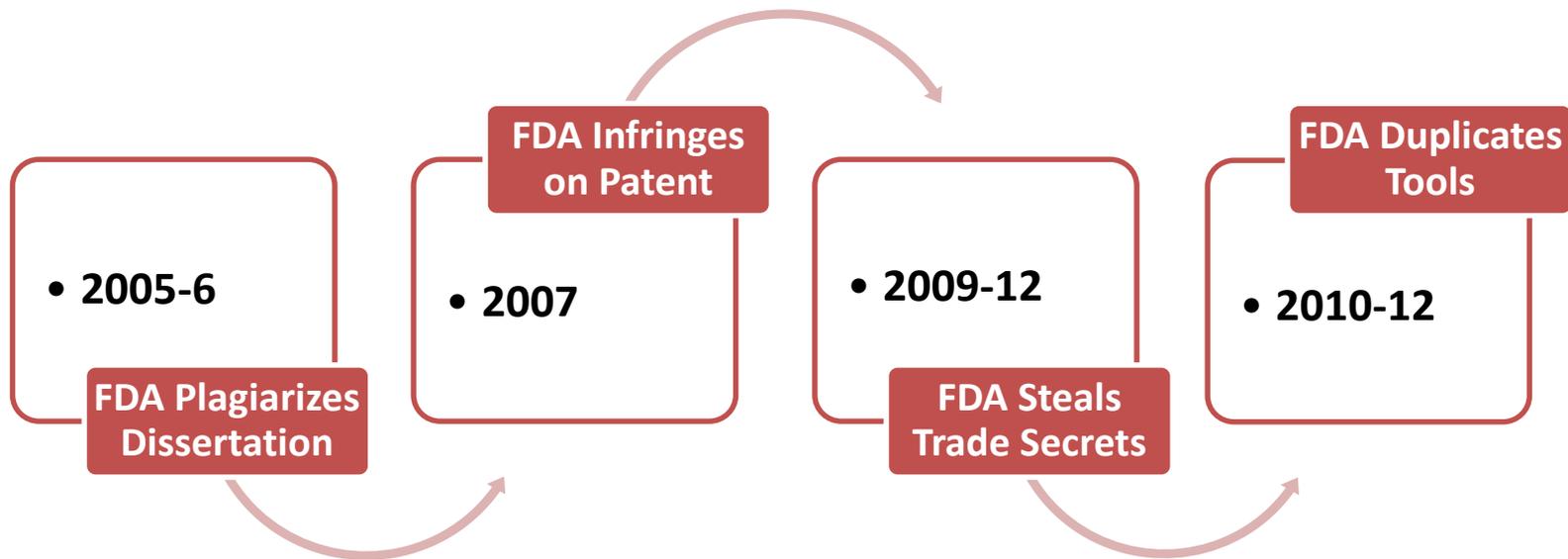


ENCLOSURE 1:

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
6. Validating the effectiveness of prevention measures and reducing risk	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 Management Method®		FDA Food Protection Plan
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan
1. Systems approach of prevention, validation [FDA uses the substitute term “intervention” for validation], and response	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 , 26-29, 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 Protection 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 an effective, proactive food safety and defense plan.”	17
“Expand the Understanding and Use of Effective Mitigation Measures”	17

**Food and Drug Administration (FDA)
Plagiarism of 2000-2006 Doctoral Dissertation Research**

Complexity Systems Management Method®		FDA Food Protection Plan
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan
2. <i>A priori</i> thinking and the consideration of threats and risks to prevent harm before an event occurs	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 from 2000-2006 Doctoral Research Dissertation		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 occur...FDA 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 prevention is at the core of FDA's Food Protection Plan...”		13

**Food and Drug Administration (FDA)
Plagiarism of 2000-2006 Doctoral Dissertation Research**

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FDA Food Protection Plan

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Food Protection Plan**

3. Scientific extrapolation of the extended order effects of adverse events ahead of time

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 Dissertation

Page

“For risk applications...what information had it been known before the adverse situation occurred could have used to mitigate its consequences?”

75

“...the potential outcomes...are structured, catalogued and archived in a supporting computer knowledgebase.”

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 occur...FDA 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 information technology, the Plan aims to identify potential hazards and counter them before they can do harm.”

6
6

**Food and Drug Administration (FDA)
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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 Quotations from 2000-2006 Doctoral Research Dissertation

Page

“...the current center of gravity for risk management rests on reaction with principal attention focused on *ex post facto* 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 *a priori* 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 on prevention is at the core of FDA's Food Protection Plan...”

