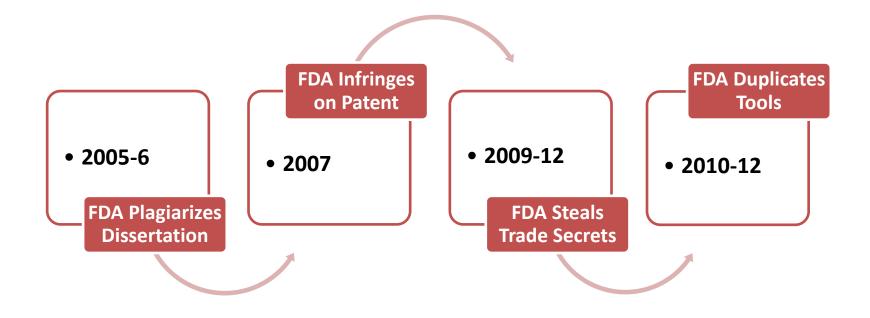
# ENCLOSURE 1:

Plagiarism evaluation of Dr. Hnatio's 2006 doctoral dissertation and the subsequent 2007 FDA Food Protection Plan

# **FDA Plagiarism Timeline**



#### Fourteen Examples of Plagiarized Content in the

#### Food and Drug Administration's (FDA) Food Protection Plan

1. Systems approach of prevention, intervention and response	8. Developing and testing the effectiveness of operational plans
2. <i>A priori</i> thinking and the consideration of threats and risks to prevent harm before an event occurs	9. Minimizing the consequences of adverse events
3. Scientific extrapolation of the extended order effects of adverse events ahead of time	10. Indicators and warnings and intelligence collection strategies
4. Increased focus on prevention	11. Application of science and information technology to identify vulnerabilities and determine the most effective countermeasures
5. Targeting areas of highest risk for attention	12. Determining and managing risk
<ol> <li>Validating the effectiveness of prevention measures and reducing risk</li> </ol>	13. Holistic view of complex systems
7. Earliest possible detection of adverse events to speed responses	14. Integrating safety and security

Food and Drug Administration (FDA) Plagiarism of 2000-2006 Doctoral Dissertation Research			
Complexity Systems M	anagement Method®	FDA Food Protection P	an
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plar	1
<ol> <li>Systems approach of prevention, validation [FDA uses the substitute term "intervention" for validation], and response</li> </ol>	9, 18, 39, 43, 45, 47, 49, 59, 64-66, 73, 75-76, 79, 80, 85-87, 94, 111-13, 117, 123, 126-8, 133, 155, 158, 159, 163, 164, 170,-71, 174,-76, 178-79, 182-86, 188-90, 192, 196, 199, 200, 203-04, , 211-12, 215, 217-18, 224, 227, 229, 232-33, 237	1-4, 6-7, 11, 13, 14-24 , 26 <sup>.</sup>	-29, 32
Representative Quotation from 2000-2006 Doctoral Research Dissertation			Page
"For risk applications scenarios are structured along a time continuum that begins with earliest possible detection of an adverse event moving sequentially through deterrence, prevention, response, immediate mitigation of consequences, and long term recovery."		85	
Samples of Plagiarized	Quotations from 2007 FDA Food Protec	tion Plan	Page
"FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention [FDA uses the substitute term intervention for validation] and response."			6
"Along with prevention and intervention [FDA uses the substitute term of intervention for validation], faster and more focused response is needed once a problem is detected."			14
"Prevention is the first essential step for a	n effective, proactive food safety and def	ense plan."	17
"Expand the Understanding and Use of Ef	fective Mitigation Measures"		17

	d and Drug Administration (FDA) 2000-2006 Doctoral Dissertation Rese	arch	
Complexity Systems Mana	agement Method®	FDA Food Protection F	Plan
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages ir Food Protection Pla	
<ol> <li>A priori thinking and the consideration of threats and risks to prevent harm before an event occurs</li> </ol>	47, 76, 80, 85-86, 90, 93, 97, 103, 113, 122, 128-30, 134, 155, 157-58, 160-62, 166-68, 171-73, 176, 178- 81, 183-85, 188, 191, 202, 225	1-4, 6, 14-22, 29, 32	
Representative Quotation f	from 2000-2006 Doctoral Research Dis	ssertation	Page
"So, what we may really need is a new cultural perspective — one that encourages us to think on an <i>a priori</i> basis about complex events and situations and to take appropriate actions to prevent serious problems before they happen and, if they occur, to have taken a close look at how to mitigate their adverse consequences ."		113	
Samples of Plagiarized Quotations from 2007 FDA Food Protection Plan			Page
"By preventing most harm before it can occurFDA can provide a food protection framework that keeps the American food supply safe."			2
"Driven by science and modern information technology, the Plan aims to identify potential hazards and counter them before they can do harm."			6
"The Plan focuses FDA's efforts on preventing problems first"			6
"This shift to an increased emphasis on preve	ention is at the core of FDA's Food Prot	ection Plan"	13

