CHEMICAL CONTAMINANTS IN CHINESE AQUACULTURE IMPORTS, U.S. IMPORT SECURITY, AND EXPOSURE ASSESSMENT AMONGST VULNERABLE SUB-POPULATIONS

by

EDWARD OTIENO NYAMBOK

B.S., Egerton University, 2005

AN ABSTRACT OF A DISSERTATION

submitted in partial fulfillment of the requirements for the degree

DOCTOR OF PHILOSOPHY

Food Science
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Abstract

Many Chinese aquaculture farmers use unapproved chemicals to treat their fish, many of which are diseased as a result of the country's poor waste management and environmental practices. During 2006-2007, the United States (U.S.), the European Union, and Japan rejected large amounts of Chinese seafood imports due to the presence of unapproved chemicals or the presence of approved chemicals at concentrations that exceeded permitted levels. This dissertation examines the sources of environmental health and food safety problems in China; it also examines how effective the U.S. and Chinese governments' regulations are in protecting consumers from hazards in Chinese aquaculture products. The study looks at specific chemical contaminants found in Chinese aquaculture imports, explores their potential toxicity or carcinogenicity, and examines the reasons for their prohibition from human food. The study exploits the available U.S. seafood consumption patterns (courtesy of the National Health and Nutrition Examination Survey—NHANES—database) and then uses probabilistic modeling (courtesy of CREMe Software Limited) to determine the extent to which specific sensitive U.S. consumer subpopulations were exposed to aquaculture chemical contaminants in the food supply in a contrived scenario using real consumption data (from NHANES) and actual contamination data (from the FDA). The study compares exposure between children and adult consumers, and also looks at exposure among women aged 18 years and older and the elderly aged 60 years and older. This study suggests a strong likelihood that NHANES children, as well as female consumers aged 18 years and older and elderly consumers aged 60 years and older, were (in the contrived scenario) all exposed to violative intake levels of chemical contaminants from Chinese aquaculture imports. Children forming the 99.5th and 99.9th percentiles of NHANES seafood consumers were exposed to higher levels of nitrofuran, gentian violet, and malachite green contaminants per kilogram of body weight than were their adult counterparts. Conversely, children were exposed to lower levels of fluoroquinolone contaminants per kilogram of body weight than were their adult counterparts. The 50th, 95th, and 99.9th percentiles of female consumers aged 18 and older and elderly consumers aged 60 years and older were exposed to violative daily intake levels of contaminants in Chinese aquaculture. The study concludes by examining what the U.S. and Chinese governments should do to address aquaculture safety.

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List of Abbreviations

CBP	U.S. Customs and Border Protection
CDC	U.S. Centers for Disease Control and Prevention
CES	Compound Evaluation System
Codex	Codex Alimentarius Commission
CPSC	Consumer Product Safety Commission
CREMe	Central Risk Exposure Modeling
DHEW	Department of Health, Education, and Welfare
DNA	Deoxyribonucleic Acid
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FD&C Act	*Food, Drug, and Cosmetic Act*
FQPA	*Food Quality Protection Act*
FSIS	Food Safety and Inspection Service
FSMA	*Food Safety Modernization Act*
GAO	U.S. Government Accountability Office, formally the General Accounting Office
GMP	Good Manufacturing Practices
GRAS	Generally Regarded As Safe
HACCP	Hazard Analysis and Critical Control Point
HSMHA	Health Services and Mental Health Administration
IPR	Intellectual Property Rights
LMG	Leucomalachite green
MRL	Maximum Residue Limit
MG	Malachite green
NAFTA	*North American Free Trade Agreement*
NCHS	National Center for Health Statistics
NFCMN	National Food Contamination Monitoring Network
NHANES	National Health and Nutrition Examination Survey
NHES	National Health Examination Survey

NHS	National Health Survey
NIH	National Institutes of Health
NNSS	National Nutrition Surveillance System
NOAA	National Oceanic and Atmospheric Administration
NRC	National Research Council
NTP	National Toxicological Program
ppb	Parts per billion
ppm	Parts per million
RNA	Ribonucleic Acid
SPS	Sanitary and Phytosanitary
TDS	Total Dietary Study
WHO	World Health Organization
WRI	World Resource Institute
WTO	World Trade Organization
WWEIA	What We Eat in America
UNICEF	United Nations Children's Fund
USDA	United States Department of Agriculture
GEMS/Food	Global Environment Monitoring System-Food Contamination Monitoring and Assessment Program
50^{th} P	50^{th} Percentile
95^{th} P	95^{th} Percentile
99.5^{th} P	99.5^{th} Percentile

Acknowledgements

This dissertation examines the effects of the increasingly globalized food supply on the safety of U.S. consumers; the study focuses on the safety of imported Chinese aquaculture products on U.S. seafood consumers. In addition, this study explores the effects of poor environmental health management practices and poor sanitary and phytosanitary regulations on the increasingly globalized food supply chains; it also explores the safety and security of the globally traded aquaculture products. This study also sheds light on important aspects of chemical contamination exposure among specific vulnerable U.S. subpopulation and the implications of that exposure upon U.S. seafood consumers. I am grateful to Almighty God for enabling me complete this study, which enlightened me and increased my understanding of the intricate nature of the world in which we live. I am also thankful to God for surrounding me with people whose love, encouragement, support, and guidance enabled me to complete my studies. I hope you will understand that my human nature may not allow me to remember all the people that I interacted with, directly or indirectly, and whose help was vital while undertaking this study. Therefore, I sincerely appreciate the help of all the people whose names I have mentioned as well as those whose names I could not remember, but whose interaction with, directly or indirectly, enabled me to successfully complete this study.

I am thankful for my wife Esther Achieng Otieno and our son Samson Nyambok Otieno, both of whom I dedicate this dissertation to; their presence in my life provided me with the joy and strength to reach this milestone. I am also thankful to Dr. Justin Kastner, my major professor, for the funding that he provided for this study, and for the opportunity to work on this dissertation while under his supervision, support, and guidance. The funding that Dr. Kastner provided through the *Frontier* Program enabled me to undertake this study as well as other unique experiential field trips that broadened my understanding of my areas of research. Dr. Kastner has a remarkable tolerance and patience for his students; his tolerance, patience, and constant guidance enabled me to improve my writing skills. His guidance enabled me to learn and appreciate the complexity of the world in which we live, and understand the importance if interdisciplinary research in developing solutions to problems in today's world. I would also like to thank the Food Science Institute and the Department of Diagnostic Medicine/Pathobiology at

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Dedication

I dedicate this dissertation to my wife Esther Achieng' Otieno and our son Samson Otieno Nyambok.

CHAPTER 1 - Introduction

Imports—including food imports—comprise an important aspect of the United States (U.S.) economy. American food processing companies increasingly depend upon imports as a source of raw materials; food processing companies in the U.S. are, in some cases, unable to obtain enough raw materials locally to sustain their processing operations. This forces the processing firms to look abroad for imports in order to satisfy their demand for raw materials. Dependence on imports comes with a number of challenges for the government, whose job it is to ensure that the products to which consumers have access are safe. The volume of U.S. seafood and aquaculture imports has significantly increased; currently, the U.S. imports more than twice the amount of food it imported in the early 1990s at the onset of the *North American Free Trade Agreement* (NAFTA) and the 1995 establishment of the World Trade Organization (WTO).[1]

Globalization is the consolidation or integration of countries, people, goods, services, and cultures around the world. It occurs as a result of many factors, including, but not limited to, reduced trade barriers, decreased transportation and communication costs, and increased dissemination of capital, knowledge, technology, culture, and people across borders. Globalization has increased the risks associated with the cross-border transmission of food-borne pathogens and contaminants.[2] Dissemination of food safety hazards can be attributed to the integration of national and international food production systems involved in the manufacturing, marketing, and distribution of food and food products across borders.[3] Globalization and trade in food has introduced new foods, food handling practices, and dietary habits into different regions. Consequently, food safety problems that were once isolated have now become globalized problems that are felt thousands of miles away. This has resulted in the emergence (or, in some cases, re-emergence) of food borne diseases and food contamination in different parts of the world. Effective and timely management of emerging food safety problems thus requires a rapid international exchange of information. Information exchange on food borne disease outbreaks is important for identifying clusters of diseases that have originated

[1] As the U.S. population rises, so too does national demand for greater volume and variety in U.S. food imports.

