

Briefing for the National Ombudsman for  
Small Business  
Case No. 1303150001

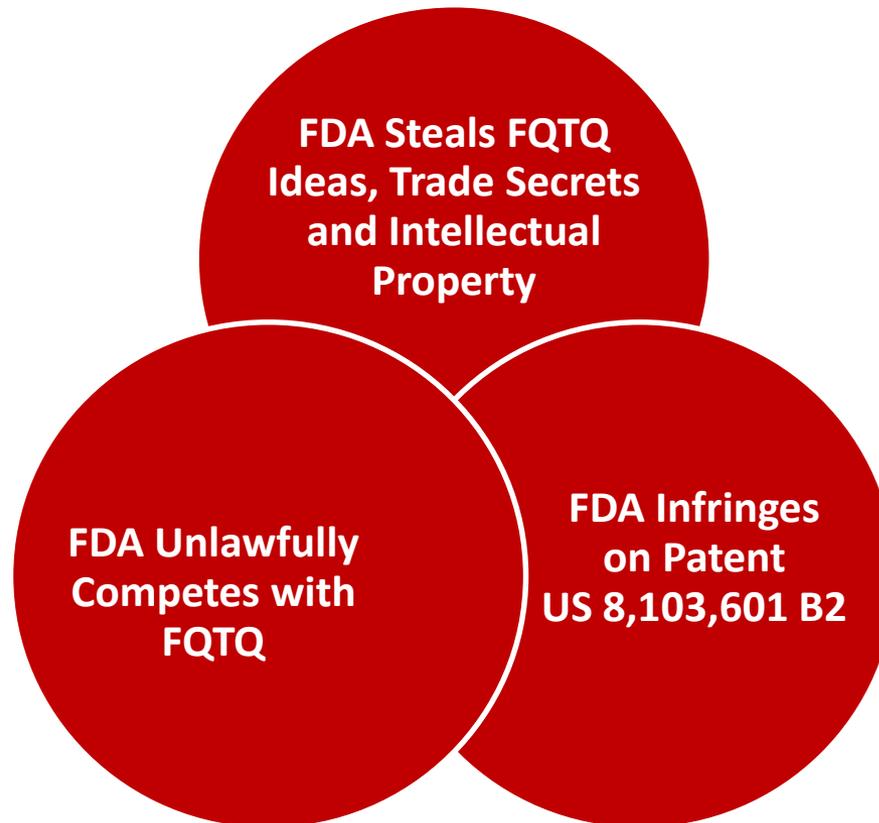
FoodQuestTQ LLC

March 19, 2013

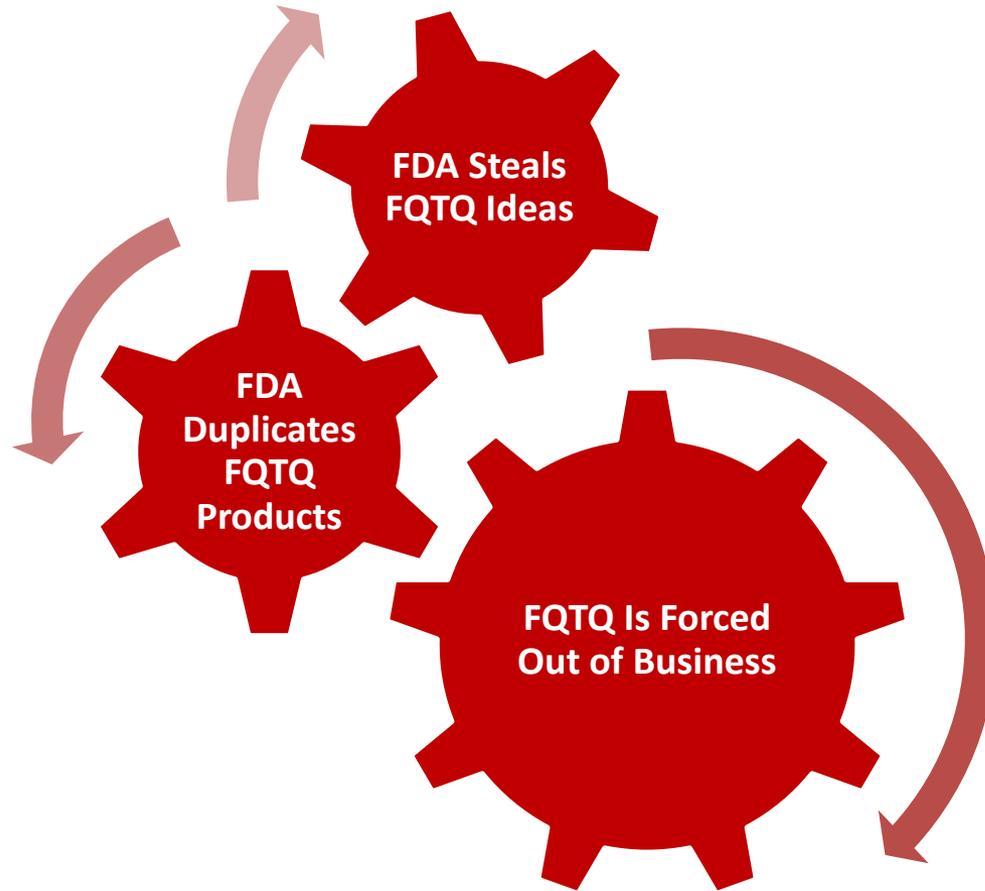
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# Three Inextricably Intertwined Issues