	Food and Drug Administration (FDA) n of 2000-2006 Doctoral Dissertation Res	earch	
Complexity Systems M	anagement Method®	FDA Food Prote	ction Plan
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pa Food Protection	
<ol> <li>Scientific extrapolation of the extended order effects of adverse events ahead of time</li> </ol>	i, ii, 1-2, 12,32, 43, 44, 45, 47-48, 50, 52, 57-58, 61-62, 64-66, 69, 73, 76, 77, 83, 87-88, 90-92, 94-95, 97, 99, 103, 111, 113, 118, 121-23, 131-32, 134, 136-37, 155	2, 4, 6, 14-22, 27-28	
Representative Quotations	from 2000-2006 Doctoral Research Disse	ertation	Page
"For risk applicationswhat information h have used to mitigate its consequences?"	ad it been known before the adverse situ	ation occurred could	75
"the potential outcomesare structured knowledgebase."	, catalogued and archived in a supporting	computer	77
"Science-based models that show participants the extended order effects of decisions are used."		94	
Samples of Plagiarized Quotations from 2007 FDA Food Protection Plan		Page	
"By preventing most harm before it can occurFDA can provide a food protection framework that keeps the American food supply safe."		2	
"It [the FDA Food Protection Plan] is a forward-oriented concept that uses science and modern information technology to identify potential hazards ahead of time."		2	
"Driven by science and modern informatic counter them before they can do harm."	on technology, the Plan aims to identify po	otential hazards and	6

Plagia	Food and Drug Administration (FDA) rism of 2000-2006 Doctoral Dissertation Re	esearch	
Complexity Systems	Management Method®	FDA Food Protection Pla	n
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan	
4. Increased focus on prevention	47, 73, 75, 76, 79-80, 85-86, 90, 93, 97, 103, 112-13, 122, 127-30, 134, 155, 157-58, 160-62, 166-68, 170-73, 176, 178-85, 188, 191, 202, 225	1-2, 6-7, 12-15, 17-19, 21, 32	
Representative Quo	tations from 2000-2006 Doctoral Research	Dissertation	Page
"the current center of gravity for risk management rests on reaction with principal attention focused on <i>ex post facto</i> response to events."		79	
"Figures 2 illustrates the shift in the center of gravity from react and respond to the anticipation and prevention of adverse events under the complexity systems management method."		80	
"So, what we may really need is a new cultural perspective — one that encourages us to think on an <i>a priori</i> basis about complex events and situations and to take appropriate actions to prevent serious problems before they happen and, if they occur, to have taken a close look at how to mitigate their adverse consequences."		113	
Samples of Plagiarized Quotations from 2007 FDA Food Protection Plan		Page	
"Driven by science and modern information technology, the Plan aims to identify potential hazards and counter them before they can do harm. A cornerstone of this forward-thinking effort is an increased focus on prevention."			6
"While American consumers enjoy one of the safest food supplies in the world, growing challenges require a new approach to food protection at FDA — an increased emphasis on prevention."			13
"This shift to an increased emphasis or	n prevention is at the core of FDA's Food Pr	otection Plan"	13

Plagia	Food and Drug Administration (FDA) arism of 2000-2006 Doctoral Dissertation I	Research	
Complexity Systems	Management Method®	FDA Food Protection Plan	า
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan	
5. Targeting areas of highest risk for attention	74-76, 77-80, 83-86, 88-89, 90-91, 93- 95, 97-100, 124-27, 130-31, 134-37, 155-56, 158, 161-63, 165-66, 169-78, 181-192, 210	6, 14, 15, 16-18, 20-22, 24, 26, 2	9
Representative Que	otations from 2000-2006 Doctoral Researc	h Dissertation	Page
"The critical nodes of a complex syste system itself that are particularly sens	m [i.e., areas of highest risk] are those core itive to changes in initial conditions."	e interrelationships within the	74
"This [risk] data includesthose point made in order to avoid catastrophic sy	s in a simulated event [ i.e., areas of highes /stem failure"	st risk] where decisions must be	91
"CSM simulations are tied to a supporting computer knowledgebase that characterizes each of the critical safety, security and programmatic nodes of operation of a product cycle [i.e., areas of highest risk] including associated fixed site food processing/manufacturing facilities."		169	
Samples of Plagia	rized Quotations from 2007 FDA Food Pro	tection Plan	Page
"The intervention element focuses on	high risk points in the food supply chain.	,	6
"Prevention needs to be augmented by targeted intervention that focuses inspection and testing on the areas of greatest risk."		14	
A comprehensive risk-based approach must consider the many variables that define risk. Such variables includewhere contamination is most likely to occur"		15	
"Examining all aspects of the product	life cycle helps define the areas of greatest	risk."	16

