

ENCLOSURE 3:

Twenty specific examples of Dr. Hnatio's ideas that have been plagiarized by the FDA in the FDA Food Protection Plan, Food Defense Plan Builder, the Mitigation Strategies Database, iRisk and the FREE-B food safety and food defense computer software tools

FDA Plagiarism Timeline

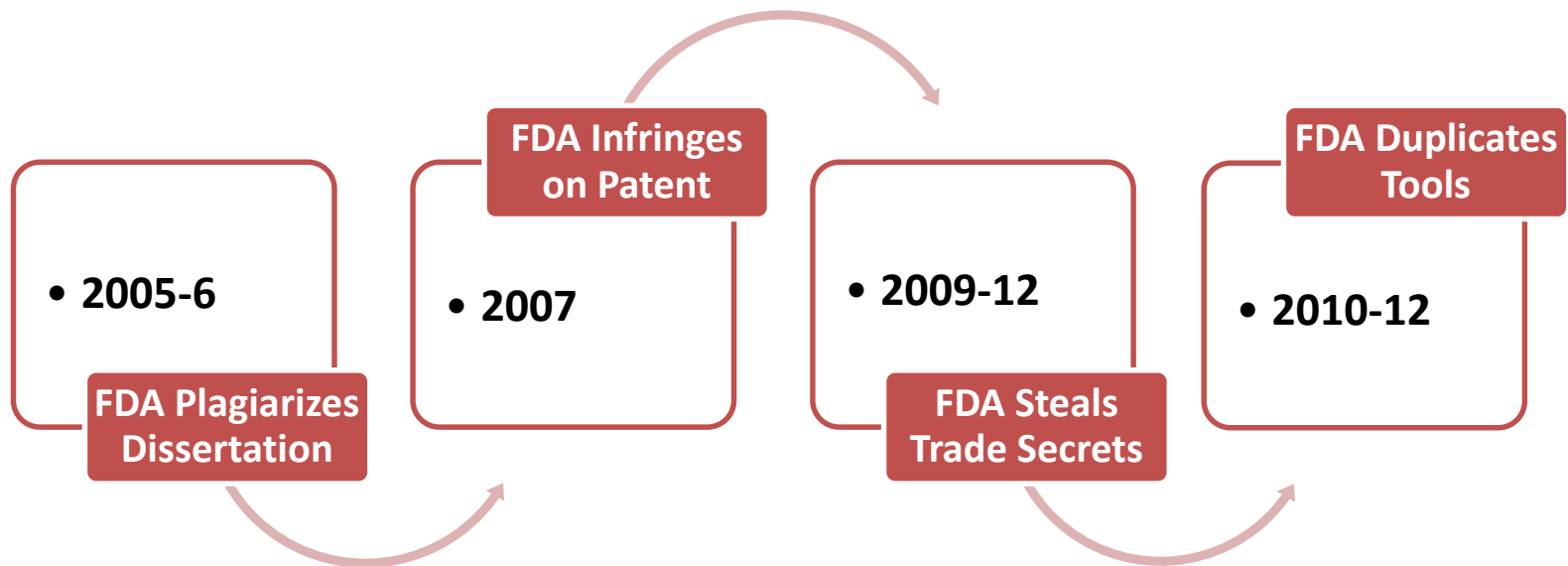


TABLE LEGEND	
TERM	EXPLANATION
FQTQ Idea	A FoodQuestTQ LLC protected idea as derived from reducing Projectioneering LLC patent , Complexity Systems Management Method, Patent No.: US 8,103,601 B2, to practice for food and agriculture. The patent is embodied under the registered trademarked name as the CSM METHOD®.
Description	The original protected idea as drawn from the Projectioneering LLC patent, Complexity Systems Management Method, Patent No.: US 8,103,601 B2, that was used by FoodQuestTQ LLC to reduce the patent to practice for food and agriculture. Ideas developed to reduce the patent to practice were treated as either trade secret or business confidential information prior to their unauthorized publication by the Food and Drug Administration.
Date Conceived	The time that the idea was first documented as the subject of an invention.
Patent	Signifies that the protected idea emanates from the Projectioneering LLC patent, Complexity Systems Management Method, Patent No.: US 8,103,601 B2.
OIP	Acronym for “Other Intellectual Property”, i.e., “business confidential” information
POISON	The FoodQuestTQ metadata repository of accidental and intentional food poisonings, industrial accidents at food facilities, equipment malfunctions of food equipment and natural hazards events affecting food operations and including growers.
Food DefenseTQ	The FoodQuestTQ automated software tool that is used by food operators along the supply chain to build and monitor effective food defense plans by asking what specific mitigating strategies are in place.
Food SafetyTQ	The FoodQuestTQ automated software tool that is used by food operators along the supply chain to build and monitor effective food safety plans by asking what specific mitigating strategies are in place.
Food Defense Architect	A more sophisticated version of Food DefenseTQ used by food operators along the supply chain to build the most effective food defense plans while continuously monitoring their performance.
Food Safety Architect	A more sophisticated version of Food SafetyTQ used by food operators along the supply chain to build the most effective food safety plans while continuously monitoring their performance.
Food Event Analysis and Simulation Tool (FEAST)	The FoodQuestTQ software tool that is used to develop and analyze food safety and food defense scenarios to promote multidisciplinary problem solving in the identification and filling of food defense and food safety gaps.
FREE	The FoodQuestTQ software tool, i.e., Food Response and Emergency Evaluation (FREE) Tool that is used to develop and analyze food safety and food defense scenarios in order to develop optimum food emergency response plans.