[2] T. Lang, "The Complexities of Globalization: The UK as a Case Study of Tensions within the Food System and the Challenge to Food Policy," *Agriculture and human values* 16, no. 2 (1999).

[3] The integration of food markets in different countries brought about by globalization has caused outbreaks of food borne diseases that were once unique to certain regions. Co-operation between different countries' governments is important in managing global food safety problems. Ibid.

from a common source.[4] Transnational cooperation between regulatory authorities is crucial to the timely identification and rectification of food safety problems. Globalization has facilitated the rise of such exporting countries as China. The integration of world markets has enabled China to emerge as a net food exporter through most of the past three decades. The country has also consistently managed to produce enough grains and other agricultural products to sustain its population of more than 1.4 billion people. China has dominated the world markets with its agricultural products, electronic goods, and service industries.[5]

The demand for seafood in the U.S. has been on the rise as the U.S. population continues to increase; therefore, most American industries depend upon imports to satisfy consumer demands for seafood. Currently, the U.S. imports more seafood than it exports. According to the National Oceanic and Atmospheric Administration (NOAA), the volume of U.S. seafood imports has more than doubled during the last 10 years. This increase in seafood imports has caused a corresponding increase in the safety concerns that government and food safety regulators have had to address in order to ensure that minimum safety requirements are met. Seafood imports have increased significantly, with shrimp accounting for 95 percent of the increase. As of 2007, 100 percent of the U.S. supply of *Pangasius bocourti* (basa fish) was imported, and 80 percent of those imports came from China; meanwhile, approximately 2 percent of catfish consumed in the country were imported, and 99 percent of those were of Chinese origin. These statistics indicate that a significant quantity of the seafood that ends up on American dinner plates is imported.[6] This increased consumption of imported seafood products means that regulators bear a heavier burden of responsibility to protect the public from food safety hazards. Unfortunately, this responsibility has gone relatively unheeded. While most consumers believe that all imported food is tested, the truth is that a large percentage is

[4] Ibid.

[5] Emergence of China as one of the leading food exporters occurred after its integration into the WTO. Bryan Lohmar and Fred Gale, "Who Will China Feed?," *Amber Waves; The Economics of Food, Farming, Natural Resources, and Rural America* 2008. Currently, Chinese products (e.g., clothing, shoes, toys, kitchen utensils such as plates, cooking pots, plates, knives, electronics, et cetera) occupy greater proportion of products in U.S. stores. Interestingly, the U.S. currently imports items as small as toothpicks from China. This illustrates the extent to which China has become an export oriented country.

[6] Asian countries contribute a significant proportion of seafood exports to the U.S. The U.S. National Oceanic and Atmospheric Administration, National Marine Fisheries Service, "Aquaculture and Trade," National Marine Fisheries Services, http://www.nmfs.noaa.gov/fishwatch/trade_and_aquaculture.htm.

not. In 2007, the FDA inspected 0.6 percent of food imports at the ports of entry, and in 2006, only 1.93 percent of all imports were inspected. These inspections included visual inspections, lab analyses, and documentation reviews.[7] The table below shows the quantity of seafood imports between 2003 and 2006, as well as the kind of inspection they underwent.

Table 1.1 The FDA Inspections of Import Shipments, 2003-2006

Year	Number of Food Import Shipments	Sensory Examination		Laboratory Inspection		Total of sensory and Lab Inspections	
		Number	Percent	Number	Percent	Number	Percent
2003	746,657	9,151	1.23	6,556	0.88	15,707	2.10
2004	849,420	10,616	1.25	5,476	0.64	16,092	1.89
2005	848,685	9,903	1.17	5,762	0.68	15,665	1.85
2006	859,357	11,534	1.34	5,071	0.59	16,605	1.93

While approximately 80 percent of seafood consumed by Americans is imported, only a small fraction of the imports undergo inspection. Examination and testing of imports is done by relevant regulatory agencies such as the Food and Drug Administration (FDA) and the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS).[8] International trade in food, plants, animals, and animal products can transmit infectious disease agents and toxic chemical contaminants across nation-state borders, posing significant safety concerns to regulators and consumers. Contaminated food imports can cause outbreaks of food-borne diseases that may result in serious financial losses for processing companies or—worse—possible death for consumers. In June 2007, 52 people in 17 states fell ill after eating a snack—Veggie Booty—that was produced by an American company. The product, which was produced using contaminated raw materials from China, contained the pathogenic *Salmonella* bacteria.[9] In March 2007, several brands of pet food were recalled from store shelves after causing illnesses and deaths in cats and dogs. The food was

[7] M. Bottari et al., "Trade Deficit in Food Safety: Proposed Nafta Expansions Contribute to Unsafe Food Imports," in *Public Citizen* (Washington, DC: Public Citizen's Global Trade Watch, 2007).

[8] The low percentage of goods inspected is due to the few resources allocated to the various regulatory agencies supposed to carry out inspections. Practically, not every food item imported into the U.S. can be inspected; inspectors usually target high risk commodities for inspections, while facilitating clearance for those deemed to pose low risks. Ibid.

[9] Reuters, "FDA Recalls Veggie Booty Snacks," Washington Reuters, http://www.reuters.com/article/healthNews/idUSN2929291520070629?pageNumber=1&virtualBrandChannel=0.

manufactured in the U.S. using vegetable ingredients from China.[10] At the end of March 2007, more than 500 cases of renal failure and over 100 cases of mortality were reported by various veterinary organizations. The cause of the deaths was traced to an industrial chemical called melamine, typically used in the manufacture of plastics.[11] Products from 13 pet food companies across the U.S. were affected, and one company in particular—Menu Foods—incurred an estimated US$42 million loss as a direct result of the recalls.[12] These instances represent just a few of the problems that U.S. consumers and companies have faced regarding the safety of imported products and raw materials.

Interestingly, in the U.S., Chinese products have been implicated in a number of safety issues. As with other U.S. imports, the volume of U.S. aquaculture imports has grown significantly over the past few years. This growth has brought new challenges to regulatory authorities, including the need for continuous monitoring to protect the public from exposure to potentially harmful substances in imports. In a sampling period between October 2006 and May 2007, the FDA found residues of chemical contaminants in Chinese aquaculture imports. Some of these chemicals, including antimicrobials such as fluoroquinolone, nitrofuran, malachite green, and gentian violet, are not permitted in human food in the U.S. Their use in food requires an approval for new drug application under section 512 of the *Food, Drug, and Cosmetic Act* (FD&C Act). Under section 402(a)(2)(c)(ii) of the FD&C Act, the presence of the antibiotics (or certain levels of their residues) in human food is considered an adulteration of the food, making it unfit for human consumption.[13,14]

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[10] Food and Drug Administration, "Transcript of the FDA Press Conference on Pet Food Recall," The United States Department of Health and Human Services, http://www.fda.gov/oc/opacom/hottopics/petfood/transcript040507.pdf.