# The Situation



# The FDA Has Stolen the Following FQTQ Ideas

## 1. FQTQ Food Protection Systems Model

*The FQTQ food protection systems model consists of deterrence, detection, delay, communication, response time, response quality and mitigation to prevent and respond to food incidents.*

- The FDA has stolen the threat continuum elements of prevention, interdiction, i.e., the FDA term of “intervention”, communication and response.

## 2. FQTQ Indicators and Warnings

*The FQTQ systems model seeks out the indicators and warnings, i.e., the FDA uses term of “signals” in order to prevent food defense and food safety incidents.*

- The FDA has stolen the methodology for identifying indicators and warnings, i.e., FDA uses the term “signals”, to identify how the actionable intelligence needed to prevent food safety and food defense incidents is identified.

## 3. FQTQ Probability of Occurrence

*The FQTQ systems model defines the probability of a food incident occurring as the combination of how vulnerable you are and the consequences that would result from a food incident.*

- The FDA has stolen the FQTQ “probability of occurrence” methodology that is used to prioritize food system vulnerability and risk.

## 4. FQTQ Risk, Risk Mitigation and Interventions

*The FQTQ systems model identifies food protection risks and the specific measures that must be implemented by food operations to reduce risk.*

- The FDA has stolen the FQTQ method and FQTQ developed taxonomy for identifying risks and implementing required risk reduction measures, i.e., the FDA uses the terms “intervention” and “risk mitigation strategies.”

## 5. FQTQ Vulnerabilities and Risk Reduction Measures

*The FQTQ systems model identifies vulnerabilities, risk reduction measures and promotes communication and multidisciplinary problem solving.*

- The FDA has stolen the FQTQ method of using scenarios to identify lessons learned, i.e., the FDA uses the term “teachable moments”, for the purpose of identifying vulnerabilities and risk reduction measures, promoting communication, and encouraging multidisciplinary problem solving, i.e., the FDA uses the term “table top exercise” to describe the same FQTQ process method called “immersions.”

# The FDA Has Stolen the Following FQTQ Ideas

## 6. FQTQ Verification

*The FQTQ systems model uses risk factors and associated risk mitigation measures called “steps.”*

- The FDA has stolen the FQTQ method and taxonomy for tying risk factors to corresponding risk reduction measures, i.e., FDA uses the term, “Risk Mitigation Strategies” to describe the FQTQ methodology.

## 7. FQTQ High Risk Areas

*The FQTQ systems model identifies and prioritizes high risk areas in the food supply and at food operations along the supply chain.*

- The FDA has stolen FQTQ methods for identifying and prioritizing high risk areas in the food supply, along the food supply chain and in operating food facilities that represent high risk based on probability of occurrence.

## 8. FQTQ Past Incidents

*Under the FQTQ systems model, past food events are gathered and analyzed.*

- The FDA has stolen the FQTQ methodology of gathering and deconstructing data concerning past events to duplicate the FQTQ methodology of systematically “reverse engineering” food related incidents to determine their probability of occurrence, exactly why the incident happened, how it could have been prevented, lessons learned and identify mitigating strategies.

## 9. FQTQ High Risk Agents

*Under the FQTQ systems model data concerning high risk agents is gathered and analyzed.*

- The FDA has stolen FQTQ methods for gathering, deconstructing and analyzing, as complex systems, food incidents and related data, i.e., the FDA iRisk modeling and other FDA tools.

## 10. FQTQ Information Collection for Intelligence

*The FQTQ systems model is used to identify the types of information that should be collected to identify actionable intelligence to prevent food incidents.*

- The FDA has stolen FQTQ methods for identifying types of information that should be collected and subjected to analysis in order to identify actionable intelligence to prevent food safety and food defense incidents.

