.midwestlabs.com</u>
- Global Laboratory Services, Inc. <u>http://www.globallaboratoryservices.com</u>
- IEH Laboratories and Consulting Group, Inc. <u>www.iehinc.com</u>
- Midwest Laboratories, Inc. <u>www.midwestlabs.com</u>
- OMIC USA Inc. <u>www.omicusa.com</u>
- SGS Brookings <u>www.sgs.com/us-gmo</u>

VI. GENERAL RESOURCES

- Organic Trade Association's Global Organic Trade Reports <u>https://www.ota.com/tradedata</u>
- GFSI position on mitigating the public health risk of food fraud <u>http://www.mygfsi.com/files/Technical_Docu-</u> <u>ments/Food_Fraud_Position_Paper.pdf</u>
- U S Michigan State University Food Fraud Department <u>http://foodfraud.msu.edu/</u>
- Nestle, "Food Fraud Prevention, Economically Motivated Adulteration" <u>https://www.nestle.com/asset-library/documents/li-</u>
 <u>brary/documents/suppliers/food-fraud-prevention.</u> <u>pdf</u>
- PWC, "Food Fraud Vulnerability Assessment and Mitigation – Are you doing enough to prevent food fraud?" <u>https://www.pwc.com/gx/en/services/food-sup-</u> ply-integrity-services/assets/pwc-food-fraud-vulnerability-assessment-and-mitigation-november. pdf_
- FSSC 22000, "Tackling Food Fraud Results of the FSSC 22000 Pilot audits on Food Fraud Prevention" <u>http://www.fssc22000.com/documents/pdf/article-ff-201702-final.pdf</u>

- FSSC22000, "Guidance on Food Fraud Mitigation," April 2018 <u>http://www.fssc22000.com/documents/graphics/</u> <u>version-4-1-downloads/fssc-22000-guidance-on-</u> <u>food-fraud-final-100418.pdf</u>
- Anti-Fraud Initiative, FiBL <u>http://www.organic-integrity.org/</u>
- BRC Global Standard for Food Safety Issue 7 -Understanding Vulnerability Assessment <u>https://www.brcglobalstandards.com/me-</u> <u>dia/63848/brc_global_standard_for_food_safe-</u> <u>ty_issue_7_faqs-1.pdf</u>
- Fraud Mitigation Guidance <u>http://citeseerx.ist.psu.edu/viewdoc/download?-</u> <u>doi=10.1.1.738.3371andrep=rep1andtype=pdf</u>
- Understanding the risk of food fraud in your business <u>https://haccpmentor.com/food-safety/food-fraudcontrol-program/</u>
- A Guidance Document on the Best Practices in Food Traceability, Comprehensive Reviews in Food Science and Food Safety, Jianrong Zhang and Tejas Bhatt

http://www.ift.org/gftc/~/media/GFTC/Best%20 Practices%20Paper.pdf

APPENDIX A: UNCERTIFIED HANDLER DECLARATION

The purpose of this form is to verify eligibility for the exclusion from certification under §205.101(b)(1). This form must be completed by any uncertified operation in your supply chain that sells and/or handles agricultural products labeled as "100 percent organic," "organic," or "made with organic" (specified ingredients or food group(s))."

Name and address of handling operation (please include any alternative names your operation may do business under):				
Name and title of responsible party (must match signature below):				
Phone:	Email:	Website:		

1. Do you handle any organic products that are not enclosed in a package or container when you receive them? \Box Yes \Box No If yes, please explain:

2. Do you open packages or containers of organic products? \Box Yes \Box No If yes, please explain:

3. Do you re-label any organic products including application of a label that obscures the original label or lot number/code?

Yes No If yes, please explain:

4. Do you ever combine or split loads of bulk/unpackaged products?

Yes
No If yes, please explain:

5. Do you process any organic products including but not limited to repacking, sorting, reconditioning, culling, icing, hydrocooling, hydro vacuum, washing, high pressure processing (HPP), ethylene or controlled atmosphere treatment or any other processing?