FPP	The FDA Food Protection Plan that contains pre-existing elements of the Projectioneering LLC patent as embodied in the Projectioneering LLC registered trademarked CSM METHOD®.
FDPB	The FDA Food Defense Plan Builder that duplicates the pre-existing FoodQuestTQ Food DefenseTQ and Food Defense Architect tools.
MSDB	The FDA Food Defense Mitigation Strategies Database that duplicates the pre-existing FoodQuestTQ Food DefenseTQ and Food Defense Architect tools.
iRISK	The FDA iRISK tool that contains elements of the pre-existing Projectioneering LLC patent as embodied in the Projectioneering LLC registered trademarked CSM METHOD®.
FREE-B	The FDA Food Response Emergency Exercise-Bundled tool that duplicates of FoodQuestTQ LLC’s pre-existing FEAST and FREE tools.

TWENTY SPECIFIC EXAMPLES OF FDA THEFT OF INTELLECTUAL PROPERTY FROM FOODQUESTTQ LLC

FQTQ Idea	Description	Date Conceived	Sources		FoodQuestTQ LLC Tool							What the FDA has Stolen	Used by FDA Without Permission in the Following FDA Imitation Products				
			Patent	OIP	POISON	FDTQ	FSTQ	FDAR	FSAR	FEAST	FREE		FPP	FDPB	MSDB	iRISK	FREE-B
1. Food Protection Systems Model	The CSM Method® defines the threat continuum elements of deterrence, detection, delay, communication, response time, response quality and mitigation.	Pre-2007	Yes	Yes								The FDA has stolen the threat continuum elements of prevention, interdiction, i.e., the FDA uses the substituted term of “intervention”; communication and response.					
2. Indicators and Warnings	The CSM Method® defines a methodology for identifying the indicators and warnings of impending food events.	Pre-2007	Yes	Yes								The FDA has stolen the method for identifying indicators and warnings of impending food events, i.e., the FDA uses the substituted term “signals”.					
3. Probability of Occurrence as a function of vulnerability and consequence	The CSM Method® 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.	Pre-2007	Yes	Yes								The FDA has stolen the “probability of occurrence” method that is used to prioritize food system vulnerability and risk.					
4. Steps	The CSM Method® defines a methodology for determining food protection risks and the specific measures that must be implemented by food operations to mitigate risks and identify interventions; these are called “steps.”	Pre-2007	Yes	Yes								The FDA has stolen the “steps” method and associated taxonomy for identifying risks and implementing risk reduction measures; the FDA uses the substitute term of “mitigation strategies” for “steps.”					
5. Immersions	The CSM Method® method of “immersions” and “real” and “simulated events” are used to identify vulnerabilities, risk reduction measures, promote communication and achieve multidisciplinary problem solving.	Pre-2007	Yes	Yes								The FDA has stolen the method of “immersions”; the FDA uses the substitute terms “table top exercise” for “immersions”; “teachable moments” for “lessons learned”, and; “scenarios” for “simulated events.”					