# The FDA Has Stolen the Following FQTQ Ideas

## 11. FQTQ Food Life Cycle

*The FQTQ food protection systems model includes the entire food life cycle.*

- The FDA has stolen the FQTQ process model of using the holistic view of the of the food system to understand and treat the food supply as a complex adaptive system.

*The FQTQ systems model identifies risk and risk reduction measures based on the reverse engineering of past food incidents, the use of futures driven scenarios and the application of advanced science and technology.*

## 12. FQTQ Risk and Risk Reduction

- The FDA has stolen process methods used by FQTQ to identify risks and their associated risk reduction measures.

## 13. FQTQ Food Protection Model

*The same FQTQ systems model used for food safety is also used for food defense.*

- The FDA has stolen the FQTQ food protection systems model that includes both food safety and food defense. This appears in the *FDA's Food Protection Plan*. More recently FDA appears to have abandoned the approach in favor of separating food safety from food defense.

## 14. FQTQ Holistic View of Food Supply

*The FQTQ food protection systems model takes an holistic view of the food supply chain.*

- The FDA has stolen the FQTQ process model of using the holistic view of the of the food supply chain and it's components to understand and treat the food supply as a complex adaptive system.

## 15. FQTQ Assessment and Inspection

*The FQTQ food protection systems model ties continuous operational performance with assessment and inspection.*

- The FDA has stolen the FQTQ process model relating to inspection and assessment in order to advance FDA's "inspectional strategies"; FQTQ has pioneered the creation of science and risk based standards for assessment and inspection, the use of both "point in time" and "continuous performance monitoring"; the identification of high risk areas to focus inspection resources and much more.

# The FDA Has Stolen the Following FQTQ Ideas

## 16. FQTQ Targeting of Resources

*The FQTQ systems model includes methods for targeting the use of resources to obtain the greatest risk reduction value at the most reasonable cost.*

- The FDA has stolen the process methods used by FQTQ to determine performance and “best investments” to mitigate risk.

## 17. FQTQ Applications of Information Technology

*The FQTQ food protection systems model process is integrally tied to a number of FQTQ information technology applications referred to as “tools.”*

- The FDA has stolen the FQTQ systems model and this listing of ideas to duplicate FQTQ tools that use information technology to make the food supply safer while simultaneously reducing the costs to industry.

## 18. FQTQ Understanding Food Protection as a Science

*The FQTQ systems model for food protection treats the food supply in scientific terms as a complex adaptive system.*

- The FDA has stolen the FQTQ process and scientific model of treating the food supply as a complex adaptive system to further the FDA’s understanding of the science of where food becomes contaminated and the associated risks.

## 19. FQTQ Identification of Vulnerabilities and Risks

*The FQTQ systems model uses the threat continuum as a method for identifying vulnerabilities and associated food protection risks.*

- The FDA has stolen the FQTQ threat continuum elements of prevention, interdiction, i.e., the FDA term of “intervention”, communication and response as a method for identifying vulnerabilities and associated food protection risks.

## 20. FQTQ Food Risk Reduction Measures

*The FQTQ systems model combines the analysis of past food incidents and scenarios of imagined future events and threat continuum analysis.*

- The FDA has stolen the FQTQ process for identifying risk reduction measure in order to expand FDA’s understanding and use of effective food risk reduction measures.

# The FDA Has Stolen the Following FQTQ Ideas

## 21. Modeling, Science and Technical Applications

*The FQTQ systems model for food protection uses advanced modeling, science based analysis and advanced information technology software.*

- The FDA has stolen the ideas listed herein and duplicated them using advanced modeling, FQTQ science based analysis and technical applications that rely on information technology, i.e., duplicate computer software tools including FDA's Food Defense Plan Builder, FREE-B, Food Defense Mitigation Strategies Database, iRisk and possibly others.

## 22. Strengthen Risk Assessment

*The FQTQ systems model uses scientifically vetted risk factors and risk reduction measures to strengthen risk assessment.*

- The FDA has stolen FQTQ process methods for tying risk factors to risk reduction measures, i.e., the FQTQ term for a risk reduction measure is a "step" and embedded the FQTQ idea in a duplicate FDA computer software tool called the *Food Defense Mitigation Strategies Database*; the FDA has also pirated the FQTQ process method of "critical nodes" in the same tool.

## 23. FQTQ Inspection and Assessment Strategies

*The FQTQ systems model modernizes inspection and assessment strategies.*

- The FDA has stolen FQTQ process methods that modernize inspectional strategies; FQTQ process methods focus limited resources on those areas of highest risk, assure the objectivity of inspection and assessment results and reduce the time and personnel costs associated with government inspections, assessments and third party audits.