Plagiari	Food and Drug Administration (FDA) sm of 2000-2006 Doctoral Dissertation F	Research	
Complexity Systems N	lanagement Method®	FDA Food Protection Pla	an
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan	
<ol> <li>Validating the effectiveness of prevention measures and reducing risk [FDA uses the substitute term "intervention" for validation]</li> </ol>	45, 59, 66-8, 70-1, 75-76, 79-80, 83, 85-86, 88-89, 90, 93-94, 99-103, 112- 13, 136-37, 155, 157-58, 169-180, 185, 187	2, 6, 14, 16, 21-23, 27, 32	
Representative Quota	tions from 2000-2006 Doctoral Researc	h Dissertation	Page
"The <i>immersion process</i> can also be used to test operational responses to high consequence agro-terrorist events involving America's food supply system including product cycle, fixed site food processing/manufacturing operations, supply chain distribution and retail sales."		169	
The same knowledgebase can be used at the tactical level to test operational safety and security responses to agro-terrorism using hypothetical simulations before a similar event happens in the real world.		173	
CSM immersions use scientifically accurate simulations of hypothetical attacks for both threat analysis and to test actual operational capabilities in response to high consequence terrorist attacks against America's food supply.		174-75	
Samples of Plagiariz	ed Quotations from 2007 FDA Food Prot	tection Plan	Page
"Intervention - Verify prevention and intervene when risks are identified"		2	
"enhancing our intervention methods at key points in the food production systemcan provide a food protection framework that keeps the American food supply safe."		2	
"The Plan focuses FDA's efforts on preventive approaches are effective."	enting problems first, and then uses risk-	based interventions to ensure	6

	ood and Drug Administration (FDA) of 2000-2006 Doctoral Dissertation Reso	arch	
Complexity Systems Ma		FDA Food Protection P	lan
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Pla	1
<ol> <li>Earliest possible detection of adverse events to speed responses [FDA also uses the substitute terms "surveillance" and "signals" as aids to early detection ]</li> </ol>		4, 6, 11-14, 16-17, 21-24, 26	5, 27
Representative Quotation	ns from 2000-2006 Doctoral Research D	Dissertation	Page
"For risk applicationsa time continuum that adverse event moving sequentially through consequences, and long term recovery."			75
"The simulations used in immersions are readdress the agro-terrorist threat from "field threat continuum from <b>early detection</b> [em mitigation of immediate consequences and	to fork" for different product cycles acr phasis added], deterrence, deceit, decer	oss the entire terrorist	155
"These indicators and warnings are catalogue to facilitate focused intelligence collection s interdiction of terrorists before they can suc distribution and fixed site food manufacturi	trategies for the <b>earliest possible detec</b> t ccessfully attack critical nodes of agricult	tion [emphasis added] and	170-71
	Quotations from 2007 FDA Food Protect	tion Plan	Page
"The intervention element focuses on surv	reillance at high risk points in the food su	upply chain."	6
"However, even the best system in the worl prevention and intervention, faster and more	•	0	14
"Improve the Detection of Food System 'Sig	nals' that Indicate Contamination"		22

Plagia	Food and Drug Administration (FDA) Irism of 2000-2006 Doctoral Dissertation I	Research	
Complexity Systems	Management Method <sup>®</sup>	FDA Food Protection Plan	า
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan	
8. Developing and testing the effectiveness of operational plans	16, 46-47, 64,67-68, 76, 78-79, 83, 86, 88-89, 90-95, 97-103, 121-24, 130-31, 134-35; 137, 155-58, 160-62, 164, 169- 75, 177-79, 180-85, 187, 189,190-91	6, 14, 16-19, 21-24, 27-31	
Representative Que	otations from 2000-2006 Doctoral Researc	h Dissertation	Page
	ed for educational, strategic and tactical opera its that confront decision makers in the real w		94
"The same knowledgebase can be used at the tactical level to test operational safety and security responses to agro- terrorism using hypothetical simulations before a similar event happens in the real world."		173	
"The complexity systems management method is a tool that can be used by the agricultural sector as part of terrorism threat, risk and operational response planning where current risk assessment tools fail to systematically identify the critical nodes of operation of complex food production, processing and supply and distribution chains for assessing potential catastrophic outcomes."		177	
Samples of Plagia	rized Quotations from 2007 FDA Food Pro	tection Plan	Page
"Interventions, in the form of targeted inspections and testing, verify that preventive controls are working and that resources are being applied to the areas of greatest concern"		14	
"developing a contingency plan to aid in a response in the event of contamination."		17	
"Develop written food protection guidelines for industry to a) develop food protection plans for produce and other food products, and b) implement other measures to promote corporate responsibility."		18	
	in a) developing food protection plans that a on steps, and c) developing contingency plans		19

Plagia	Food and Drug Administration (FDA) arism of 2000-2006 Doctoral Dissertation I	Research	
Complexity Systems	Management Method®	FDA Food Protection Plan	۱
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan	
9. Minimizing the consequences of adverse events	75-76, 79-80, 85-86, 113, 123, 126, 128, 170, 175, 176, 182, 187-88, 193, 200, 211, 217, 224	4, 17, 21-22	
Representative Que	otations from 2000-2006 Doctoral Researc	ch Dissertation	Page
	um that begins with earliest possible detec ention, response, <b>immediate mitigation o</b>	-	75
"The simulations used in immersions are referred to as "full spectrum" because they are specially crafted to address the agro-terrorist threat from "field to fork" for different product cycles across the entire terrorist threat continuum from early detection, deterrence, deceit, deception, prevention, response, <b>mitigation of immediate</b> <b>consequences and long-term economic recovery</b> [emphasis added]."		155	
"These teams [immersion teams] also identify the <b>range of potential consequences</b> [emphasis added] of a successful attackThe results are catalogued and archived in the supporting computer knowledgebaseto 'baseline' onsite and external resources that could be called upon <b>to respond to and mitigate the consequences</b> [emphasis added] of a successful terrorist attack"		170	
Samples of Plagia	rized Quotations from 2007 FDA Food Pro	tection Plan	Page
"Expand the Understanding and Use of Effective Mitigation Measures"		4, 17	
"1.3 EXPAND THE UNDERSTANDING A	ND USE OF EFFECTIVE MITIGATION MEASU	JRES "	21
"Develop new mitigation tools and im	plement appropriate risk management stra	ategies."	22

