



FDA FSMA Update

Where do we go from here?



Exploring FSMA's impact so far...

- 1 in 6 Americans get sick
- 128,000 are hospitalized
- 3,000 die each year



Since enacting FSMA, the incidents of recalls have increased 92.7% according to FDA's own statistics. In this session we will the explore impact to your business of the FSMA rules, changes at the agency and the advancements of technology to help solve for the challenges that FDA's intent of the rules; food safety and transparency.

FDA Partnerships

- Department of Justice (DOJ)
 - Announced Partnership with FDA
 - Adopted a policy of initiating criminal investigations against any company (or its employees) that sells a product that cause human illness.
- Principal Deputy Assistant Attorney, Benjamin C. Mizer
 - “FDA and DOJ view any human illness caused by a food product as a potential violation of the law.”



Food Police

What consumer action groups are saying

Shift from **deferred prosecution** and **large fines** to individual criminal and civil liability for executives, officers, employees

Goal is to **target individuals** higher up the corporate hierarchy early in an investigation, includes civil actions against individuals who may not have the necessary financial resources or pay a significant judgment

Food Safety News

Breaking news for everyone's consumption

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Why the CEO and Board Need to Pay Attention to FSMA

BY BILL MARLER | SEPTEMBER 9, 2015

OPINION

In the spring of 2007, I was asked to testify before the U.S. House of Representative's Energy and Commerce Committee, which was the committee tasked with modernizing our food safety system. From those hearings, which stretched from 2007 to 2009, came the Food Safety Modernization Act (FSMA). On the Senate side of the hill, work was also being done, but with much less fanfare, on its version of the sweeping new legislation. My testimony, which only lasted for about 15 minutes with questions, was part of a hearing entitled, "A Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?" My pitch was pretty straightforward — modernize our food safety system and deny me the opportunity to sue food companies on behalf of my clients. The politicians and the audience seemed to relish the idea of "putting me out of business."

After me came a table full of CEOs whose companies had caused some of the larger foodborne illness outbreaks in the preceding years. Producers of lettuce, pot pies, beans and chili sauce were forced to stand and swear under oath to tell the truth. Their army of lawyers was right behind them to help them avoid making any statements that might haunt them later.

As I watched these CEOs squirm under questioning, it was clear that all of them wished they were anywhere in the world other than where they were now sitting. As many of them stumbled through the grilling by both Democrats and Republicans on the committee, something was becoming painfully clear to all: It was past time to set aside the hollow arguments against regulation and seek a responsible solution to reduce the 48 million cases of foodborne illness in the U.S. each year (with an estimated cost to



Food supply challenges



- ❑ FDA reports that since the FSMA rules released, recalls have increased 92.7 percent
- ❑ In 2017 U.S. Department of Agriculture oversees meat production, reports recalls jumped 83.4% in the same period
- ❑ Recalls can take up to two weeks to track in the supply chain with the average recall costing \$10M.
- ❑ Major recalls in 2018 were with Romaine Lettuce and Ground Beef. At one point FDA advised not to consume lettuce.
- ❑ Significant losses in food perishable product are incurred due time, temperature and inventory. Reported that 40% of food is wasted in our supply chain.
- ❑ Bloomberg reports that food fraud costs are up to \$40 billion every year – Food Authentication
- ❑ Salmon Example: Oceana Reports that 43% of Salmon fish is mislabeled. Additionally 69% of the wild-caught Salmon was actually farm raised.

Agencies using FSMA rules for enforcement

Temperature controlled transport company pays State of California \$19.4M in a settlement

What To Expect When the FDA Visits Your Facility For a Swabathon

Steve Decker / August 10, 2017



Major developments in the Food Safety Modernization Act (FSMA) have given the FDA new authority under the law. If the FDA decides to conduct a swabathon at your facility, you should expect a minimum of 100 to 300 swabs to be taken and a team of several investigators to conduct the swabathon. Based on the type of swabathon, you may also be required to hold production in your facility. This need is based on several

Another Transport Company was court sanctioned for FDA oversight for services. According to the order, ranging from \$89.35 to \$107.09 per hour.