[11] Melamine when added to wheat gluten used in pet food gave a false positive for high protein content of pet-food. Melamine is high in Nitrogen content—66 percent, unlike normal protein which has 16-17 percent Nitrogen. This gave a false positive test for the presence of high levels of proteins in the raw material imports.

[12] Associated Press, "104 Deaths Reported in Pet Food Recall," The New York Times: Science, http://www.nytimes.com/2007/03/28/science/28brfs-pet.html?_r=1&ex=1176264000&en=8ee0fb91fd221e4b&ei=5070.

[13] Murray M. Lumpkin, "Safety of Chinese Imports: Oversight and Analysis of the Federal Response," U.S. Department of Health and Human Services, Food and Drug Administration, http://www.fda.gov.er.lib.ksu.edu/ola/2007/chineseimport071807.html.

[14] U.S. Food and Drug Administration, Department of Health And Human Services, "The Federal Food, Drug, and Cosmetic Act 402(a)(2)(C)(Ii)," http://www.fda.gov/opacom/laws/fdcact/fdcact4.htm.

Descriptive and Normative Research Questions

This dissertation assesses impacts of globalization on the safety of U.S. aquaculture imports, and it specifically focuses on Chinese aquaculture products. Since it is difficult to focus on the safety issues of imports without addressing various aspects of risk assessment, an exposure assessment is at the heart of this study. This was done in an effort to answer the following research questions regarding Chinese aquaculture products:

1. What is the origin of food safety and environmental health problems in the aquaculture industry in China?
2. How effective are the U.S. and Chinese governments' regulations in protecting consumers from hazards in Chinese aquaculture products?
3. Considering the prevailing U.S. seafood consumption patterns (amongst the entire population as well as within specific sensitive sub-populations), was the dietary intake of specific chemicals from Chinese aquaculture imports within safe levels (in a contrived scenario using actual consumption and contamination data)?
4. What should the U.S. and Chinese governments do to address aquaculture safety?

The first two research questions—both of which are addressed in this chapter—were studied through extensive reviews of various publications such as government documents, Congressional hearings, import data, laboratory test results, food safety conference presentations by experts, etc. In order to obtain firsthand information on the subject matter, interviews were also conducted with U.S. government officials from agencies such as the Food and Drug Administration (FDA) and Customs and Border Protection (CBP). Both questions are answered at length in this chapter, and the analysis appears below. The analysis of the first two questions is followed by a literature review regarding the contaminants of concern. The third research question is addressed in chapters 3, 4, and 5 using available epidemiological, statistical, and NHANES data. Questions 1, 2, and 3 are descriptive questions that seek to establish the source of problems surrounding the Chinese aquaculture industry and U.S. import safety. The fourth research question, addressed in chapter 6, is a normative question—that is, it involves a discussion of what the various governments *should* do about these issues.

Sources of Environmental and Food Safety Problems in China

China is a large country with a diverse population; the country has a rapidly growing economy with many industries and agricultural farms. China's economy is heavily dependent upon industries and agriculture for its development; the country has over 700 million small and large scale farms spread across 300 million hectares of farm land.[15,16] According to the International Energy Outlook Report for 2009, China stands as the largest food exporter in the world. The country also attracts a great deal of foreign direct investment through transnational corporations.[17] Currently, one-third of all U.S. food and textile imports come from China. In 2004, it was the world's largest producer of aquaculture products, producing 91 billion pounds of seafood—roughly 70 percent of the world's total seafood output for that year.[18] In 2007, the volume of China's seafood exports declined to 72 billion pounds because, due to excessive levels of chemical contaminants, a number of countries rejected its products. China's industrial development, which has required heavy use of natural resources, has led to significant environmental degradation; more than 90 percent of China's urban-area rivers are polluted.[19] China's processing companies and power plants have caused significant air, land, and water pollution. This affects aquaculture farms, which are heavily dependent on inland waters for fish farms.

Chinese fish farms are largely family-run operations that sell fish to larger production facilities, which in turn export the products.[20] China's widespread environmental pollution, including water pollution, has created serious problems for the country's farmers. China's water pollution issues result from "industrial and urban sewage," inadequate quality control systems, use of illegal chemicals to fight fish diseases, and poor regulatory enforcement. Water pollution in China

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[15] Fengxia Dong, & Jensen, H. H "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures," *Choices; The Magazine of Food, Farm, and Resource Issues* 2007.

[16] Linden Ellis and Jennifer Turner, "Sowing the Seeds: Opportunities for U.S.-China Cooperation on Food Safety," The Woodrow Wilson International Center for Scholars, http://www.wilsoncenter.org/topics/pubs/CEF_food_safety_text.pdf.

[17] Energy Information Administration, "International Energy Outlook," in *Official Energy Statistics from the U.S. Government* (2009).

[18] Linden Ellis and Jennifer Turner, "Sowing the Seeds: Opportunities for U.S.-China Cooperation on Food Safety."

[19] Wenran Jiang, "Impacts of China's Development Model on Food Safety," in *Food Import Safety: Systems, Infrastructure and Governance* (University of Wisconsin, Madison: 2009).

[20] Dan Shapley, "Seafood Imports Halted," The Daily Green, http://www.thedailygreen.com/healthy-eating/eat-safe/3088.

negatively affects the safety and quality of food produced by Chinese farmers. China also has poor regulatory enforcement so that farmers "have little means or incentives to maintain high standards."[21] Speaking to journalists at an interview with the *International Herald Tribune*, an official with the Chinese Ministry of Agriculture acknowledged the serious pollution and water quality problems facing Chinese farmers. "Water quality is the top issue for Chinese aquaculture," said Ding Xiaoming, the director of Aquaculture and Fisheries Bureau. "Without good water quality, Chinese aquaculture cannot develop."[22]

Poor disposal techniques for sewage and chemical waste can result in contamination of feeding grounds for fish. Fish products harvested from contaminated feeding grounds present serious health hazards to consumers. Dr. Beveridge, in his study *Aquaculture and the Environment,* explored the relationship between the demand for environmental goods and the impact of those goods upon the environment. Aquaculture is carried out in ecologically open regions and is highly dependent upon environmental resources. An increase in demand for environmental resources negatively impacts the environment.[23] In China, like in many other countries, inland aquaculture requires the use of local surface or ground water. The resulting waste—food remains and fecal matter—is confined to the ponds (except during harvesting). This accumulation of waste degrades the water quality in the fish ponds, resulting in rapid growth and multiplication of bacteria and other pathogenic microorganisms. An ecosystem is a self-regulating entity in which any deviation from the norm is met by corrective measures that return the system to its norms.[24] If the system is unable to correct an abnormality, it becomes unstable.[25] Rapid accumulation of waste, multiplication of bacteria, and multiplication of other pathogenic organisms in aquaculture farms require external intervention to correct the systems. The external intervention is, in some cases, carried out using

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[21] Ibid.

[22] David Barboza, "China Says Its Seafood Is Safer," http://www.iht.com/articles/2008/01/18/business/17cndfish.php.

[23] Beveridge, "Aquaculture and the Environment: The Supply of and Demand for Environmental Goods and Services by Asian Aquaculture and the Implications for Sustainability," in *Aquaculture Research* (The Institute of Aquaculture, University of Stirling, United Kingdom, 1997).

[24] S. L. Pimm, "The Complexity and Stability of Ecosystems," *Nature* 307, no. 5949 (1984).