 \Box Yes \Box No If yes, please explain:

6. Do all organic products remain in the same package or container for the entire time they are in your possession?

Yes
No If no, please explain:

7. What do you do when incoming packages or containers of organic product have been damaged?

8. Describe the measures implemented to prevent commingling of organic and nonorganic products:

9. Describe the measures you have implemented to prevent contamination of organic products from substances such as cleaners, sanitizers, and pest control products:

10. Explain how you maintain audit trail records sufficient to track organic product back to its certified organic source, including original lot number:

11. Do you import or export organic products?
Yes No If no, please explain:

12. If you are importing, describe the documentation you collect to verify that the products are not fumigated or treated with a prohibited substances upon entry to the country:

13. Describe how frequently you change organic suppliers and how the certified organic operation you are buying from can verify the source, volume, organic certification, and import compliance of each shipment. You may attach sample documents to demonstrate your system.

14. Do you agree to provide copies of audit trail records to the certifier upon request?
Yes No If no, please explain:

§ 205.100 (c) Any operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in §3.91(b)(1) of this title per violation.

(2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

Certified organic operations must maintain records sufficient to demonstrate compliance. Certified operations may only source from uncertified handlers who provide full supplier traceability back to the last certified operation for each shipment. This means:

- Purchase invoices, BOL, and other audit trail records must designate products as organic and include a description of the product and amount transferred.
- Uncertified handler audit trail records must link directly back to the last certified operation, including transport, storage, processing/handling, shipping, and/or distribution. Documents generated by the last certified operation proving purchase/delivery/transfer to the uncertified handler must be available.
- The last certified operation must be listed on invoices and/or lot numbers applied by the last certified operation must match lot numbers on uncertified handler audit trail records.
- For each delivery, uncertified handlers must provide a complete, current organic certificate for the last certified operation, as well as import documentation as relevant.
- All certified suppliers must be approved by the certifier as part of the certified operation's Organic System Plan (OSP).
- Traceability will be verified as a part of the certified operation's audit and review. If organic product cannot be traced back to the last certified operation, the certified organic operation making purchases will not be allowed to source organic products from the uncertified handler.

I declare under penalty of perjury (under the laws of the United States of America) that the foregoing is true and correct.

Executed on: ____

(date)

Printed Name: ______

APPENDIX B: ORGANIC FRAUD VULNERABILITY ASSESSMENT TOOL

The self-assessment tool presented in this Guide is specific to organic fraud prevention and focuses on the vulnerabilities inherent to both the ingredient/product and the business (general, geographic, economic, and agronomic) as well as the vulnerabilities under the control of the buyer (supply chain assessment). Each factor in the assessment tool requires a response or answer that should be assigned to a vulnerability level. For each assessment factor, the company must also evaluate whether there is an existing mitigation measure in place to address the vulnerability. The example answers in vulnerability rating column provide guidance on the types of factors and/or activities that result in low to high vulnerability. **Any factor assigned to medium or high-vulnerability that does not have a mitigation measure in place requires development and implementation of a mitigation strategy.**

PRODUCT ASSESSMENT	VULNERABILITY (V) LEVEL AND REASON 1=LOW 2=MEDIUM 3=HIGH NA	MITIGATION MEASURES IN PLACE TO ADDRESS VULNERABILITY? YES/NO - DESCRIBE	NEED TO DEVELOP A MITIGATION MEASURE? YES/NO
GENERAL	No = high		
Current organic certificate on-file?	No = high		
Supplier is listed in the NOP Integrity Database?	No = high		
Certifier is listed on NOP website?	No = high		
Product arrives with a transaction certificate when required?	No = high		
Have there been reports of organic fraud for this ingredient/material?	Yes = medium to high		
GEOGRAPHIC FACTORS			
Country of Origin - Is the product imported?	No = low		
Does the product cross multiple borders?	No = low		
Have there been incidents of fraud from this region?	Yes = medium to high		