The company also must pay all costs of:

- Supervision
- Inspection
- Investigations
- Analyses
- Examinations

FDA COMPLIANCE
== H E L P ==



Sanitary Transportation of Food impact on fleets

FSMA includes new sanitary transportation operational practices will impact refrigerated fleets:

Trailer Design

Sanitary Cleaning

Pre-Cool Requirement

Temperature Transport Requirement

Shipper/Loader/Carrier Data Retention

Food Safety Training Requirement



Sanitary Transportation Roles

SHIPPER

THE ONE WHO INITIATES THE LOAD

THE ONE WHO PREPARES FOR TRANSPORT AND
LOADS TRAILER

LOADER

CARRIER

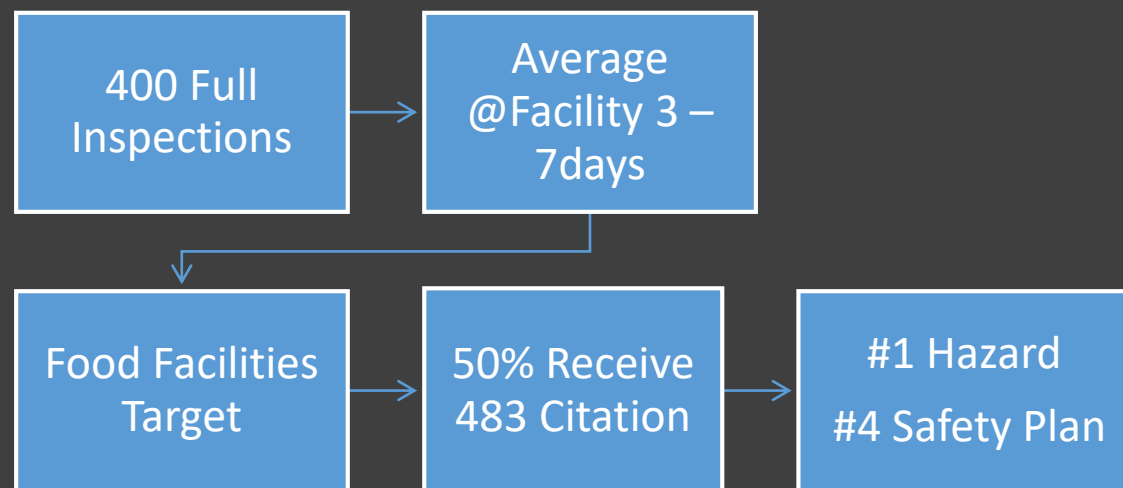
THE ONE WHO PHYSICALLY MOVES
THE FOOD BY MOTOR TRANSPORT

THE ONE WHO RECEIVES LOAD AFTER
TRANSPORT

RECEIVER

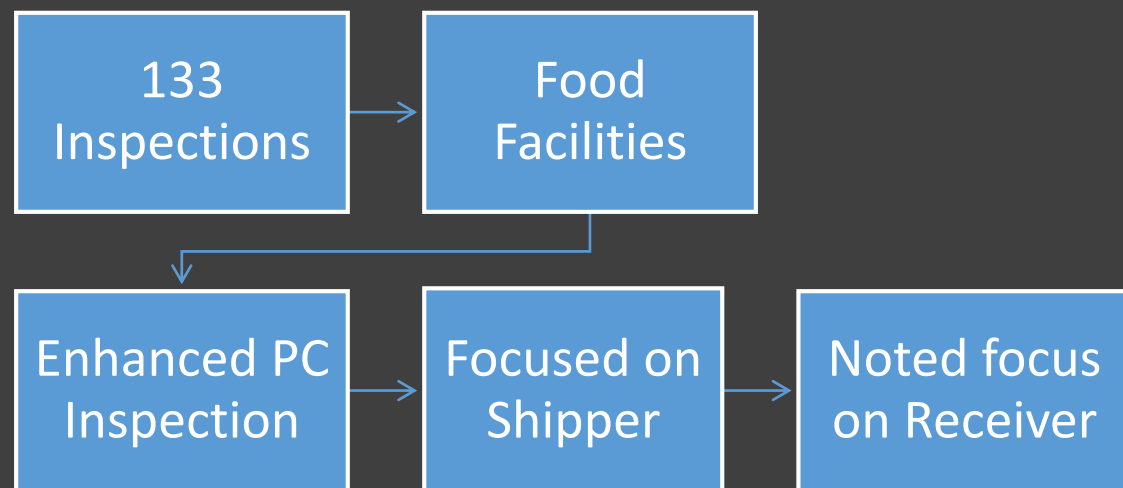


Preventative Controls Inspections





Sanitary Transport Inspection



Industry



IBM
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Follow

In a simulated recall using [#blockchain](#), [@Walmart](#) traced the origin of a bag of sliced mangoes in 2.2 seconds. Other systems took over 6 days: bitly.com/2E8zilH via [@WSJ](#)