[25] Ibid.

unapproved chemicals.[26] Overcrowded fishponds contaminated by sewage, agricultural runoff, and industrial chemicals often result in fish diseases, causing some Chinese farmers to resort to illegal veterinary drugs to keep the fish alive.[27] Some of the aquaculture chemicals used in this process have carcinogenic and mutagenic properties.[28] Several importing countries, including the U.S., have raised complaints regarding the quality of Chinese seafood. In the past, Japan and the European Union (EU) have banned seafood imports from China due to excessive residues of unapproved chemicals.[29]

The sources of food safety problems in the Chinese aquaculture industry cannot be properly understood without an appreciation for the relationship between food safety and the environment. One reason behind the use of antimicrobial chemicals in Chinese aquaculture is poor environmental waste management. Poor management of aquaculture farms, poor disposal of industrial waste, and poor disposal of sewage wastes all result in the contamination of fishponds. The occasional use of unapproved veterinary drugs by Chinese aquaculture farmers represents an effort to resolve the problems that have risen from poor environmental waste management.[30] The safety of Chinese aquaculture products is further complicated by counterfeiting that has spread across every sector of the country's economy. The integration of world markets has resulted in an unprecedented increase in cases of intellectual property violations.[31] The international community has singled out China as the leading violator of intellectual property rights (IPR). In 2004, goods from China accounted for 54 percent of all goods seized for violation of IPR by EU customs authorities. In 2005, 65 percent of all

[26] Widespread use of unapproved aquaculture chemicals among some Chinese farmers has been widely reported in the media. Rick Weiss, "Tainted Chinese Imports Common," Washington Post, http://www.washingtonpost.com/wp-dyn/content/article/2007/05/19/AR2007051901273_pf.html.

[27] Ibid.

[28] Murray M. Lumpkin, "Statement of Murray M. Lumpkin, M.D. Deputy Commissioner for International and Special Program before Committee on Commerce, Science, and Transportation; United States Senate."

[29] Barboza, "China Says Its Seafood Is Safer."

[30] L. Cao, "Environmental Impact of Aquaculture and Countermeasures to Aquaculture Pollution in China," *Environmetal science and pollution research international* 14, no. 7 (2007).

[31] Terence P. et al., "The Crisis in Intellectual Property Protection and China's Role in That Crisis," 2007.

goods seized by U.S. Customs and Border Protection (CBP) officials for IPR infringement originated from China, and in 2006, the number increased to 81 percent.[32]

China's counterfeiting companies are thriving as a result of their ability to produce highly sophisticated product replicas. According to Terence Stewart, a trade lawyers' advisory group, "Chinese companies not only manufacture copies of branded products, but also duplicate anti-theft devices used by companies to protect their innovations, such as holograms, which are devices commonly used for security protection."[33] China has one of the most sophisticated hologram manufacturing industries in the world, and also excels at copying packaging designs and security inks that distinguish genuine products from fake ones. They have the "technical skill and equipment to copy almost anything and everything produced anywhere in the world, including the most protective deterrent and detection products."[34]

The counterfeiting of agricultural inputs—specifically, the replacement of approved aquaculture chemicals with cheap, unapproved alternatives—has created problems for Chinese aquaculture farmers in international markets. According to *Xinhua*, the Chinese state news agency, China uses about 1.2 million tons of pesticides on approximately 300 million hectares of farmland.[35] Official statistics from Chinese agencies show that "the country produces about 300 types of pesticides and about 800 additional pesticide mixtures."[36] An estimated 20 to 40 percent of all pesticides and chemicals produced in China are counterfeits.[37] In 2005, China produced around 1.04 million tons of pesticides, of which only 428,000 tons were exported.[38] According to *Xinhua*, the pesticide system is so complicated that "even agricultural experts are hardly able to identify the

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[32] Peggy E. Chaudhry, "Changing Levels of Intellectual Property Rights Protection for Global Firms: A Synopsis of Recent U.S. And EU Trade Enforcement Strategies," *Business Horizons* 49, no. 6 (2006).

[33] Terence P. et al., "The Crisis in Intellectual Property Protection and China's Role in That Crisis." 2007, Pg 15.

[34] Chaudhry, "Changing Levels of Intellectual Property Rights Protection for Global Firms: A Synopsis of Recent U.S. And EU Trade Enforcement Strategies." Pg. 465

[35] Li Zijun, "Soil Quality Deteriorating in China, Threatening Public Health and Ecosystems," http://www.worldwatch.org/node/4419.

[36] Yang Yang, "Pesticides and Environmental Health Trends in China," Woodrow Wilson International Center for Scholars http://www.wilsoncenter.org/index.cfm?topic_id=1421&fuseaction=topics.item&news_id=225756.

[37] Ibid.

[38] ———, "Pesticides and Environmental Health Trends in China," Woodrow Wilson International Center for Scholars http://www.wilsoncenter.org/index.cfm?topic_id=1421&fuseaction=topics.item&news_id=225756.

actual product."[39] An estimated 30 percent of all pesticides consumed with food in China are highly toxic.[40] Every year, between 53,300 and 123,000 Chinese consumers are poisoned by pesticides.[41] This problem started in the early 1980s, when Chinese agricultural and local government officials started advocating the use of chemical fertilizers and pesticides to improve yields; the officials received incentives for promoting the use of fertilizers and pesticides. This resulted in a decrease in the use of human and animal waste on farmland. In an effort to increase their farms' productivity, many Chinese farmers have begun to use pesticides in excess; this is partly because they lack education on proper application procedures and partly because they are unsure as to the authenticity of their chemicals and fertilizers. In some cases, unsuspecting farmers buy counterfeit fish medication and use it on their fish farms. The counterfeit medication may contain anything from toxic chemicals to carcinogenic substances, and some of the chemicals lack the active ingredients necessary to treat the fish.[42] This has resulted in increased use of different chemicals. According to the 2004 *China Marine Environment Report*, about 2.48 million tons of pesticides flow into China's Zhu River each year.[43] This has seriously polluted other tributary rivers and coastal waters in the province of Guangdong.[44] When used in fish farms, the chemicals contaminate the feeding grounds for fish; moreover, some chemicals accumulate and remain in fish for a long time, and they eventually enter the food chain.[45] Approximately 7 percent of China's arable farmland is heavily polluted because of excessive use of chemicals and fertilizers. Agricultural chemicals and fertilizer runoff pollute rivers and coastal regions. Aquaculture operations also face problems from industrial

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[39] Xinhua News Agency, "China to Standardize Naming of Pesticides," http://news.xinhuanet.com/english/2007-12/19/content_7281443.htm.

[40] Organic Consumers Association, "Pesticide Residues a Major Threat to China's Agricultural Exports," http://www.organicconsumers.org/toxic/chinapesticides012103.cfm.

[41] Ibid.

[42] Ibid.

[43] Y. Wang, "Environmental Degradation and Environmental Threats in China," *Environmental monitoring and assessment* 90, no. 1-3 (2004).

[44] Yang Yang, "Pesticides and Environmental Health Trends in China."