7
13

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Complexity Systems Management Method®

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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, 29

Representative Quotations from 2000-2006 Doctoral Research Dissertation

Page

“The critical nodes of a complex system [i.e., areas of highest risk] are those core interrelationships within the system itself that are particularly sensitive to changes in initial conditions.”

74

“This [risk] data includes...those points in a simulated event [i.e., areas of highest risk] where decisions must be made in order to avoid catastrophic system failure ...”

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 Plagiarized Quotations from 2007 FDA Food Protection 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 include...where contamination is most likely to occur...”

15

8/28/2014
“Examining all aspects of the product life cycle helps define the areas of greatest risk.”

⁸ 16

Food and Drug Administration (FDA)
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Plagiarized Content

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**Plagiarized Pages in
Food Protection Plan**

6. Validating the effectiveness of prevention measures and reducing risk [FDA uses the substitute term “intervention” for validation]

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 Quotations from 2000-2006 Doctoral Research Dissertation

Page

“The *immersion process* 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 Plagiarized Quotations from 2007 FDA Food Protection Plan

Page

“Intervention - Verify prevention and intervene when risks are identified”

2

“...enhancing our intervention methods at key points in the food production system...can provide a food protection framework that keeps the American food supply safe.”

2

“The Plan focuses FDA's efforts on preventing problems first, and then uses risk-based interventions to ensure preventive approaches are effective.”

96

**Food and Drug Administration (FDA)
Plagiarism of 2000-2006 Doctoral Dissertation Research**

Complexity Systems Management Method®		FDA Food Protection Plan
Plagiarized Content	Pages in Doctoral Research Dissertation	Plagiarized Pages in Food Protection Plan
7. Earliest possible detection of adverse events to speed responses [FDA also uses the substitute terms “surveillance” and “signals” as aids to early detection]	43, 75-77, 81-83, 85-86, 93, 98, 127, 129, 135, 157-163, 165-68, 170-71, 173-74, 176, 179, 181, 182-83, 185-86, 188, 190, 192	4, 6, 11-14, 16-17, 21-24, 26, 27

Representative Quotations from 2000-2006 Doctoral Research Dissertation	Page
“For risk applications...a time continuum that begins with earliest possible detection [emphasis added] of an adverse event moving sequentially through deterrence, prevention, response, immediate mitigation of consequences, and long term recovery.”	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 [emphasis added], deterrence, deceit, deception, prevention, response, mitigation of immediate consequences and long-term economic recovery.”	155
“These indicators and warnings are catalogued and archived in the supporting knowledgebase and can be used to facilitate focused intelligence collection strategies for the earliest possible detection [emphasis added] 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 Protection Plan	Page
“The intervention element focuses on...surveillance at high risk points in the food supply chain.”	6
“However, even the best system in the world cannot prevent all incidents of foodborne illness. Along with prevention and intervention, faster and more focused response is needed once a problem is detected.”	14
8/28/2014 “Improve the Detection of Food System ‘Signals’ that Indicate Contamination”	10 22

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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 Quotations from 2000-2006 Doctoral Research Dissertation

Page

“The resulting knowledgebase can be used for educational, strategic and tactical operational uses as a planning and response tool to manage analogous events that confront decision makers in the real world.”

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 Plagiarized Quotations from 2007 FDA Food Protection 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

“FDA will continue to work with industry in a) developing food protection plans that address safety and defense vulnerabilities, b) implementing prevention steps, and c) developing contingency plans to improve response to an outbreak of foodborne illness.”

1119

Food and Drug Administration (FDA)
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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 Quotations from 2000-2006 Doctoral Research Dissertation

Page

“For risk applications...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** [emphasis added].”

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, **mitigation of immediate consequences and long-term economic recovery** [emphasis added].”

155

“These teams [immersion teams] also identify the **range of potential consequences** [emphasis added] of a successful attack ...The results are catalogued and archived in the supporting computer knowledgebase...to ‘baseline’ onsite and external resources that could be called upon **to respond to and mitigate the consequences** [emphasis added] of a successful terrorist attack...”

170

Samples of Plagiarized Quotations from 2007 FDA Food Protection Plan

Page

“Expand the Understanding and Use of Effective Mitigation Measures”

4, 17

“1.3 EXPAND THE UNDERSTANDING AND USE OF EFFECTIVE MITIGATION MEASURES “

21

“Develop new mitigation tools and implement appropriate risk management strategies.”

