

Welcome to Today's OnTrak Webinar:

Recall, FSMA & Criminal Risk: How They Affect Your People and Your Brand

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Recall, FSMA & Criminal Risk: How They Affect Your People and Your Brand



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RECALL RISK

HOW IT AFFECTS YOUR PEOPLE AND BRAND



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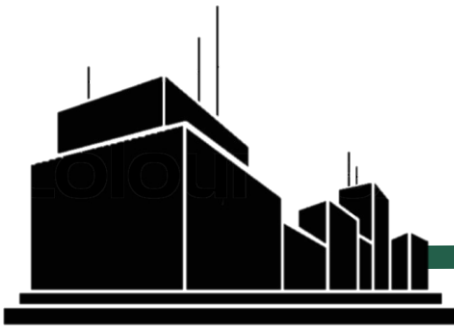
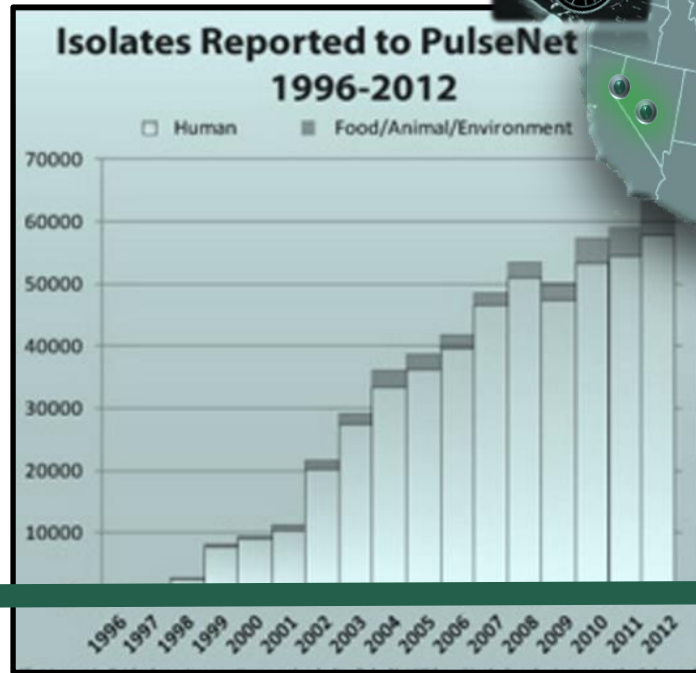
EVOLVING INDUSTRY EXPOSURE

RECALLS = **CRIMINAL** **CIVIL REGULATORY**



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~1,000,000 **UNSOLVED** ILLNESSES



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THE FDA'S WAR ON PATHOGENS



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“THEY’RE COMING...”



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WHAT IS THE REASON FOR **FDA AGRESSION?**



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FOOD SAFETY MODERNIZATION ACT

RULES AND REGULATIONS



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FOOD SAFETY MODERNIZATION ACT



WHAT WILL YOUR FIRST FSMA INSPECTION LOOK LIKE?



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FOOD SAFETY MODERNIZATION ACT



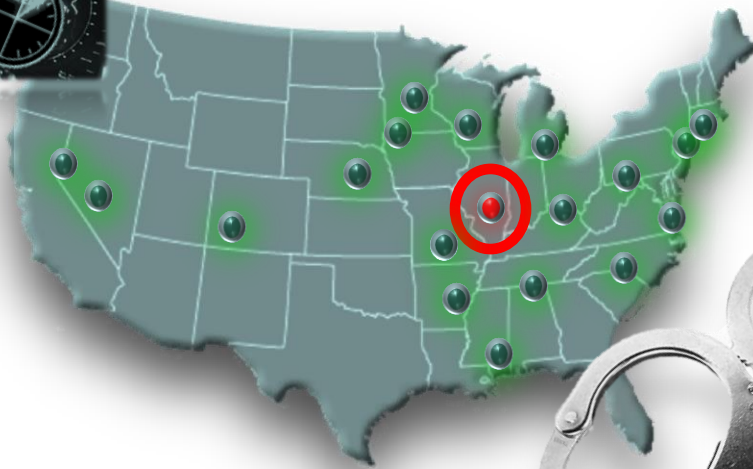
WHAT HAPPENS IF YOU ARE NOT COMPLIANT?