Food and Drug Administration (FDA) Plagiarism of 2000-2006 Doctoral Dissertation Research			
Complexity Systems M	lanagement Method®	FDA Food Protection P	lan
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Pla	
<ol> <li>Indicators and warnings and intelligence collection strategies [FDA uses the substitute term "signals"]</li> </ol>	76, 83, 86, 89, 93, 98-99, 122, 135, 156- 61, 163-68, 170-71, 173-74, 179, 181- 83, 185-86, 190, 192, 221, 224, 228	4, 12, 14, 21, 22, 24, 26-27,	31
Representative Quotati	ons from 2000-2006 Doctoral Research Di	ssertation	Page
"For risk applications, the precursor warning s catastrophes are identified."	signals that can lead to disasters or cause disa	sters to escalate to become	93
"the warnings of impending adverse situations are validated by immersion participants and strategies to implement highly focused intelligence collection are considered."			98
"Critical nodes of product cycle, distribution and fixed site food processing/manufacturing operationsare analyzedto identify the indicators and warningsThese indicators and warnings arearchived in the supporting knowledgebaseto facilitate focused intelligence collection strategies for the earliest possible detection and interdiction of terrorists before they can successfully attack critical nodes of agricultural product cycle, distribution and fixed site food manufacturing operations."		170-71	
Samples of Plagiarized	Quotations from 2007 FDA Food Protect	on Plan	Page
"Signals of potential problems come in the form of consumer complaints, inspection data, positive test results, adverse event reports, and other reports of illness."			12
"A successful and fully integrated food protection system will identify signals that indicate the need for intervention."			14
"Working with its food safety partners, FDA w either potential or actual harm to consumers.		y react when signals indicate	14
"An integrated, IT infrastructure with data gat		y built into the systems is	31

Plagiar	Food and Drug Administration (FDA) ism of 2000-2006 Doctoral Dissertation Res	earch	
Complexity Systems	Management Method®	FDA Food Protection Pl	an
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan	
<ol> <li>Application of science and information technology to identify vulnerabilities and determine the most effective countermeasures</li> </ol>	I, 3-4, 6-8, 10, 12-13, 17, 25, 33, 43, 49, 51-53, 56-58, 64, 67-68, 73, 76-77, 83-84, 90, 91-95, 98-100, 103, 108, 110, 123- 24, 132-136, 155-58, 164, 167-73, 169, 179-85, 190-92, 197, 208, 220-22, 225	2-7, 14-17, 24-25, 30-32	
Representative Quot	ations from 2000-2006 Doctoral Research D	issertation	Page
"Quantitative, i.e., science-based, [computer driven] models are used to scientifically extrapolate the extended order effects of the outcomes of possible decisions that could be made to manage each scenario."			76
"Analogously derived science-based [computer driven] simulations of hypothetical events and situations involving systems relationships among critical nodes of operation of a complex system are used during immersions."		90-91	
"Science-based [computer driven] models	that show participants the extended order effe	cts of decisions are used."	94
"science-based scenarios and critical decision points of simulations involving potential future events and situations should be systematically "reverse engineered" usingcutting edge information technology developments including quantitative and computational social science modeling, advanced simulations and computer knowledgebases where all information is structured for repeatability."		123	
Samples of Plagiarized Quotations from 2007 FDA Food Protection Plan		Page	
"It [the FDA Food Protection Plan] is a forward-oriented concept that uses science and modern information technology to identify potential hazards ahead of time."			2
science underpinning how and where food	sed on science. FDA's Food Protection Plan emp becomes contaminated and the associated risk entions to reduce the likelihood of contamination	s. The Plan also highlights the	16

Food and Drug Administration (FDA) Plagiarism of 2000-2006 Doctoral Dissertation Research								
Complexity Systems Management Method <sup>®</sup> FDA Food Protection Pla								
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plar						
12. Determining and managing risk       9, 75-76, 79-80, 83, 85, 88-89, 93-95, 97-100, 127, 131, 134-35, 136, 154-56, 158-59, 160-62, 168-71, 174-77, 180-83, 186-89, 191, 193       2-4, 6, 11, 14-22, 24-29, 31-32								
Representative Q	uotations from 2000-2006 Doctoral Research Dis	sertation	Page					
"The same red teams determine the outcomes and extended order effects of a range of different decisions for each of the critical nodes [i.e., determine areas of highest risk]"								
"Subject matter experts are asked to determine those points in the simulation where decisions must be made in order to avoid unacceptable outcomes [i.e., determine areas of highest risk]."								
"CSM food production cycle, distribution and processing/manufacturing facility immersions can be repeated with different participants to update a supporting knowledgebase in order to continuously refine product cycle, distribution and fixed food processing/ manufacturing site threat and risk plans, e.g., design basis threat."								
"A critical aspect of the CSM immersion process ishow to focus limited resources in the most efficient manner to achieve reasonable risk before a similar event happens in the real world. The CSM method considers the entire threat continuum from early detection, deterrence, prevention response, near term mitigation to long-term programmatic recovery."								
Samples of Plag	iarized Quotations from 2007 FDA Food Protection	on Plan	Page					
"A comprehensive risk-based approach r	nust consider the many variables that define risk."		15					
"Establish a risk-based process [i.e., met cause the greatest burden of foodborne	hods to determine risk] to continuously evaluate whic disease."	h FDA-regulated products	20					
	allows the FDA to maximize the effectiveness of its availated by the greatest risk to human and animal health	, .	21					