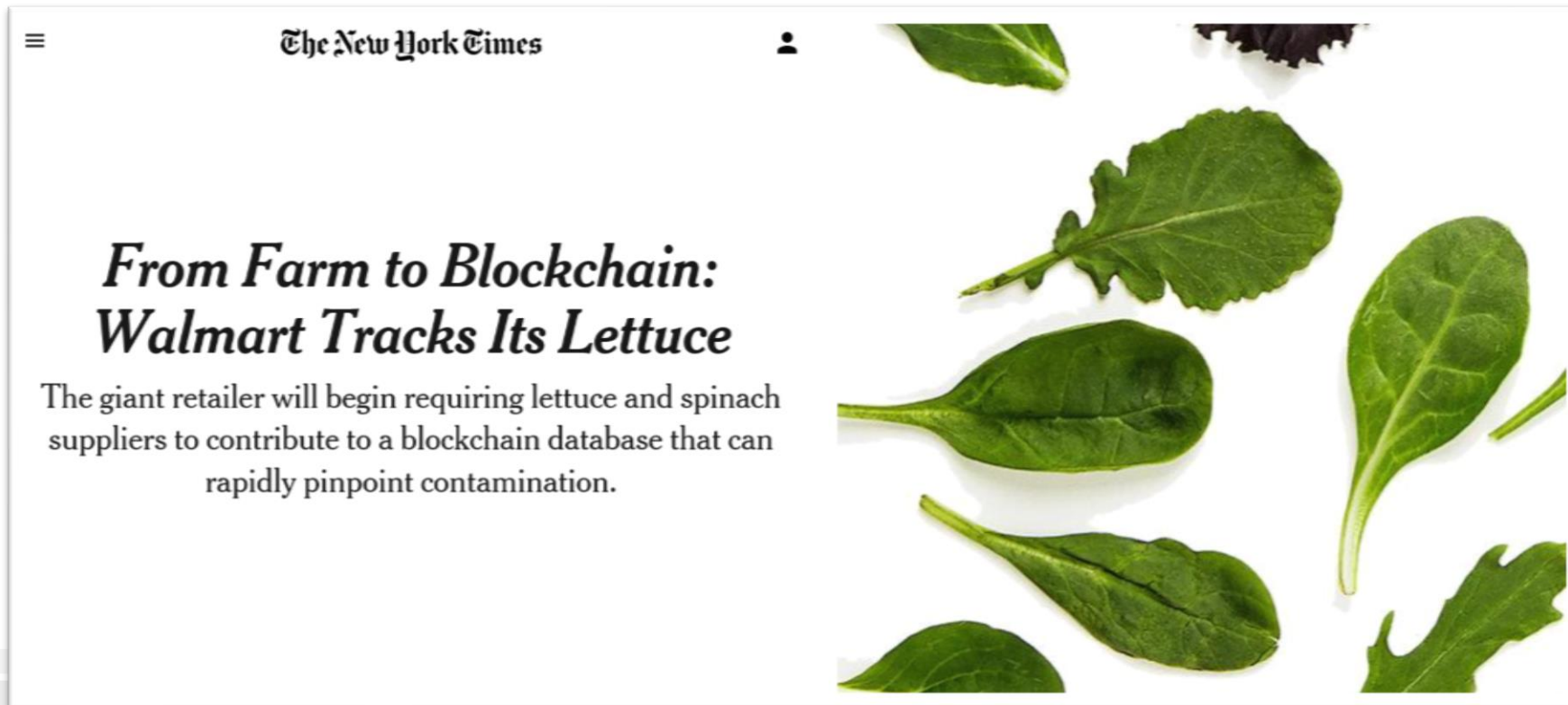
Business Interest in Blockchain Picks Up While Cryptocurrency Causes Con...

Walmart and British Airways are among the companies testing blockchain's potential to help manage global, complex supply chains. Corporate spending on blockchain

Walmart utilizes Blockchain technology to track and trace mangos as a proof of concept

Industry

In 2018 Frank Yiannas, Walmart, VP of Food Safety mandates the first blockchain in retail for lettuces suppliers



FDA's New Commissioner Food Policy & Response

Former Walmart VP of Food Safety takes on top job for food policy at FDA.