12²22

**Food and Drug Administration (FDA)
Plagiarism of 2000-2006 Doctoral Dissertation Research**

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FDA Food Protection Plan

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Food Protection Plan**

10. Indicators and warnings and intelligence collection strategies [FDA uses the substitute term “signals”]

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 Quotations from 2000-2006 Doctoral Research Dissertation

Page

“For risk applications, the precursor warning signals that can lead to disasters or cause disasters to escalate to become catastrophes are identified.”

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 operations...are analyzed...to identify the indicators and warnings...These indicators and warnings are...archived in the supporting knowledgebase...to 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 Protection 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 will improve its response system to more rapidly react when signals indicate either potential or actual harm to consumers.”

14

“An integrated, IT infrastructure with data gathering, sorting, mining, and trending capability built into the systems is critical to the success of FDA's food protection efforts

13
31

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**Food and Drug Administration (FDA)
Plagiarism of 2000-2006 Doctoral Dissertation Research**

Complexity Systems Management Method®

FDA Food Protection Plan

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Food Protection Plan**

11. Application of science and information technology to identify vulnerabilities and determine the most effective countermeasures

1, 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

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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 effects 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” using...cutting edge information technology developments including quantitative and computational social science modeling, advanced simulations and computer knowledgebases where all information is structured for repeatability.”

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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

“A successful plan for food protection is based on science. FDA's Food Protection Plan emphasizes the need to know the science underpinning how and where food becomes contaminated and the associated risks. The Plan also highlights the use of science to determine optimal interventions to reduce the likelihood of contamination.”

16

14

**Food and Drug Administration (FDA)
Plagiarism of 2000-2006 Doctoral Dissertation Research**

Complexity Systems Management Method®

FDA Food Protection Plan

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Food Protection Plan**

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 Quotations from 2000-2006 Doctoral Research Dissertation

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]”

95

“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].”

156

“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.”

169

“A critical aspect of the CSM immersion process is...how 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.”

176

Samples of Plagiarized Quotations from 2007 FDA Food Protection Plan

Page

“A comprehensive risk-based approach must consider the many variables that define risk.”

15

“Establish a risk-based process [i.e., methods to determine risk] to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease.”

20

“A comprehensive, risk-based approach allows the FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health.”

15 21

**Food and Drug Administration (FDA)
Plagiarism of 2000-2006 Doctoral Dissertation Research**

Complexity Systems Management Method®

FDA Food Protection Plan

Plagiarized Content

**Pages in Doctoral
Research Dissertation**

**Plagiarized Pages
in Food Protection Plan**

13. Holistic view of complex systems
[FDA uses the terms production
life cycle and supply chains]

8, 10, 11, 21, 23, 52-56, 61, 169, 170-
74, 177-80

2-3, 6, 14-16, 19-21, 27-28, 32

Representative Quotations from 2000-2006 Doctoral Research Dissertation

Page

“...multidisciplinary groups of experts examine, from the holistic frame of reference, real (or imagined) systems to identify patterns of interest, i.e., behaviors, exhibited by a complex system or systems of systems at t_1 .”

74

“The complex system is viewed holistically to determine the critical nodes of a system’s operation, i.e., those core interrelationships or activities unique to a given system that are particularly sensitive to changes in initial conditions.”

84

“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.”

169

“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.”

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Samples of Plagiarized Quotations from 2007 FDA Food Protection Plan

Page

“Examining all aspects of the product life cycle helps define the areas of greatest risk.”

16

“FDA designed its Plan for the full life cycle of food—from production to consumption...”

17

“By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products.”

16
21

**Food and Drug Administration (FDA)
Plagiarism of 2000-2006 Doctoral Dissertation Research**

Complexity Systems Management Method®		FDA Food Protection Plan
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, 171-78, 183, 187-88, 190	3, 7, 15-17, 19-20, 32

Representative Quotations from 2000-2006 Doctoral Research Dissertation	Page
“CSM simulations are tied to a supporting computer knowledgebase that characterizes each of the critical safety, security [emphasis added] and programmatic nodes of operation of a product cycle including associated fixed site food processing/manufacturing facilities.”	169
“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.”	175
“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.”	176

Samples of Plagiarized Quotations from 2007 FDA Food Protection Plan	Page
“FDA is implementing a Food Protection Plan (the Plan) that addresses both food safety and food defense for domestic and imported products.”	3
“Encompasses [i.e., the FDA Food Protection Plan] food safety (unintentional contamination) and food defense (deliberate contamination)”	7
“The best way to handle food safety and food defense is to develop approaches that appropriately address both.” 8/28/2014	17 16