[45] Wang, "Environmental Degradation and Environmental Threats in China."

pollution. Industrial pollution is a significant threat to aquaculture operations, as some factories dump effluent directly into waterways used to irrigate crops and raise farmed fish.[46]

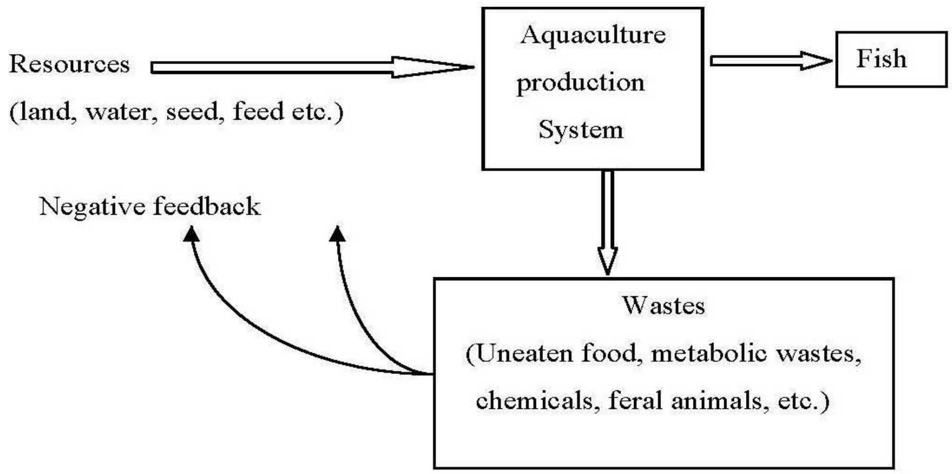

Figure 1.1 Aquaculture system and environmental demands.[47]

As mentioned earlier, the detection of unapproved antimicrobial chemicals in Chinese aquaculture products has resulted in bans on Chinese aquaculture imports in Japan and the EU. While Chinese authorities have made efforts to address these food safety problems, one major setback has been the structure of the Chinese regulatory system. The structure of China's regulatory system is such that there is an overlap between 13 ministries in charge of domestic food safety. According to Daoghang, the Vice Director of China's Ministry of Science and Technology's National Center for Biotechnology Development, this overlap of diverse ministries "result[s] in finger-pointing and turf battles when problems arise."[48] There are large numbers of small-scale Chinese agricultural producers, making it difficult for the government to regulate every aspect of production. The county's ability to protect the quality of its food production has also been held back by its weak legal, political, and regulatory infrastructure, its policies of economic protectionism

[46] Zamiska, Nicholas, and Spencer. J, "China Faces a New Worry: Heavy Metals in the Food," *Wall Street Journal,* http://www.freerepublic.com/focus/f-news/1865683/posts.

[47] Adapted from: Beveridge, "Aquaculture and the Environment: The Supply of and Demand for Environmental Goods and Services by Asian Aquaculture and the Implications for Sustainability."

[48] Linden Ellis and Jennifer Turner, "Food Safety: Where We Stand in China," Woodrow Wilson International Center for Scholars, http://www.wilsoncenter.org/index.cfm?fuseaction=events.event_summary&event_id=329237.

which aggressively safeguard local industries, its poor enforcement of existing food safety laws, and its lack of product liability laws. The country has also been held back by its failure to successfully monitor the large quantities of food products being produced by its multitude of industries and farms involved in food processing and international trade. China also has limited independence in the judicial system, making it difficult to protect "whistleblowers."[49]

While market liberalization has led to an increase in the volume of food imported by the U.S., it has also given rise to concerns regarding the safety of internationally traded foods and drugs. China is the leading supplier of seafood, garlic, and apple juice concentrate to the U.S.[50] According to Dr. Michael Doyle, the director for the Center for Food Safety at the University of Georgia, "China has gone from literally nowhere to [number 3] in food imports behind Canada and Mexico…. if [the U.S.] is going to continue to import more and more of [their] food, [they need] to have a better inspection program."[51] The volume of Chinese exports increased significantly following China's full-membership admission to the World Trade Organization (WTO) on December 11, 2001; by 2004, China's agricultural export values exceeded US$17.3 billion.[52] The Chinese agricultural industry is large, comprising more than 700 million small-scale and large-scale farms spread across the country.[53] Although there are different systems of production—some focused on export processing, others focused on domestically consumed goods—it is difficult to keep the two apart in the national supply chain. This makes it difficult for the central and local governments to facilitate, coordinate, and support the effective implementation of food safety regulations.[54] Chinese aquaculture exports have often failed to pass sanitary and phytosanitary (SPS) inspections. This is partly due to laxity on the part of food safety regulators and partly due to the inability of the government to enforce SPS and GMP regulations.[55] As many Chinese farmers are more driven by profit margins than they are by a desire to produce quality products, many have begun to replace

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[49] ———, "Sowing the Seeds: Opportunities for U.S.-China Cooperation on Food Safety."

[50] David Barboza, "Limit on China Seafood Has Global Overtones," *New York Times*, July 3 2007.

[51] Ibid. Pg 1.

[52] Fengxia Dong, Helen H Jensen, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures," *Choices; The Magazine of Food, Farm, and Resource Issues*, March 20, 2009 2007.

[53] Ibid.

[54] Ibid.

[55] Dong, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures."

high-quality food and drugs with lower-priced, unsafe substitutes.[56] In 2009, a GAO study reported cases of mislabeled shrimp imports. In one case, single packages of frozen shrimp sported two different country-of-origin labels. In another case, cheap fish were being sold as more expensive species.[57] There is also extensive misuse of agricultural chemicals and fertilizers among Chinese farmers.[58]

U.S. consumers rely on the FDA to protect them from the hazards of unsafe food and drug imports. The FDA protects consumers through various means. Inspections ensure that the minimum SPS requirements for imports are met. Risk assessment enables countries to set maximum residue limits (MRLs) for various pesticides and chemical contaminants in food. Regulations on maximum residue limits of chemicals in food are set in accordance with the WTO's *Agreement on the Application of Sanitary and Phytosanitary Measures.* The Codex Alimentarius Commission (Codex)—the international standard-setting body for food safety—has more than 2,500 MRLs for pesticide residues in food. The EU has more than 22,000 MRLs, while the U.S. has about 8,600.[59] In comparison, China has about 484 MRLs for pesticides, of which less than 20 percent conform to Codex levels.[60] Although many developed countries have strict inspection programs for food imports to ensure they conform to SPS requirements, the Chinese government has been reluctant in developing and enforcing SPS and GMP measures in the food industry. Due to China's status as the world's leading food exporter, this laxity in developing and enforcing food safety standards has contributed to significant food safety problems in international markets.[61] In summary, there are several sources of problems in the Chinese aquaculture industry. The table below shows a summary of the problems.

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[56] The House Energy Committee and Commerce Committee's Oversight and Investigation Subcommittee, *Testimony of William Hubbard, Senior Advisor, Coalition for Stronger FDA*, April 22 2008.

[57] Elizabeth Weise, "GAO Study: Fraudulent Fish Easily Slip into Food Stream," usatoday.com, http://www.usatoday.com/money/industries/food/2009-03-22-fish-fraud_N.htm.

[58] Fengxia Dong, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures."

[59] Dong, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures."

[60] Fengxia Dong, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures."

[61] Organic Consumers Association, "Pesticide Residues a Major Threat to China's Agricultural Exports."

Table 1.2 Sources of food safety problems in China's aquaculture industry

• Complex regulatory system. • Poor environmental waste management. • Excessive use of agricultural chemicals such as fertilizers, pesticides, veterinary drugs, etc. • Counterfeits resulting from replacement with low-priced unsafe food and drug ingredients. • Laxity of the Chinese government in developing and enforcing SPS and GMP measures in food industries. • Large number of Chinese agricultural producers, making it difficult for regulatory authorities to oversee important aspects of production.