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THE HUMAN ILLNESS STANDARD

NEW ENFORCEMENT POLICY



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AGGRESSIVE ENFORCEMENT

THE FOOD POLICE ARE COMING

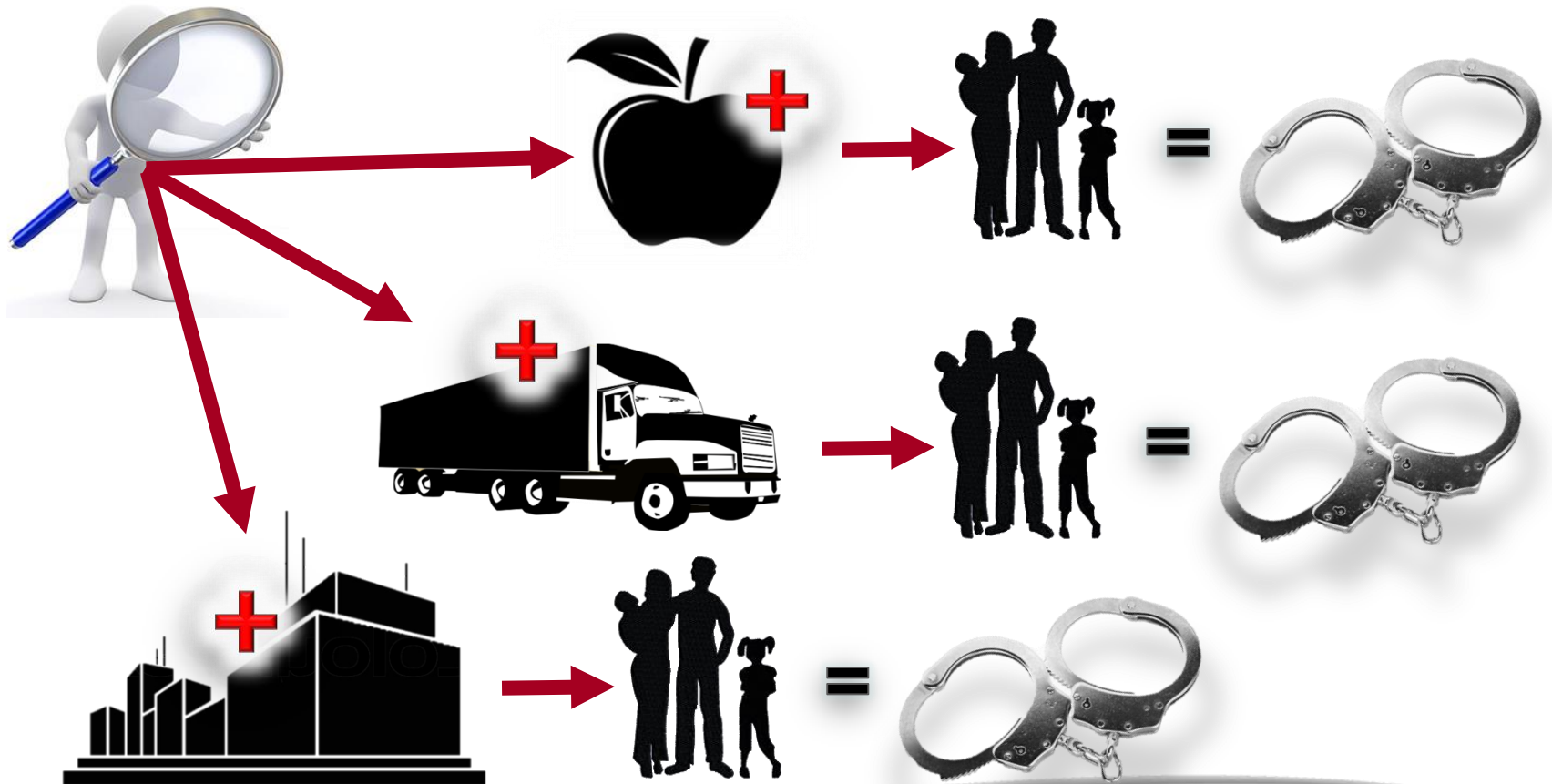


- “INVESTIGATORS” VS “INSPECTORS”
- ROUTINE FDA “SWAB-A-THONS”
- SOLVING PULSENET “COLD CASES”