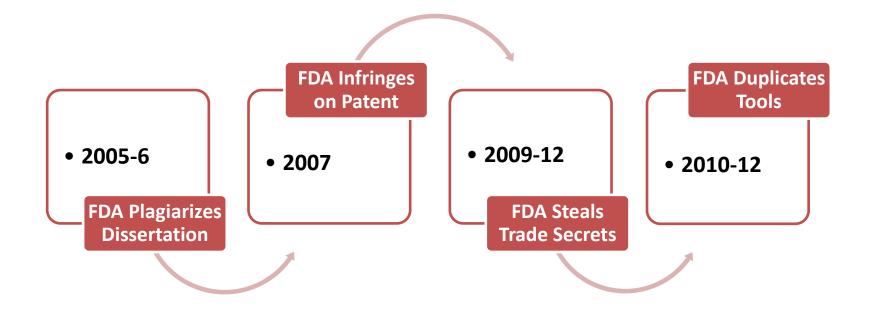
Plagia	Food and Drug Administration (FDA rism of 2000-2006 Doctoral Dissertation						
Complexity Systems N	lanagement Method®	FDA Food Protection Plan					
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan					
<ol> <li>Holistic view of complex systems</li> <li>[FDA uses the terms production life cycle and supply chains]</li> </ol>	A uses the terms production $\begin{bmatrix} 8, 10, 11, 21, 23, 52-56, 61, 169, 170 \\ 74, 177-80 \end{bmatrix}$ 2-3, 6, 14-16, 19-21, 27-28, 32						
Representative Quo	otations from 2000-2006 Doctoral Resea	arch Dissertation	Page				
	examine, from the holistic frame of refer riors, exhibited by a complex system or s		74				
	ally to determine the critical nodes of a of a of a of a given system that are particularly se		84				
different participants to update a supp	on and processing/manufacturing facilit orting knowledgebase in order to contin manufacturing site threat and risk plan	nuously refine product cycle,	169				
distribution and fixed food processing/ manufacturing site threat and risk plans, e.g., design basis threat." "The simulations used in immersions are referred to as "full spectrum" because they are specially crafted to address the agro-terrorist threat from "field to fork" for different product cycles across the entire terrorist threat continuum from early detection, deterrence, deceit, deception, prevention, response, mitigation of immediate consequences and long-term economic recovery."							
Samples of Plagia	rized Quotations from 2007 FDA Food F	Protection Plan	Page				
"Examining all aspects of the product li	fe cycle helps define the areas of greate	est risk."	16				
"FDA designed its Plan for the full life c	ycle of food–from production to consur	nption"	17				
"By analyzing data collected throughou food products."	It the food product life cycle, we are bet	ter able to detect risks posed by	21				

Food and Drug Administration (FDA) Plagiarism of 2000-2006 Doctoral Dissertation Research								
Complexity Systems N	Nanagement Method®	FDA Food Protection Plan	า					
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan						
14. Integrating safety and security       42, 45, 48-49, 59, 114, 154, 169, 171-       3, 7, 15-17, 19-20, 32         78, 183, 187-88, 190       3, 7, 15-17, 19-20, 32								
Representative Quotations from 2000-2006 Doctoral Research Dissertation P								
"CSM simulations are tied to a supporting computer knowledgebase that characterizes each of the critical <i>safety, security</i> [emphasis added] and programmatic nodes of operation of a product cycle including associated fixed site food processing/manufacturing facilities."								
"The process is designed to break down traditional stove piping between and among safety, security, and policy and scientific personnel at all levels from the local business, central government, to the individual states to local communities."								
"The CSM process recognizes the symbiotic relationship between food safety and security across the threat continuum. Investments already made in food safety, when integrated with security, can have significant collateral benefits."								
Samples of Plagiaria	zed Quotations from 2007 FDA Food Prot	tection Plan	Page					
"FDA is implementing a Food Protection domestic and imported products."	Plan (the Plan) that addresses both food	safety and food defense for	3					
"Encompasses [i.e., the FDA Food Protection (deliberate contamination)"	ction Plan] food safety (unintentional con	tamination) and food defense	7					
"The best way to handle food safety and both."	l food defense is to develop approaches t	hat appropriately address	16					

# ENCLOSURE 2:

Ideas contained in Dr. Hnatio's 2007 patent disclosure that have been plagiarized by the FDA