Steps Taken By the U.S. and Chinese Regulatory Authorities

China monitors its food safety and consumption trends in two major ways: through the Nationwide Food Contamination Monitoring Network (NFCMN), as well as through the Total Dietary Study (TDS), the latter of which is similar to the U.S. National Health and Nutrition Examination Survey (NHANES). The NFCMN operates in 17 provinces and is mainly concerned with monitoring levels of contaminants, with the aim of early detection for emergency response. China has made serious efforts to collect reliable data on food safety, and it conducted its first health census in 2002. China's national survey on diets and health status, which is done every 10 years, involves taking samples from 132 regions in 31 provinces across the country. During the survey, physical examinations, laboratory tests, and household dietary studies are conducted. This is to assess the exposure of regional populations to contaminants.[62]

Regulatory officials in Japan, the U.S., and a number of EU countries have occasionally found Chinese food exports to contain unapproved chemicals or approved chemicals at concentrations above the importing countries' maximum residue limits. A large percentage of Chinese aquaculture exports to the U.S., the EU, and Japan were rejected in 2007 due to excessive levels of unapproved antimicrobial residues. This resulted in an Import Alert on Chinese aquaculture and seafood, issued by the FDA in 2007.[63] The Chinese government has, according to some, been swift and firm in its action against farmers suspected of using unapproved drugs. In its efforts to

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[62] Ellis and Turner, "Food Safety: Where We Stand in China."

[63] Food and Drug Administration, "FDA Detains Imports of Farm-Raised Chinese Seafood " *Food and Drug Administration News* (2007).

secure the safety of its nation's food, the government faces difficulties in constantly inspecting small-scale Chinese farmers. This is due to the large numbers and the wide geographical distribution of fish farms, as well as to ongoing problems with government-level corruption and deceit. During an effort to rein in the aquaculture industry, the Chinese government blacklisted several seafood processors and the revoked licenses of companies found to have exported food tainted with illegal drugs or banned substances.[64] Chinese authorities also closed down shoddy aquaculture operations and tightened regulations against the use of banned antibiotics in aquaculture. The Chinese government has also begun to pursue policies that encourage consolidation and standardization of farms, and the government has adopted new policies such as:[65]

a. Establishment of mechanisms to enable the traceability of products, including the use of farm records and third-party certifiers;
b. A ban on the use of toxic and unapproved chemicals in food;
c. The blacklisting of several seafood processors and revocation of licenses of companies found to be exporting food tainted with illegal drugs or banned substances;
d. The establishment of end-product testing for residues of unapproved chemicals and drugs; and
e. The drafting of new food laws such as: *The Food Hygiene Law* and the *Food Safety Law*, drafted by the Ministry of Health; and the *Law of Quality and Safety for Agricultural Products*, drafted by the Ministry of Agriculture.

The *Food Safety Law*, submitted to the People's Republic of China's legislative body in 2007, clarified specific responsibilities of government bureaus at all levels. The aim was to ensure no overlap in responsibility of different bureaus dealing with food safety issues while also fostering a culture of internal accountability. The new laws specified that the responsibility for food safety rested with the government's Ministry of Health, and it instituted higher fines for violators as well as penalties for officials who failed to enforce the laws. The laws authorized the web-posting of important food safety issues on which the public could provide feedback.

The U.S., meanwhile, boasts a multi-agency (and, admittedly, complicated) network of agencies responsible for food policy, including food safety and trade policy. The United States

[64] Barboza, "China Says Its Seafood Is Safer."

[65] Ellis and Turner, "Food Safety: Where We Stand in China."

Department of Agriculture (USDA) is the U.S. federal executive department responsible for developing and executing policies on farming, agriculture, and food; it aims to promote agricultural production, commerce, meat and poultry product safety, natural resource protection, and hunger elimination both in the U.S. and abroad.[66] The FDA, which is under the Department of Health and Human Services, is responsible for ensuring the safety of food and medical products consumed in the U.S. The USDA FSIS and the FDA work together with state and local authorities to carry out in-plant inspections that focus on product safety, food plant hygiene, economic fraud, etc., to ensure that they conform to regulatory production standards. The two agencies have a hard task of ensuring that sufficient, wholesome, and safe food is available to consumers. This section of the dissertation examines some of the weaknesses in this regulatory infrastructure that compromise the effectiveness of import regulations. It also examines other steps taken by the U.S. government to protect consumers from hazards in imported food.

Under the 2002 *Public Health Security and Bioterrorism Preparedness and Response Act* (Bioterrorism Act), the USDA (through the FSIS) and the FDA are responsible for protecting consumers from intentional and unintentional contamination of food. They work closely with state and local authorities, food industries, and importers to ensure that every step of the food supply continuum is monitored from farm to the table. Under the *Federal Meat Inspection Act*, the *Poultry Product Inspection Act*, and the *Egg Products Act*, the USDA, through the FSIS, is responsible for the safety of the country's meat, meat products, poultry, and certain eggs. The FDA is responsible for scrutinizing the safety of most food and medical products consumed in the U.S. They work closely with state and local regulatory agencies to carry out in-plant inspections to ensure regulatory compliance. Another agency—the National Marine Fisheries Service (NMFS) in the Department of Commerce—conducts voluntary, fee-for-service inspections of seafood. The Environmental Protection Agency (EPA) regulates the use of pesticides and establishes their maximum residue levels (MRLs) on food and animal feed.[67] The FDA maintains a database of foods being imported;

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[66] United States Department of Agriculture "Mission Statement," The United States Department of Agriculture, http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB/.cmd/ad/.ar/sa.retrievecontent/.c/6_2_1UH/.ce/7_2_5JN/.p/5_2_4TR/.d/0/_th/J_2_9D/_s.7_0_A/7_0_1OB?PC_7_2_5JN_navid=MISSION_STATEMENT&PC_7_2_5JN_navtype=RT&PC_7_2_5JN_parentnav=ABOUT_USDA#7_2_5JN.

[67] GAO, "The Fda's Food Protection Plan Proposes Positive First Steps but Capacity to Carry Them out Is Critical," in *Federal Oversight of Food Safety* (United States Government Accountability Office, 2008).

from this database, it selects those that are to be singled out and sampled for laboratory analysis. Selection of samples is based on an evaluation of the hazards associated with the product and their likelihood of occurrence. Analyses include, but are not limited to, checks for hazards such as pathogens and checks for residues of banned substances such as veterinary drugs, chemicals, pesticides, toxins, unapproved food additives, et cetera.[68] Courtesy of the Bioterrorism Act of 2002, the FDA is now authorized to detain shipments of suspicious food imports at U.S. ports of entry until they are tested and cleared for consumption. The agency can also refuse to allow contaminated food or drugs to enter the country. The FDA conducts periodic inspection of food processing facilities in the U.S. to ensure that they comply with regulations; however, this is not always the case with foreign food processing facilities whose products are sold within the U.S. A 2008 GAO report noted a significant increase in sampling and testing of seafood by the FDA, from less than 1 percent in 1999 to 1.2 percent in 2002. This indicates increased efforts by the FDA to ensure the safety of imported seafood.[69]

The FDA and the FSIS developed a Hazard Analysis and Critical Control Point (HACCP) procedure for mitigating risks which may arise from food contaminated by toxic chemicals or infectious agents.[70] To ensure the safety of food imports, foreign food processors are often required by the FDA to provide inspection reports. This may be from third party agencies certifying that products offered for import have undergone inspections and conform to regulations. Such an approach has its own challenges, as it is normally difficult to determine whether the scope of other countries' inspections meet the agencies' needs and standards.[71] In some cases, foreign inspection reports may not be available in English.

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[68] Food and Drug Administration, "How FDA Regulates Seafood," The U.S. Department of Health and Human Services, http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm106813.pdf.

