

How 'fsma SaaS' guarantees on-going FSMA Compliance for domestic and foreign suppliers through error-proofing technology

...reducing the risk of FDA citations

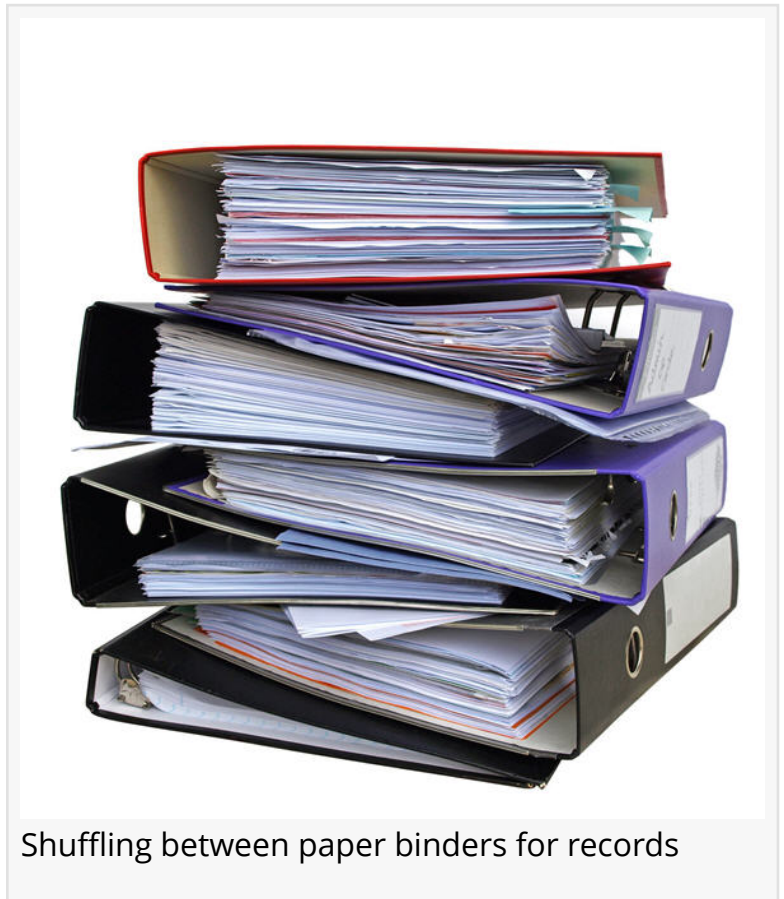
SARASOTA, FLORIDA, UNITED STATES, October 14, 2020 /EINPresswire.com/ -- United Natural Produce Alliance (UNPA) President Loren Israelsen stated. "Both domestic and foreign suppliers are often not equipped to meet the new Food Safety Modernization Act (FSMA) record-keeping requirements and the industry is suffering from certifier audit fatigue'

The number of citations identified by the FDA was 2300 in 2018 and 3000 in 2019 for the audited companies. The number of companies audited is limited by the number of FDA auditors. It is unknown how many violations qualify as citations from unaudited companies. Even so, a review of annual records, show repeated citations from audited companies, indicating current recording keeping practices do not adequately serve [FSMA compliance](#).

The statement by Mr. Israelsen informs us that current practices and tools utilized by organizations are generally, not enabling on-going FSMA compliance. Consequently, entities can be subject to unnecessary citations because their recordkeeping tools do not facilitate ease of use or do not act as guard rails to ensure compliance.

The FDA's 'recordkeeping' citations may cause companies to discontinue business. According to Registrar Corp 'FDA routinely removes facilities from its database that fails to renew. FDA deregistered 47,000 companies at the beginning of 2019'. The UNPA President's is clear that food companies are experiencing recordkeeping challenges. Perhaps unacceptable recordkeeping caused the deregistration of companies because if their products were successfully sold pre-FSMA, their deregistration is likely to be due to recordkeeping regulations.

Overview of requirements



Shuffling between paper binders for records

Did food companies deregister because they were unable to operationalize the law?

According to the FDA, the five most common food safety citations are:

- o Sanitation Monitoring
- o Pest Control
- o Manufacturing, Processing, Packing, and Holding Controls
- o Sanitary operations and plant maintenance
- o Personnel

A regulatory violation is a non-conforming requirement to the law, whether discovered by the FDA or not.