# **FDA Plagiarism Timeline**



	Complexity Systems Mana	gement Method, Pater	nt No.: US 8,103,601 B2		
Projection	eering LLC Patent Claims	Patent Clain for Food and A	Trade Secret for Food	Business Confidentia	
	<ul> <li>A. Inputting a first plurality of data defining parameters of said complex adaptive system;</li> </ul>		A . Determine the rules of operation for the different segments of the food supply chain, i.e., what they do and how they operate;	No	Yes
	<ul> <li>B. Defining a plurality of fundamental events which determine behavior of said complex adaptive system;</li> </ul>		B. Gather, study and group into categories past food safety, food defense and site safety and security events as they affect different segments of the food supply chain;	Yes	Yes
1. A method of assessing	C. Modifying at each of a plurality of times at least one of said first plurality of data to define a plurality of initial conditions;	1. Manage and assess the	C. Identify the operational conditions, i.e., the environment in which the different segments of the food supply operate;	Yes	Yes
1. A method of assessing and managing behavior of a complex adaptive system, comprising the steps of:	D. Testing each of said first plurality of data to determine a first subset of said first plurality of data which are most relevant to said plurality of fundamental events for each of said plurality of initial conditions in order to develop a plurality of scenarios of behavior of said complex adaptive system, and;	performance of the food life cycle across supply chain:	D. Develop scenarios of past and imagined events affecting different segments of the food supply chain, and;	No	Yes
	E. Measuring an effect of each one of said plurality of initial conditions of each respective one of said developed plurality of scenarios on said first subset of data to provide status information which is capable of being tested to indicate likelihood of an event occurring in said complex adaptive system.		E. Use the scenarios to determine the combinations of rules and operational conditions that indicate when, where and how likely an adverse event will occur.	Yes	Yes

Complexity Systems Management Method, Patent No.: US 8,103,601 B2										
Projection	eering LLC Patent Claims		Patent Claims as Reduced to Practice for Food and Agriculture by FoodQuestTQ							
2. The method of claim 1 further including the steps of:	A. Testing each of said scenarios to determine for each scenario precise events which must occur to cause said complex adaptive system to exhibit said scenario; and determining for each tested scenario critical decision points.	2. The method of claim 1 further including the steps of:	A. Reverse engineer scenarios of past and imagined events to develop event paths that cause different events; determine where, when and why human interventions are required to prevent and mitigate adverse outcomes.	Yes	Yes					
3. The method according to claim 1 including the further step of applying to said status information a first algorithm providing an estimate of an event sequence interruption.		<ol> <li>Apply the CSM systems approach, i.e., deterrence, detection, communication, response time, response quality, consequence and mitigation to determine strengths and weaknesses using scenarios.</li> </ol>		Yes	Yes					
4. The method according to claim 3 wherein values obtained from said applying of said first algorithm provide an event quotient for each of said first subset of data.		<ol> <li>Apply values for deterrer response quality, conseq</li> </ol>	Yes	Yes						
5. The method according to claim 3 further including the step of modifying said first plurality of data as a function of a result of said application of said first algorithm.		5. Input additional data to i reduction countermeasu	Yes	Yes						
6. The method according to claim 4 wherein said event quotient further includes a functional relationship based on an algorithm related to occurrence of natural events and an effect of said natural events on said first subset of data.		<ol> <li>Determine the likelihood of weather and geologic events affecting/effecting agriculture and food facilities for the different segments along the food supply chain in different regions.</li> </ol>		Yes	Yes					
7. The method of claim 1 w of the complex adaptive s	herein said first subset of data are critical nodes system.	7. Determine the most imp affect/effect the outcom		Yes	Yes					

Projectio	Projectioneering LLC Patent Claims		Patent Claims as Reduced to Practice for Food and Agriculture by FoodQuestTQ			
8. The method of claim 2 further including the	A. Modifying said first plurality of data to simulate predetermined events occurring in said complex adaptive system;	8. The method of claim 2 further including the	A. Develop simulated scenarios that produce predetermined outcomes; determine the affects/effects on where, when and why human interventions are required to prevent			
steps of:	B. Determining the effects from said simulated events on said critical decision points; and forming decision fault trees from said determined effects.	steps of:	and mitigate adverse outcomes, i.e., critical decisions points; use decision/fault trees and other means to visualize the scenario, the sequence of events and the critical decision points.	Yes	Yes	
<ol><li>The method of claim 8 further including forming decision maps and computer models to manage said predetermined events.</li></ol>		9. Create decision maps and comp	puter models to manage predetermined events.	Yes	Yes	
10. A method of increasing the likelihood of behavior of a complex adaptive system, comprising the steps:	<ul> <li>Defining fundamental elements which control the functioning of the complex adaptive system;</li> </ul>		A. Defining the rules of operation for the different segments of the food supply chain across the food life cycle, i.e., what they do, when they do it and how they operate.	No	Yes	
	<ul> <li>B. Assigning a plurality of sets of initial values at a respective plurality of times to a plurality of features of the complex adaptive system;</li> <li>C. Determining which ones of said plurality of features of the complex adaptive system are most directly related to said fundamental elements for each of said plurality of sets of</li> </ul>	10. Preventing and improving responses to food safety, food	<ul> <li>B. Assigning baseline values for the probability of different events occurring; how vulnerable the activity is to different food safety, food defense and site safety and security events; the consequences associated with different types of events, and; for deterrence, detection, communication, response time,</li> </ul>	Yes	Yes	
	<ul> <li>initial conditions in order to develop a plurality of scenarios of behavior of said complex adaptive system, and;</li> <li>D. Measuring an effect of each one of said plurality of sets of initial conditions of each</li> </ul>	defense and food site safety and security events by:	<ul> <li>response quality, consequence and mitigation.</li> <li>C. Determining which of the features in b., above, are most directly related to the rules of operation, i.e. fundamental elements, and the environment, i.e., operational conditions, and develop scenarios.</li> </ul>	Yes	Yes	
	respective one of said developed plurality of scenarios on said ones of said plurality of features most directly related to said fundamental elements to generate sets of data functionally related to the likelihood of a particular occurrence in said complex adaptive system.		<ul> <li>D. Measure the affect/effect of fundamental elements and operational conditions and generate scenarios to produce outcomes.</li> </ul>	Yes	Yes	