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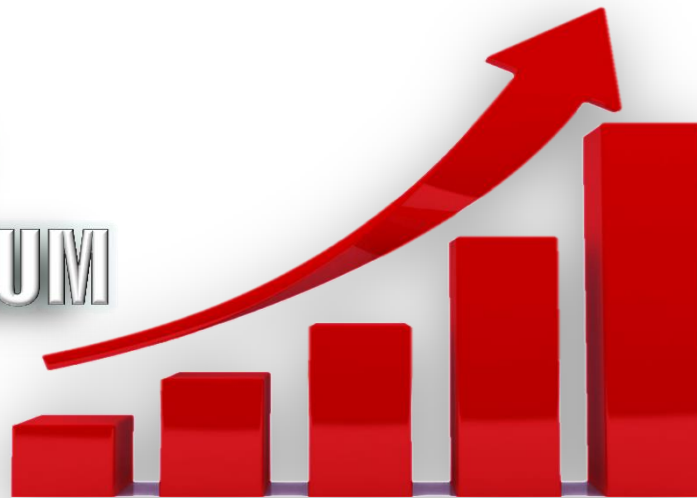
ROUTINE FDA "SWAB-A-THONS"



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WHAT IS THE RISK THAT YOUR PRODUCTS WILL BE INVOLVED IN A RECALL IN THE NEXT 24 MONTHS?

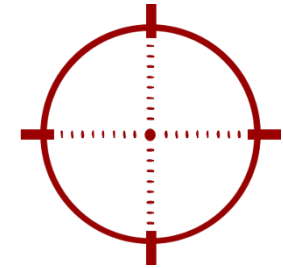
- HIGH
- MEDIUM
- LOW



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CAN YOU BE HELD **PERSONALLY LIABLE?**

PARK DOCTRINE



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CAN YOU BE HELD **PERSONALLY LIABLE?**

PARK DOCTRINE

- (1) You are aware of a condition that could lead to product contamination;
- (2) you are in a position to correct or eliminate the condition; and
- (3) you fail to correct or eliminate the condition.

**MISDEMEANOR
CHARGE**



**\$250,000
1 YEAR IN PRISON**



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CAN YOU BE HELD **PERSONALLY LIABLE?**



SunOpta



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WHAT CAN YOU DO TO PROTECT YOURSELF AND YOUR COMPANY?



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“PLAY FDA FOR A DAY”

CONDUCT YOUR OWN MICROBIOLOGICAL PROFILING



CONFIDENTIAL
ATTORNEY-CLIENT
PRIVILEGED



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USE RESULTS TO PROTECT YOUR COMPANY

SEEK AND DESTROY HARBORAGES

DEVELOP ADDITIONAL INTERVENTIONS

REFINE MONITORING LOCATIONS AND FREQUENCY

ENHANCE YOUR CORRECTIVE ACTION PROCEDURES

GAIN AN INCREASED LEVEL OF SECURITY



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KNOW WHAT FDA WILL FIND WHEN THEY ARRIVE

NOTHING



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KNOW YOUR SUPPLIERS



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KNOW YOURSELF



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DOCUMENT AND MANAGE FSMA COMPLIANCE



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**DEVELOP
IMPLEMENT
MAINTAIN**



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CHANGE THE DIALOGUE

A ROBUST
FOOD SAFETY CULTURE

COMPASSION
COMMITMENT
COMMUNICATION



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A PARTING THOUGHT



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