*The FQTQ systems model contains a specific modules for improving immediate responses to the full range of emergencies that could impact food operations anywhere along the food supply chain.*

## 24. FQTQ Response Module

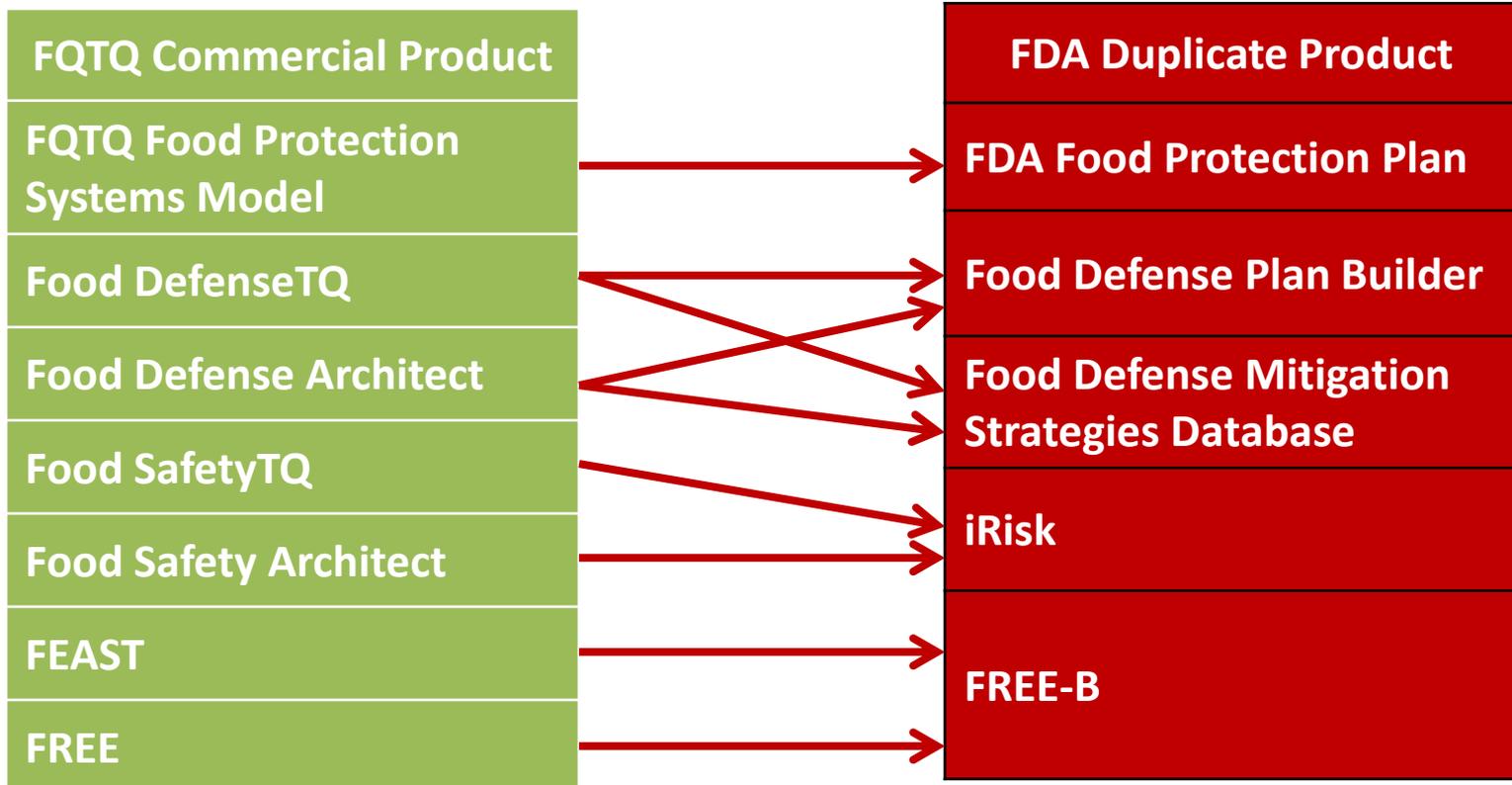
- The FDA has stolen FQTQ process methods that are used to improve immediate responses to food related emergencies including the simulation of emergencies, the use of decision maps, event templates and more.
- The FDA combined two FQTQ computer software tools known as the Food Event Analysis and Simulation Tool (FEAST) and the Food Response Emergency Evaluation (FREE) tool to create a duplicate FDA tool called FREE-B.