Complexity Systems Management Method, Patent No.: US 8,103,601 B2									
Projectic	oneering LLC Patent Claims	Patent Claims as for Food and Agric	Trade Secret for Food	Business Confidential					
<ul> <li>A. Testing each of said scenarios to determine for each scenario precise events which must occur to cause said complex adaptive system to exhibit said scenario, and:</li> </ul>		<ol> <li>The method of claim</li> <li>10 further including</li> <li>the steps of:</li> </ol>	A. Reverse engineer test scenarios and develop event paths that cause different events; determine where, when and why	Yes	Yes				
the steps of:	<ul> <li>B. Determining for each tested scenario critical decision points.</li> </ul>		human interventions are required to prevent and mitigate adverse outcomes.						
12. The method according to claim 10 including the further step of applying to said set of data a first algorithm providing an estimate of an event sequence interruption.		12. Apply CSM Method system process model where the interdiction of an event, i.e., prevention, is a function of deterrence, detection, communication, prevention, response time, response quality to produce an estimate of event sequence interruption.		Yes	Yes				
13. The method according to claim 12 wherein values obtained from said applying of said first algorithm provide an event quotient for each of said ones of said plurality of features most directly related to said fundamental elements.		<ol> <li>Apply values to detern communication, preve quality to produce an quotient.</li> </ol>	Yes	Yes					
14. The method according to claim 11 further including the step of modifying said plurality of features as a function of a result of said application of said first algorithm.		14. Modify assigned values through the introduction of risk reduction measures that achieve the interdiction of an event, i.e., prevention.		Yes	Yes				
includes a functional re occurrence of natural e	o claim 13 wherein said event quotient further lationship based on an algorithm related to vents and an effect of said natural events on said features most directly related to said	the probability of wea occurring in a region, an event occur, i.e., w ranking, and the actio	ds vulnerability ranking based on ther and geologic events the consequences should such eather and geologic events ns taken to mitigate the es, i.e., adjusted event quotient.	Yes	Yes				

Complexity Systems Management Method, Patent No.: US 8,103,601 B2										
Projectioneering LLC Patent Claims			ims as Reduced to Practice Agriculture by FoodQuestTQ	Trade Secret for Food	Business Confidential					
16. The method of claim	A. Modifying said plurality of features to simulate predetermined events occurring in said complex adaptive system;	16. The method of claim	A. Determine the affects/effects of predetermined event paths for scenarios resulting in different events; determine the affects/effects of different							
16. The method of claim 11 further including the steps of:	B. Determining the effects from said simulated events on said critical decision points; and forming decision fault trees from said determined effects.	16. The method of claim 11 further including the steps of:	event paths on where, when and why human interventions are required to prevent and mitigate adverse outcomes, i.e., critical decision points, and; use decision/fault trees and other means to visualize the scenario, the sequence of events, and the critical decision points.	Yes	Yes					
	<ol> <li>The method of claim 16 further including forming decision maps and computer models to manage said predetermined events.</li> </ol>		nd computer models to manage predetermined	Yes	Yes					

Projectionee	ring LLC Patent Claims		educed to Practice ture by FoodQuestTQ	Trade Secret for Food	Business Confidentia
	A. A first computer readable program code means containing a first plurality of data defining parameters of said complex adaptive system and a plurality of defined relationships which control the functions of the complex adaptive system;		A. A computer readable program code containing data defining the rules and operational conditions of food defense, food safety and food site safety and security and the defined relationships which control the occurrence, prevention and mitigation of different events;	and e Yes ed	Yes
18. A computer program product for use with a digital computer for	B. A second computer readable program code means causing a modification at each of a plurality of times at least ones of said first plurality of data to define a plurality of initial conditions;	<ol> <li>The Food ProtectionTQ suite of automated computer software tools with computer readable codes that apply CSM Method process model comprising:</li> </ol>	B. A computer readable program code that can adjust the rules, fundamental elements, for food defense, food safety and food site safety as operational conditions change;	Yes	Yes
assessing and managing behavior of a complex adaptive system, said computer program product including a computer usable medium having a plurality of computer readable program code means embodied in said medium, comprising:	C. A third computer readable program code means for testing each of said plurality of data to determine a first subset of said first plurality of data which are most relevant to said plurality of defined relationships for each of said plurality of initial conditions in order to develop a plurality of scenarios of behavior of said complex adaptive system, and;	<ul> <li>Food Defense Architect;</li> <li>Food DefenseTQ;</li> <li>Food Safety Architect;</li> <li>Food SafetyTQ;</li> <li>Food Mapper;</li> <li>Food Event Analysis and Simulation Tool (FEAST), and;</li> <li>Food Response Emergency Evaluation Tool (FREE).</li> </ul>	C. A computer readable program code to determine which rules and operational conditions are most significant in producing outcomes in scenarios, and;	Yes	Yes
	D. A fourth computer readable program code means for determining an effect of each one of said plurality of initial conditions of each respective one of said developed plurality of scenarios on said first subset of data to provide status information which is capable of being tested to indicate likelihood of an event occurring in said complex adaptive system.		D. A computer readable program code for determining the affect/effect operational food defense, food safety and food site safety and security conditions that provide status information that can be tested to indicate the likelihood, i.e., probability, of an event occurring.	Yes	Yes