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6. Food Protection Hot Spots	The CSM Method® defines a method for identifying and prioritizing the importance of high risk areas at food operations and along the supply chain based on probability of occurrence.	Pre-2007	Yes	Yes								The FDA has stolen the method for identifying and prioritizing high risk areas in the food supply, along the food supply chain and in operating food facilities based on probability of occurrence; the FDA has substituted the term "high risk areas" for "hot spots."					
7. Reverse engineering of past and simulated events	The CSM Method® defines a method whereby past and simulated food events are gathered, deconstructed and analyzed, i.e., "reverse engineering."	Pre-2007	Yes	Yes								The FDA has stolen the method for gathering, deconstructing and analyzing past and simulated food events to determine their probability of occurrence, lessons learned and to identify mitigating strategies.					
8. Identification of High Risk Agents	The CSM Method® defines a method to identify high risk agents by gathering deconstructing and analyzing poisoning events.	Pre-2007	Yes	Yes								The FDA has stolen the method for gathering, deconstructing and analyzing, as complex systems, food incidents and related data to identify high risk agents.					
9. Actionable Knowledge	The CSM Method® defines a method to identify, gather and analyze information to produce actionable knowledge for risk mitigation.	Pre-2007	Yes	Yes								The FDA has stolen the 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.					
10. Cradle to grave	The CSM Method® is based on a holistic "cradle to grave" systems of systems view of the food supply from raw ingredients through human consumption, symptomology and health outcomes, i.e., the science-based view of the food supply as a complex adaptive system.	Pre-2007	Yes	Yes								The FDA has stolen the method of using the holistic "cradle to grave" systems of systems science-based view of the of the food supply, i.e., the FDA uses substitute terms such as "from field to fork" and "entire supply chain."					

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11. Risk Reduction Countermeasures	The CSM Method® defines the methods to determine 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 information technology.	Pre-2007	Yes	Yes								The FDA has stolen the methods used to identify risks and their associated risk reduction measures. i.e., the FDA substitutes the term “mitigation strategies” for risk countermeasures.					
12. Food Risk Model	The CSM Method® defines a systems risk model that subsumes both food safety and food defense.	Pre-2007	Yes	Yes								The FDA has stolen the food protection systems model that subsumes both food safety and food defense.					
13. Perpetual Assessment	The CSM Method® ties continuous operational performance with perpetual assessment and inspection.	Pre-2007	Yes	Yes								The FDA has stolen the method for tying continuous operational performance with perpetual assessment and inspection, i.e., the FDA substitutes the term “inspectional strategies.”					
14. Best Investments	The Food CSM Method® defines methods for targeting the use of resources to obtain the greatest risk reduction value at the most reasonable cost.	Pre-2007	Yes	Yes								The FDA has stolen the methods to determine performance and “best investments” to mitigate risk, i.e., the FDA substitutes the term “mitigation strategies for “best investments.”					
15. Operational Tools	The CSM Method® defines methods for integrally tying the use of specific information technology applications to food industry operational requirements.	Pre-2007	Yes	Yes								The FDA has stolen methods for integrally tying the use of specific information technology applications to food industry operational requirements, i.e., the development of “operational tools” that rely on the application of information technology.					

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16. Food Protection as a Science	The CSM Method® defines a systems model and methods for treating food protection as a science that relies on quantitative statistical methods for determining risk values.	Pre-2007	Yes	Yes								The FDA has stolen the model and methods for treating food protection as a science that relies on quantitative statistical methods for determining risk values.					
17. Modeling, Science-based Analysis and Information Technology	The CSM Method® defines methods that combine advanced modeling, science based analysis and advanced information technology to produce operational software applications.	Pre-2007	Yes	Yes								The FDA has stolen methods that combine advanced modeling, science based analysis and advanced information technology to produce operational software applications.					
18. Critical Nodes	The CSM Method® defines critical nodes as those elements in a system that are most sensitive to changes in their environments and the methods used to identify them.	Pre-2007	Yes	Yes								The FDA has stolen the methods of determining critical nodes.					
19. Food Emergency Response	The CSM Method® defines methods for determining best response alternatives for food emergencies.	Pre-2007	Yes	Yes								The FDA has stolen methods for determining best response alternatives for food emergencies.					
20. Automated Method to Develop Food Defense Plans	The CSM Method® defines the use of automated methods for developing operational software tools.	Pre-2007	Yes	Yes								The FDA has stolen the methods for developing automated food defense tools.					