[69] GAO, "The Fda's Food Protection Plan Proposes Positive First Steps but Capacity to Carry Them out Is Critical."

[70] U.S GAO, "Food Processing Security," in *Food Processing Security*, ed. The United States General Accounting Office (Washington, DC 20548: United States Senate, 2003).

[71] House Energy and Commerce Committee's Oversight and Investigations Subcommittee, *FDA Foreign Drug Inspection Program: Weaknesses Place Americans at Risk*, Testimony of MS Cross before the Senate House Energy and Commerce Committee's Oversight and Investigations Subcommittee on the FDA Foreign Drug Inspection Program: Weaknesses Place Americans at Risk, April 22, 2008.

The FDA often carries out inspections of foreign establishments that export food and drugs to the U.S. There are many foreign establishments that export food and drugs to the U.S., but the FDA has limited funding and limited manpower. This makes the inspection process difficult; with the FDA's current human resources, it would take 13 years to carry out a one-time inspection of all foreign establishments.[72] In the 2007 fiscal year, the U.S. government allocated US$10 million for foreign inspection services, and in the 2008 fiscal year, US$11 million was allocated for use in foreign inspections. These funds are far below what is needed to conduct sufficient inspection of foreign food and drug establishments. The FDA often conducts biennial inspections of U.S. food and drug establishments; a similar inspection schedule for foreign food and drug establishments would cost close to US$70 million per year.[73] FDA data shows that inspections of foreign food-processing facilities, which were about 190,000 in number, decreased from 211 in the 2001 fiscal year to fewer than 100 in the 2007 fiscal year. Insufficient funding was the major cause of this reduction in FDA inspections of foreign food facilities.[74] In the U.S., the FDA works with the Consumer Product Safety Commission (CPSC) to ensure that products available on the market are safe. The public relies on these two institutions to ensure that every product on the market is safe for consumption. However, while globalization has led to an increase in food and drug import volumes, these two agencies have experienced serious budget cutbacks. Meanwhile, the other major agency also responsible for protecting consumers from the hazards of imported goods—the U.S. Customs and Border Protection (CBP) agency—is not being fully utilized to address emerging threats to U.S. food safety and security.[75]

While the FDA has deployed many of its resources toward the protection of U.S. consumers, contaminated food imports often evade inspection nets. Currently, there are stiff penalties for U.S. producers who violate U.S. food safety rules and regulations. These may include forced withdrawal of products from the markets, resulting in financial losses, suspension of production licenses, and in some cases litigation. However, this is not always the case with violative imported products; importers whose products violate regulations know that it is unlikely they will be caught, and that in

[72] Ibid.

[73] Ibid.

[74] GAO, "The Fda's Food Protection Plan Proposes Positive First Steps but Capacity to Carry Them out Is Critical."

[75] Senate Finance, *Statement of Jean Halloran Director, Food Policy Initiatives Consumer Union on Import Health and Safety Standards*, Congressional Testimony, October 18, 2007.

the event that they are caught, they are unlikely to be punished.[76] Furthermore, some unscrupulous importers have taken additional steps to counterfeit safety labels, making it difficult to identify and isolate counterfeit products. While it is imperative that domestic producers conform to high standards of production and undergo regular GMP and HACCP inspections, foreign production facilities only worry about the possibility of inspectors intercepting their products at the ports of entry. Meanwhile, domestic producers who comply with regulations can still be penalized for using contaminated ingredients from other countries. Counterfeits have not been limited to products alone; globalization has led to integration of countries that have not historically had strong intellectual property protection philosophies. This has caused a re-emergence of problems associated with intellectual property rights. The quest to access lucrative international markets has resulted in desperate actions such as the counterfeiting of safety-related labels. One such instance occurred in 2008, when Chinese companies began to counterfeit the Underwriter's Laboratory logo.[77] Counterfeiting of consumer products is a serious problem in international trade; it can result in serious injury or potential death of consumers who buy defective or contaminated products.[78] In 2005, EU customs officials seized more than 75 million counterfeit and pirated goods, of which more than 5 million were counterfeit foodstuffs, drinks, and alcohol products.[79] Counterfeit goods can undermine consumer confidence in the safety of branded products, leading to a loss of market shares. The wide range of counterfeit and pirated products not only costs businesses billions of dollars in lost sales, but also costs governments losses in tax revenues from legitimate sales.[80] Violation of intellectual property rights causes the loss of millions of jobs, damages the reputation of businesses whose products have been counterfeited, and can harm consumers.[81] Other losses include bad product reputation, potential liability arising from counterfeit goods, and expenses incurred in

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[76] *Testimony of William Hubbard, Senior Advisor, Coalition for Stronger FDA*.

[77] Chaudhry, "Changing Levels of Intellectual Property Rights Protection for Global Firms: A Synopsis of Recent U.S. And EU Trade Enforcement Strategies."

[78] Ibid.

[79] meatprocess.com, "Counterfeit Food a 'Serious Threat' Says Ec," http://www.meatprocess.com/news/printNewsBis.asp?id=72010.

[80] Terence P. et al., "The Crisis in Intellectual Property Protection and China's Role in That Crisis." 2007, 10-15.

[81] Chaudhry, "Changing Levels of Intellectual Property Rights Protection for Global Firms: A Synopsis of Recent U.S. And EU Trade Enforcement Strategies."

the process of trying to remove counterfeit products from the market.[82] Companies are occasionally forced to defend themselves in lawsuits stemming from counterfeit products, attempting to prove that the faulty product is not, in fact, theirs. Counterfeiting within the food industry does not simply undermine the basis of product innovation; it also has the potential to cause serious public health problems. Food industry counterfeiting may take place in the form of low-quality, unsafe foods being labeled with the seals of companies whose products are historically known to be safe. In 2009, the Government Accountability Office (GAO) reported increasing instances of cheap fish being sold as more expensive species.[83] In certain cases, low quality fish imports were being shipped to the U.S. through third-party countries whose products were not on Import Alert.[84] In doing so, the imports effectively escaped screening at the ports of entry.[85] Some seafood consumers have reported suspicious instances where their purchases had different country of origin labels on them.[86]

In 2007, the U.S. food market registered an increase in reported cases of contaminated Chinese seafood and aquaculture imports. This increase caused the FDA to issue an Import Alert on Chinese aquaculture and seafood imports. In a press statement following the announcement of the Import Alert, Dr. Robert Brackett, the director for the FDA Center for Food Safety and Applied Nutrition, said:

> *"The levels of contaminants that have been found are very low, and FDA is not advising consumers to destroy or return farm-raised seafood that they may have already purchased and have in their homes. The agency is not seeking a recall of products already in the marketplace."*[87]

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[82] Kong Qingjiang, "The Judicial Enforcement of Intellectual Property Rights in China: On the Eve of WTO Accession," *The Journal of World Intellectual Property* 4, no. 6 (2001).

[83] GAO, "Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention," in *Report to the Ranking Member, Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard, Committee on Commerce, Science, and Transportation* (U.S. Senate, 2009).

[84] Elizabeth Weise, "GAO Study: Fraudulent Fish Easily Slip into Food Stream."

[85] Ibid.

[86] Ibid.

[87] Food and Drug Administration, "How FDA Regulates Seafood." Pg 1.