Meet Frank Yiannas, Deputy Commissioner for Food Policy and Response

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Frank Yiannas is the Deputy Commissioner for Food Policy and Response, a position he assumed in December of 2018. He is the principal advisor to FDA Commissioner Scott Gottlieb in the development and execution of policies related to food safety, including implementation of the landmark FDA Food Safety Modernization Act (FSMA). His leadership role within the Agency covers a broad spectrum of food safety priorities, such as outbreak response, traceback investigations, product recall activities, and supply chain innovation across the full spectrum of FDA-regulated products.

Mr. Yiannas is, in effect, the Agency's chief ambassador to reduce food safety risks and achieve high rates of compliance with FDA food safety standards, working to develop innovative collaborations with external partners and stakeholders and effective relationships with government and industry leaders, as well as consumer groups.

A renowned food safety expert and author, Mr. Yiannas came to FDA from leadership roles with two industry giants: Walmart and the Walt Disney Company. Through his career, he's been recognized for his role in elevating food safety standards and building effective food safety management systems based on modern science and risk-based prevention principles.

Insights; Frank's Twitter Account



Frank Yiannas ✓ @FrankYiannasFDA · Apr 7

Encouraging to see that some supply chain management and continue to work together to food industry norm.



US retailers ramp up blockchain spend by the U reach \$112.4 million, according to finance.yahoo.com



Frank Yiannas ✓ @FrankYiannasFDA · Mar 27

There's a strong public health & business case for new tools now make it more possible than ever to work, consumers are counting on us. [#traceability](#) [#smarterfoodsafety](#)



Food traceability undergoing tech revolution. We've come a long, long way from our reliance on record-keeping. And that's a very good thing. fooddive.com



Frank Yiannas ✓ @FrankYiannasFDA · Apr 1

The funds we're requesting will help us leverage new and emerging technologies to create a more digital, traceable, diverse, and safer food system. [#smarterfoodsafety](#)



FDA Requests Funds for a More High-Tech, Digital Food Safety System
In a statement penned by U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb and Deputy Commissioner Frank Yiannas, the agency is requesting \$1.2 billion for a more high-tech, digital food safety system. foodsafetymagazine.com



FDA's 2020 Budget Request

FDA News Release

Statement from FDA Commissioner Scott Gottlieb, M.D., and Deputy Commissioner Frank Yiannas on new steps to strengthen FDA's food safety program for 2020 and beyond

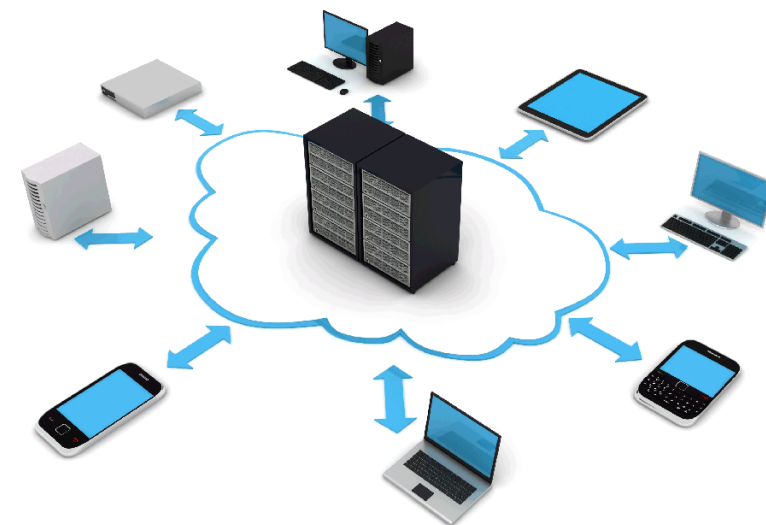
The President's 2020 Budget includes new resources to advance the agency's food safety program, and expand food safety monitoring



“In recent years, we’ve seen emerging track and trace technologies that can assist response efforts to allow the FDA to intervene in time to alert consumers, implement recalls, and avoid human illnesses. This includes blockchain technology.”

Why Blockchain

Blockchain is a shared, distributed ledger that facilitates the process of recording transactions and tracking assets in a trusted business network.