PRODUCT ASSESSMENT	VULNERABILITY (V) LEVEL AND REASON 1=LOW 2=MEDIUM 3=HIGH NA	MITIGATION MEASURES IN PLACE TO ADDRESS VULNERABILITY? YES/NO - DESCRIBE	NEED TO DEVELOP A MITIGATION MEASURE? YES/NO
Country-specific low price compared with the rest of the market?	Yes = medium to high		
Is there a robust domestic market?	Yes = low		
Does COO have an organic regulation and competent authority?	Yes = low		
Can in-country certifiers provide statistics on total production by volume?	Yes = low		
Is there a high corruption level in the country where you are buying your ingredient/product from?	Yes = high		
ECONOMIC FACTORS			
Drastic increases/fluctuations in market price?	Yes = high		
Scarce supplies?	Yes = medium to high		
High demand, low or scarce supply?	Yes = high		
Sudden change in volumes traded?	Yes = medium to high		
In line with market trends?	Yes = high		
Selling a commodity below the cost of production?	Yes = medium to high		
High value and high demand crop/ingredient?	Yes = medium to high		
AGRONOMIC FACTORS			
Production challenges? (i.e. pests and diseases)	Yes = medium to high		
Does the product requirement fumigation treatment for entry into the United States?	Yes = medium to high		
Volume (i.e. bushels) / acres ratio vs previous year, consistent?	Yes = medium to high		

SUPPLY CHAIN ASSESSMENT	VULNERABILITY (V) LEVEL AND REASON 1=LOW 2=MEDIUM 3=HIGH NA	MITIGATION MEASURES IN PLACE TO ADDRESS VULNERABILITY? YES/NO - DESCRIBE	NEED TO DEVELOP A MITIGATION MEASURE? YES/NO
VISIBILITY OF SUPPLY CHAIN			
Do you have visibility of the supply chain back to farm?	No = medium to high		
Can traceability of the supply chain be accomplished back to the farm?	No = medium to high		
Does the supplier also handle conventional products?	Yes = medium to high		
Is the supply chain long and/or complex?	Yes = medium to high		
Is the supply chain audited by your business or by 3rd party entities?	No = medium to high		
Are there uncertified entities in the supply chain?	Yes = high		
SUPPLIER RELATIONSHIP	VULNERABILITY (V) LEVEL AND REASON 1=LOW 2=MEDIUM 3=HIGH NA	MITIGATION MEASURES IN PLACE TO ADDRESS VULNERABILITY? YES/NO - DESCRIBE	NEED TO DEVELOP A MITIGATION MEASURE? YES/NO
Do you have a supplier approval program in place?	No = high		
Does your supplier program encourage your suppliers to also develop an organic fraud prevention plan?	No = medium to high		
Has the supplier filled out a new supplier questionnaire?	No = high		
Is the supplier certified?	No = high		
Is the supplier listed in the NOP Integrity Database?	No = high		
Is the certifier listed on NOP website?	No = high		
Long-standing relationship?	No = medium to high		
Have you ever met the supplier in person?	No = medium		
Is this a spot purchase?	Yes = medium to high		
Supplier/manufacturer of the ingredient is audited by your company?	Yes = low		
Is there good communication between you and your supplier?	Yes = low		

SUPPLY CHAIN ASSESSMENT	VULNERABILITY (V) LEVEL AND REASON 1=LOW 2=MEDIUM 3=HIGH NA	MITIGATION MEASURES IN PLACE TO ADDRESS VULNERABILITY? YES/NO - DESCRIBE	NEED TO DEVELOP A MITIGATION MEASURE? YES/NO
Does the supplier provide accurate documentation of product?	Yes = low		
Has your supplier been involved in a criminal activity?	Yes = high		
OTHER SUPPLY CHAIN OR AUTHENTICITY FACTORS			
Is this material/ingredient subjected to routine authenticity tests?	Yes = low		
Is your company certified to a GFSI recognized scheme?	Yes = low		
Is the supplier GFSI certified to FSSC 22000 or SQF?	Yes = low		