Complexity Systems Management Method, Patent No.: US 8,103,601 B2											
Projectioneering LLC Patent Claims	Patent Claims as Reduced to Practice for Food and Agriculture by FoodQuestTQ	Trade Secret for Food	Business Confidential								
19. The computer program product according to Claim 18 including a fifth computer readable code means for testing each of said scenarios to determine for each scenario precise events which must occur to cause said complex adaptive system to exhibit said scenario; and determining for each tested scenario critical decision points.	19. A computer readable code for testing scenarios to determine the precise events, i.e., event paths, which must occur to cause different food defense, food safety and food defense and site safety and security scenarios and determine where, when and why human interventions are required to prevent and mitigate adverse outcomes, i.e., critical decisions points for each tested scenario.	Yes	Yes								
20. The computer program product according to Claim 19 including a sixth computer readable code means for applying to said status information a first algorithm providing an estimate of an event sequence interruption.	20. A computer readable program code that applies the CSM Method system process model to the above data where the interdiction of an event, i.e., prevention, is a function of deterrence, detection, communication, prevention, response time, response quality to produce an estimate of event sequence interruption.	Yes	Yes								

# 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**

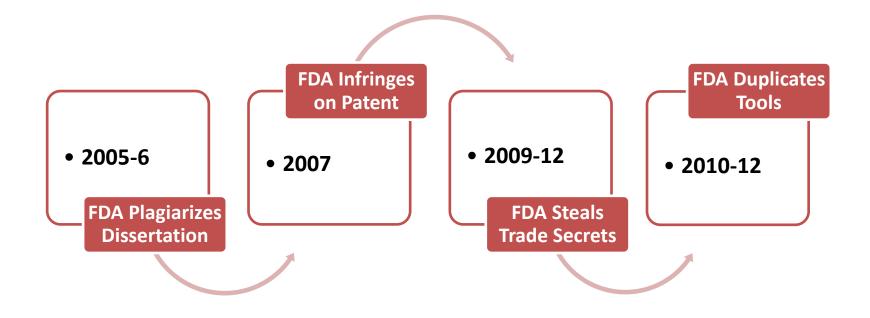


	TABLE LEGEND
TERM	EXPLANATION
FQTQ Idea	A FoodQuestTQ LLC protected idea as derived from reducing Projectioneering LLC patent , Complexity Systems Management Method, Patent No.: US 8,103,601 B2, to practice for food and agriculture. The patent is embodied under the registered trademarked name as the CSM METHOD <sup>®</sup> .
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 <sup>®</sup> .
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 <sup>®</sup> .
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	Soui	rces		FoodQuestTQ LLC Tool			What the FDA has Stolen		rmissio	y FDA W n in the I tation P	Followi				
			Patent	OIP	POISON	FDTQ	FSTQ	FDAR	FSAR	FEAST	FREE		FPP	FDPB	MSDB	iRISK	FREE-B
1. Food Protection Systems Model	The CSM Method <sup>®</sup> 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 <sup>®</sup> 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."					

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

FQTQ Idea	Description	Date Conceived	Sou	rces	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		
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."							
<ol> <li>Reverse engineering of past and simulated events</li> </ol>	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 <sup>®</sup> 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."							

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

FQTQ Idea	Description	Date Conceived	Soui	rces		F	oodQu	iestTQ	LLC Toc	)		What the FDA has Stolen	Pe	rmissio	, n in the	DA Without n the Following n Products			
			Patent	OIP	POISON F	DTQ	FSTQ	FDAR	FSAR	FEAST	FREE		FPP	FDPB	MSDB	iRISK	FREE-B		
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 <sup>®</sup> 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 <sup>®</sup> 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 <sup>®</sup> 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.							

## TWENTY SPECIFC EXAMPLES OF FDA THEFT OF INTELLECTUAL PROPERTY FROM FOODQUESTTQ LLC

FQTQ Idea	Description	Date Conceived	Sou	rces		FoodQuestTQ LLC Tool What the FDA has Stolen				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
16. Food Protection as a Science	The CSM Method <sup>®</sup> 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 <sup>®</sup> 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.					