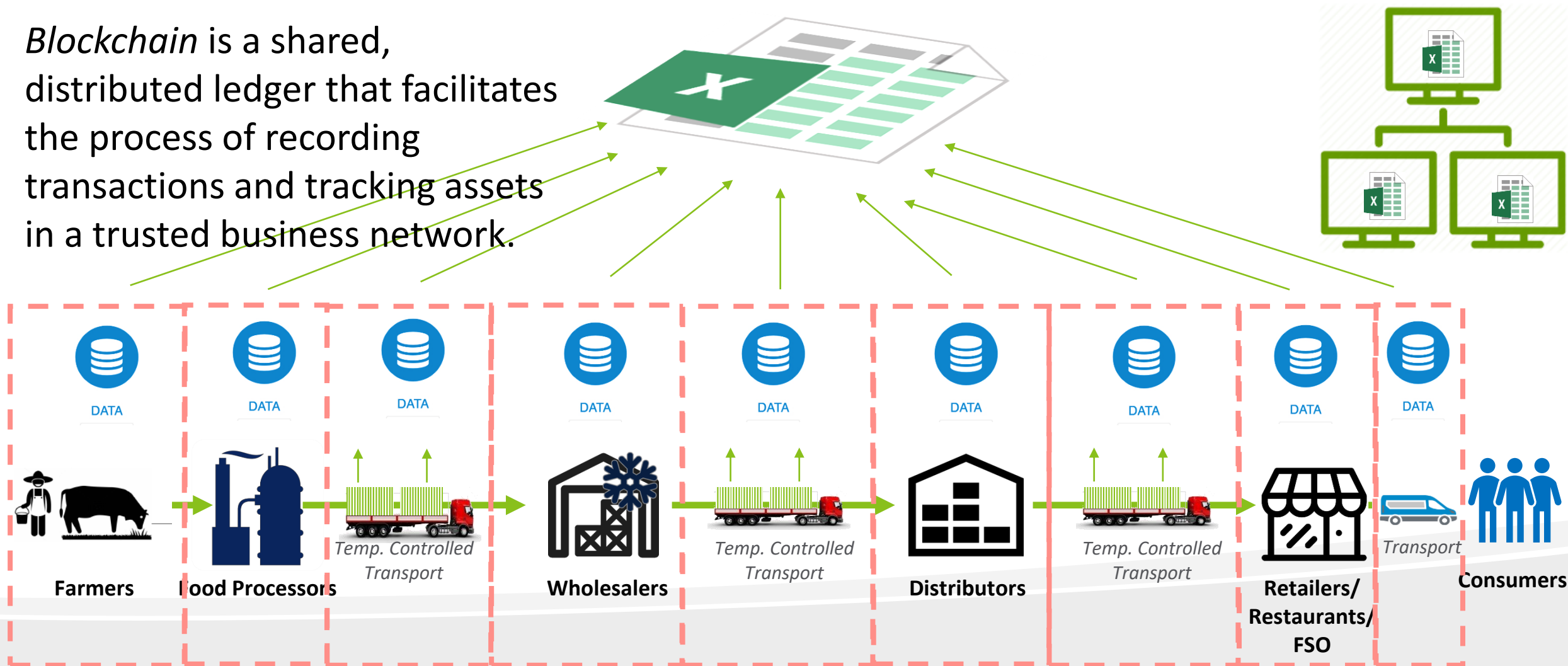


Variabilities Current Data Systems

- ☐ Single point attack – change data for all
- ☐ Requires data validation entry/exit
- ☐ Added layers of expense
- ☐ Data limited to ecosystem

Blockchain; The Future Of Food Supply Chain

Blockchain is a shared, distributed ledger that facilitates the process of recording transactions and tracking assets in a trusted business network.





Digital Convergence

There Will be 20.4 Billion IoT Devices by 2020



Connected Company



Connected Employee



Connected Asset



Connected Consumer



Connected World

Understanding your role within FSMA

The first Deputy Commissioner and the third Deputy Commissioner



- Understand your role within FMSEA rules
- Start engaging technology
- Develop FSMA strategies

“The key... is that the new law explicitly places primary responsibility for food safety -- for prevention -- on food producers and processors,” Taylor said.

(Former FDA Deputy Commissioner for Foods, Michael R. Taylor)

Resources

GCCA STF Refrigerated
Transportation Best Practices Guide

IBM Blockchain Guide

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