An FDA citation is issued for a found violation, usually by an FDA audit. A citation may not mean that the food is defective, a citation can mean that the legal recordkeeping requirements are not met. The five common citations are not for defective food. Since an audit is a sampling exercise, violations of this nature may be



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*United Natural Produce Alliance (UNPA) President
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- o Reanalysis 117.170
- o Validation 117.160 (b) ii & iii
- o (re)training 117.180(d)
- o Verification- Corrective Action Review by PCQI per 117.165 4(i) within 7 days
- o Corrective Action Review of Supplier Food Safety Records by Receiving facility 117.475(c) 8,9, 10

At any point in the food safety workflow when a violation occurs, the recordkeeping must be completed within seven days to remain compliant. Otherwise, violations can be subject to a citation, whenever audited in the future, if the seven day-period is exceeded.



missed or overlooked internally. Companies need ways to manage violations before they potentially turn into citations during an FDA unscheduled audit.

When a nonconformity occurs, according to FSMA a corrective action is required to remain compliant. Along with the corrective action, several other clauses are to be satisfied. The other clauses can be formatted as a sub-set of the Corrective action as follows.

- Corrective Action 117.150,
 - o Correction 117.150a 2, or containment – such as in the case of a recall
 - o Root cause 117.150 2 i
 - o Corrective Action 117.150 2 ii

Companies should assess their methods on whether their existing paper or software tools are effective in managing non-conformities.

Companies should determine if there is an effective workflow to efficiently conduct all the relevant legal requirements. If your system produces violations and gains citations, then your recordkeeping system is not efficiently or effectively managed. If you jump around shuffling paper or opening and closing different programs; the list of the five top citations occurs because of improper recordkeeping management tools. Improved management system techniques are required to fulfill the recordkeeping requirements.

Control Techniques

'[fsma SaaS](#)' is a single management system technology, which equips domestic and foreign organizations with techniques to prevent recordkeeping violations. Error-proofing techniques by digitized native apps are available to the operator, attendant or PCQI. When a nonconformity occurs, an automated workflow is triggered in 'fsma SaaS' to maintain ongoing FSMA compliance requirements.

Each food safety plan/ preventive control is a binary event and triggers a corrective action when the requirement is not met. The 'fsma SaaS' corrective action format contains the respective FSMA clause requirement. The regulatory problems expressed by Mr. Israelsen can be mitigated because 'fsma SaaS' automatically enables the management of regulatory non-conformities to be met through its workflow. Notifications are also triggered to alert management of the non-conformity, through "fsma SaaS's" Management by Exception technology. The top five citations and others are managed in the 'fsma SaaS' workflow. If your company is deregistered, has inadequate recordkeeping tools, or experiencing one or more of the five citations, then the 'fsma SaaS' single management system is for you.

Your organization will be protected from recordkeeping citations, as 117.305 is completed with electronic sign-off and time-stamped in the digitized system. No knowledge of the FSMA law is needed, just follow the 'fsma SaaS' flow, to maintain your compliance.

Jeffrey Lewis CEO of 'fsma SaaS' states, 'it is our mission to automate the operationalization of the law efficiently, through our paperless, digitized single management system, which manages and controls all disciplines in a single program. The legal requirements are embedded in the technology. Paper shuffling and moving between different software programs are inefficient, as FSMA has requirements for many different operational disciplines. Organizations can focus on their food production. 'fsma SaaS' maintains on-going recordkeeping compliance for users by avoiding citations, through the effectiveness of its controls to ensure the requirements are completed according to the legal requirements. It is especially important for receiving facilities to



ensure that their suppliers have effective controls to ensure uninterrupted supplies'.
The UNPA is assured of relief to their recordkeeping challenges and redemption for deregistered foodies because of the 'fsma SaaS' recordkeeping offering.

About 'fsma SaaS'- fsmafoodsafety.com

'fsma SaaS' is a developed award-winning single management system, with error-proofing technology to support ongoing regulatory compliance and management standard conformity. Contact jeffrey@fsmafoodsafety.com to try for free.

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