COMPANY ASSESSMENT	VULNERABILITY (V) LEVEL AND REASON 1=LOW 2=MEDIUM 3=HIGH NA	MITIGATION MEASURES IN PLACE TO ADDRESS VULNERABILITY? YES/NO - DESCRIBE	NEED TO DEVELOP A MITIGATION MEASURE? YES/NO
Does your company have an established fraud monitoring and verification system in place?	No = high		
Has your company implemented an organic fraud prevention plan?	No = high		
Is your company GFSI certified?	Yes = low		
Have past food fraud incidences occurred within your company?	Yes = high		
Does your company have established and agreed upon ethical codes of conduct?	No = high		
Does your company have an employee screening program in place?	No = high		
Does your company have whistleblowing guidelines and protections in place?	No = medium to high		

APPENDIX C: COMPLAINT TEMPLATE - REPORTING ORGANIC FRAUD

It is essential to maintain a routine watch of USDA National Organic Program (NOP) announcements regarding fraudulent certificates, investigations, suspensions, and revocations as well as monitoring other official and industry publications, which may give early warning of information or changes that may trigger new threats of organic fraud, or change the priority of existing threats.

This document provides guidance on what to do when a business engaged in organic trade suspects or detects fraud. It includes a template that will help businesses collect and organize the necessary information to be shared in order to submit an actionable complaint.

WHAT DO YOU DO WHEN YOU SUSPECT OR DETECT FRAUD?

In short, reject the product, return it to the vendor/supplier/producer and report it to your own ACA, the ACA of your supplier and the competent authority (e.g. USDA-NOP, State Organic Program). Please note that it is most effective to file the complaint to BOTH your certifier and the USDA-NOP. **For other com-plaints within California**, both the <u>California State Organic Program</u> and the <u>National Organic Program</u> should be contacted as they can levy fines and embargo products.

WHAT IS THE PROCESS FOR REPORTING FRAUD?

Anyone who suspects a violation of the USDA organic regulations can and should file a complaint. When you report an alleged violation, you must provide as much information as possible to help ensure a thorough investigation. Provide your contact information, and the NOP will contact you if necessary for clarification or when the case is closed. It is recommended practice to check in with NOP on a regular basis to see if they need any additional information.

File complaints by e-mail or mail to the addresses below:

Email: <u>NOPCompliance@ams.usda.gov</u> Phone: (202) 720-3252

Mailing Address:

NOP Compliance and Enforcement Branch Agricultural Marketing Service United States Department of Agriculture 1400 Independence Avenue, S.W. Mail Stop 0268, Room 2648-S Washington, D.C. 20250-0268

Reports should be written, verifiable, and accompanied with evidence documenting the suspected fraud. Evidence should be first-hand. We recommend sending a copy of the complaint to any organic certifiers involved and your certifier as well.

COMPLAINT TEMPLATE

Follow this suggested template to organize your complaint:

If you are willing to discuss the issue further or wish to be notified when the case is closed, please include your name and contact information with your complaint. If you would like to remain **CONFIDENTIAL**, clearly state this with your submission and mark all documents accordingly.

FILER'S INFORMATION

- 1. Company
- 2. Name of person filing the complaint, title
- 3. Contact email/phone
- 4. Date Submitted
- 5. Your certifier (if applicable)
- 6. State whether you wish to remain confidential