## 25. FQTQ Enhanced Risk Communications

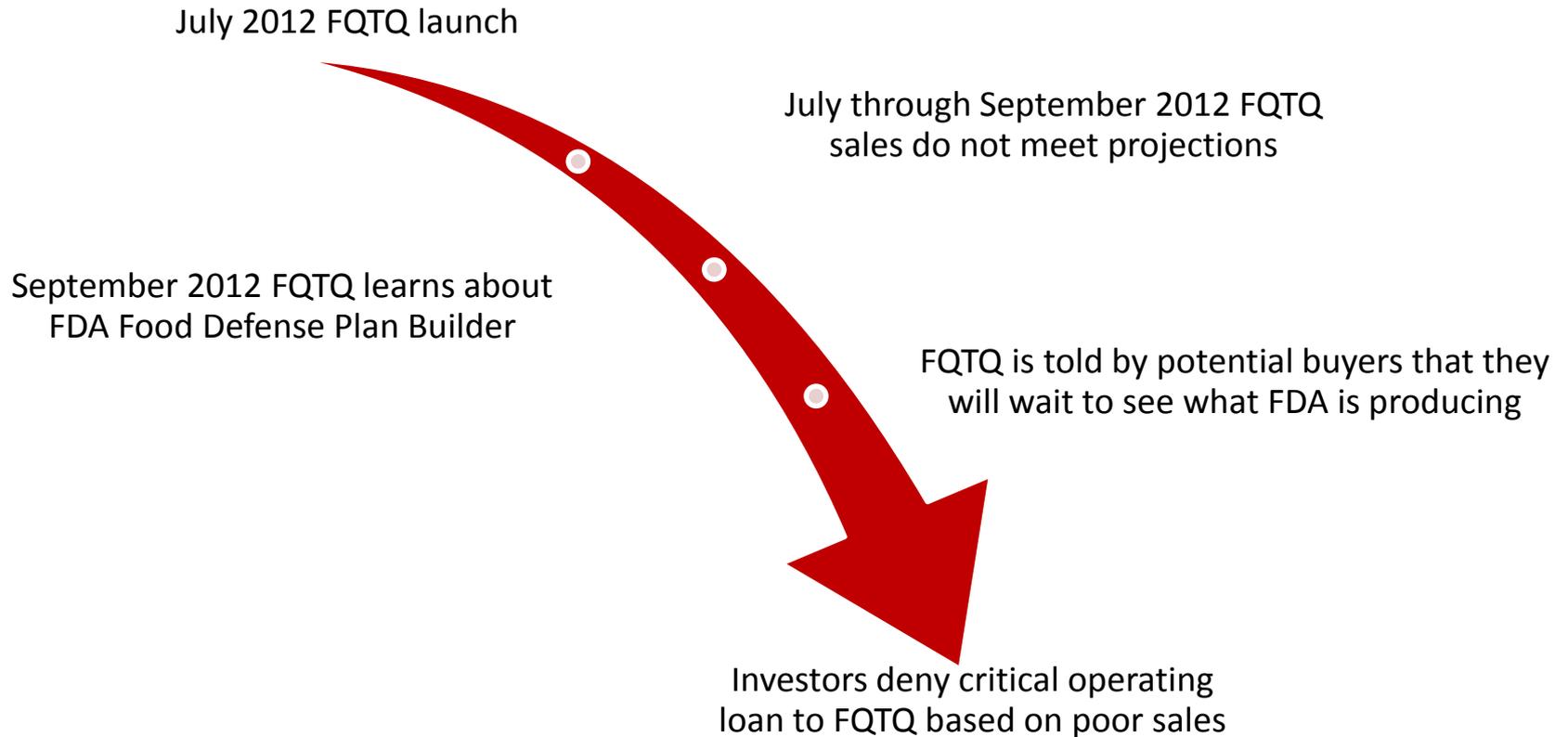
*The FQTQ systems model for food protection improves risk communications.*

- The FDA has stolen FQTQ process methods that enhance risk communications including FQTQ immersion environments, FQTQ methods of improved risk identification, risk communication, incident interdiction and mitigation.

# FDA Duplicates FQTTQ Products



# FQTQ Is Forced Out of Business



# FDA Infringes on Patent US 8,103,601 B2

The patent has 20 claims and 101 associated objects of the invention



**How FQTQ reduced the patent to use for food was FQTQ trade secret information until it was revealed by FDA in the FQTQ tools they duplicated and released to the public**



**FQTQ has prepared an extensive technical crosswalk that demonstrates flagrant infringement by the FDA on patent US 8,103,601 B2**



FQTQ is prepared to share the results of the crosswalk with the National Small Business Ombudsman if it will assist in the timely resolution of this matter

# FDA Unlawfully Competes with FQTQ