COMPLAINT INFORMATION

1. Nature of complaint - detailed explanation of the identified regulatory violation

- a. Use of fraudulent organic certificates to market or sell agricultural products
- b. Misrepresentation of conventional as organic (not fraudulent certificates)
- c. Labeling violation
- d. Excess volume (evidence that volume exceeds organic supply)
- e. Lack of documentation
- f. Evidence of contamination by a prohibited substance (pesticide use, fumigation, treated seed, etc.)
- g. Changing identity
- h. Inability to follow an audit Documentation not in alignment with product (not matched, excessive documents, wrong documentation type, etc.
- i. Use of uncertified co-packers or other handlers in the processing of agricultural products to be sold, labeled or represented as organic
- j. Distribution by an uncertified/readily confirmed entity
- k. Below market value
- I. Other: Please explain
- 2. Severity of the complaint indicate the severity of the complaint and explain why
 - a. Minor The violation is un-willful, correctable and is not a result of a systemic failure in OSP
 - b. Major The violation is un-willful but is a systemic failure of OSP and inability to comply with the regulation; warrants a proposed suspension
 - c. Severe The violation is a willful violation of the organic regulations and warrants revocation

3. Reference the section of the rule(s) you think the complaint violates

- a. 7 CFR XXX
- b. Explain why it violates this section of the rule

4. The source of the product, list:

- a. Full Business name (s)
- b. Brand name of the product
- c. Contact name
- d. Address
- e. Phone number
- f. Certification agency of that source

5. Other parties involved in transactions, list:

- a. Reference certificate documents information offered as proof of compliance (list operator name, certifier, certificate number)
- 6. The type (including variety, if applicable) of contaminated/fraudulent product
- 7. The lot number or other identifying mark, if any, of the product ("best by")
- 8. The quantity of product, if known
 - a. Is this entire lot or just contaminated product?
 - b. E.g., 1 lot, etc.
- 9. If the complaint involves a contaminated product
 - a. The name of the prohibited contaminant, if known
 - b. The amount of the prohibited material, if known
- 10. The length of time that the violation has been occurring, if known
- 11. The basis of knowledge of the fraud (food safety testing, observation, phone call, etc.)
- 12. If testing was performed, the test results themselves and any information about the sampling protocol and chain of custody
- 13. Any information about the likely source or reason for the contamination/fraud
- 14. Who the product has already been sold to (if applicable)
- 15. Any additional information relevant to the situation (images of labels, attachments and additional documentation accepted)
- 16. What action has complainant already completed?
- 17. Has there been any industry action? If so, what?
- 18. Nature of the supply chain (who is selling the product? Who else is buying? Market saturation level?)

Remember, filling a complaint should follow the big 5 W's: Who, What, When, Where, and Why. Please review your information for accuracy when before you submit.

The Organic Trade Association has developed the **Organic Fraud Prevention Solutions** privatesector program to help protect your business, and grow consumer confidence in organic.



Organic Fraud Prevention Solutions improves your internal quality assurance programs.

- It helps prevent organic fraud in your supply chain
- It provides a business-to-business marketing advantage

The program provides step-by-step training and resources.

- Identify **weaknesses** and gaps
- Design internal mitigation measures
- Implement **monitoring** and verification tools
- Update your **Organic System Plan**

The program complements and reinforces the U.S. Department of Agriculture's Organic standards and the work of the accredited certifying agencies.

 It is a quality assurance program, not a certification or verification program

Organic Fraud Prevention Solutions is designed and tested by the organic sector. It minimizes vulnerabilities for organic farmers, handlers, traders, processors, distributors and retailers. **Organic Fraud Prevention Solutions** is open for enrollment*

- Be **publicly recognized** as an Organic Fraud Prevention Solutions enrollee
- Receive the comprehensive Organic Fraud Prevention Best Practices Guide
- Secure your training slot (free to Organic Trade Association members)
- Receive business-critical updates on program developments and fraud news

An Organic Trade Association Resource

*Pre-enrollment is available for Organic Trade Association members. All program participants must be certified organic or listed by a USDA recognized Material Review Organization.

Learn More: OTA.com/OrganicFraudPrevention



Headquarters

The Hall of the States, 444 N. Capitol St. NW, Suite 445-A Washington, D.C., 20001 (202) 403-8513

Member Services

28 Vernon St., Suite 413 Brattleboro VT 05301 (202) 403-8630

www.OTA.com

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