The FDA issued an Import Alert as a precaution to eliminate problems that could potentially result from extended exposure to hazardous chemical residues in food.[88] This was not the first time that products from China had been put on Import Alert. The U.S. regulatory authorities have dealt with many cases, for example, including instances of contaminated toothpaste, contaminated pet food, unsafe children's toys, et cetera. On July 1, 2007, President Bush issued an executive order establishing an Interagency Working Group on Import Safety to enhance import safety. The group was charged with the responsibility of reviewing import safety problems and making recommendations for actions to address them. Speaking at a press conference on November 6, 2007, the President said,

> *"Today the working group presented me with 14 recommendations for areas where we can begin implementing such an approach… For example, we will establish new incentives for importers that follow strong safety practices and demonstrate a good track record. We will increase our training of inspectors in foreign countries, so they can stop dangerous goods at their boarders instead of ours. We will work for higher and more uniform standards for high-risk foods and consumer goods. And we will work to increase penalty for those who violate the U.S. import laws and regulations."*[89]

In the report to the President, the FDA unveiled a *Food Protection Plan* addressing both imported and locally produced food. The plan aimed at increasing the capacity of the FDA to coordinate with other federal agencies in protecting the U.S. food supply chain, preventing safety problems from arising, responding effectively if problems do arise, and facilitating communication with importers and the public. The action plan for import safety developed by the Interagency Working Group contained 50 action steps that provided a road map for improved consumer protection. The action plan provided a means for enhancing the safety of the increasing volume of imports into the country. The plan proposed a strategy for risk-based prevention and provided a verification model for allocating import safety resources based on risks.[90] It also recommended steps

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[88] Ibid.

[89] President Bush, "Import Safety Action Plan: Increasing Protection of American Consumers " http://www.importsafety.gov/report/actionplan.pdf. Pg. 1.

[90] The Interagency Working Group on Import Safety, "Action Plan for Import Safety: A Roadmap for Continual Improvement.," (Department of Health and Human Services, Department of State, Department of Treasury, Department

to replace current "snapshot" safety inspections done at the borders with cheaper inspection alternatives. The new model would increase the impact of inspections by identifying and targeting those points posing the greatest risks and directing resources to those areas. This new proposed approach to managing safety problems associated with imports would be instrumental in preventing contaminated products from reaching consumers. Below is a summary of the recommendations made by the Interagency Working Group:[91]

a. Authorize the FDA to require producers of high-risk foods from certain countries to certify that their products conform to regulations;
b. Introduce a system of voluntary certification for foreign manufacturers so that U.S. inspectors can quickly clear products from certified importers;
c. Provide incentives to importers who uphold higher safety practices for high-risk products;
d. Establish information sharing agreements with foreign governments to facilitate the timely exchange of import- and recall-related data;
e. Publicize names of certified producers and importers in order to increase transparency and thus allow consumers and distributors to make informed decisions on the safety of products;
f. Require the FDA to recall adulterated or contaminated products from the market;
g. Establish agreements with foreign countries in which the FDA can certify equivalency of food safety standards, thus shifting some of the FDA's inspection burdens to foreign governments wishing to export food to the U.S.;
h. Explore the possibility of certifying third-party inspectors who would conduct inspections on behalf of the FDA in foreign and domestic food processing facilities;
i. Consider accrediting private laboratories to conduct testing on seafood; and
j. Consider entering into an agreement with the National Oceanic and Atmospheric Administration (NOAA) in which the NOAA uses its resources to conduct seafood inspections on behalf of the FDA.

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of Justice, Department of Agriculture, Department of Commerce, Department of Transportation, Department of Homeland Security, Office of Management and Budget, United States Trade Representative, Environmental Protection Agency, and Consumer Product Safety Commission, 2007).

[91] Ibid.

The report stressed the value of increasing the presence of U.S. inspectors in foreign countries, enhancing standards of inspection, and strengthening penalties for violators. Overseas inspectors would work with foreign governments to train and enhance the capacity of foreign inspection agencies; this effort would be a good model of cross-border cooperation. This would ensure international conformity with U.S. safety standards and reduce the inspection workload at U.S. ports of entry. The report recommended that inspection agencies be given the capacity to enhance their standards by taking industry best practices into consideration. This would enable the agencies to use the knowledge and understanding of those who best know how the products are made. As for the federal government, the report recommended the institution of stronger penalties for those who violate import laws and incentives for those who comply with the laws and regulations.[92]

The Interagency Working Group presented President Bush with a strategic framework detailing immediate steps to be taken by federal agencies in order to speed up their participation in a computerized "single window system" for electronically reporting imports. This would facilitate the exchange of information among and between U.S. governmental agencies and exporting countries. The working group's action plan also recommended that the FDA be given the authority to recall adulterated or contaminated products in cases where the affected food posed a significant threat to life. Such authority would be especially valuable in cases where implicated firms refused to carry out voluntary product recalls.[93] Historically, the FDA has encouraged companies to conduct voluntary recalls; the FDA had no legal powers to withdraw defective products from the market. However, the new recommendations by the Interagency Working Group on Import Safety gave the FDA more powers and a legal basis to protect consumers. While the U.S. government has given various federal agencies the task of protecting consumers from hazards in imports and locally produced goods, "the primary budget-related question faced by Congress is how to fund the agency sufficiently for it to

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[92] Sections of this thesis have been published in the *Journal of Environmental Health*: "United States Import Safety, Environmental Health, and Food Safety Regulation in China" by Edward Nyambok and Justin Kastner (January 2012).

[93] The Interagency Working Group on Import Safety, "Action Plan for Import Safety: A Roadmap for Continual Improvement.."

carry out its responsibilities, while also funding competing national needs, and ensuring that the agency operates cost-effectively."[94]

With imports increasingly accounting for a significant proportion of products consumed in the U.S., the U.S. government has established a number of laws, regulations, and institutions to protect consumers. The question of how effective those institutions and regulations are, however, has long lingered in the minds of policy formulators and food safety regulators. The dilemma the FDA now faces is the question of how best to give people access to useful products while protecting them from unsafe ones.[95] While creating too many regulations raises costs and prevents products from reaching consumers, creating too few regulations places consumers at risk. In 2007, the FDA inspected less than 0.6 percent of the total food it regulated at the ports of entry. These included fruits, vegetables, grains, seafood, dairy products, and animal feed. In 2006, 1.93 percent of all U.S. seafood imports were inspected at ports of entry.[96] When imported goods are on Import Alert, the FDA detains the goods until they are proven to meet certain minimum requirements. Goods on Import Alert are considered to be "guilty until proven innocent." The burden of proof normally lies with the importer, who provides laboratory reports and other required materials to confirm that their goods have undergone testing and are fit for human consumption. The FDA also verifies the safety of imported products by conducting tests in its labs. The volume of food shipments coming into the U.S. is very high; while the FDA operates about 450 budgeted positions involved with import screening, an estimated 20 million shipments of food and medical supplies arrive at U.S. ports of entry annually.[97] Resources that are allocated to the FDA for inspections are often insufficient and thus the FDA is unable to meet the minimum inspection levels necessary to protect the public from unsafe imports. In addition to the physical screening and the laboratory screening, the FDA also maintains a large database that details the contents and the country-of-origin of different kinds of shipments coming into the country. The "prior notice" import regulation requires importers to furnish the agency with this kind of information at least 48 hours before the goods arrive at a U.S.

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[94] CRS, "Food and Drug Administration (FDA): Overview and Issues," in *CRS Report for Congress* (U.S. Library of Congress, 2008). Pg 4.

[95] Ibid.

[96] Bottari et al., "Trade Deficit in Food Safety: Proposed Nafta Expansions Contribute to Unsafe Food Imports."

[97] Associated Press, "Experts Question the Fda's Ability to Police Safety of Imported Food," http://www.msnbc.msn.com/id/20163930/.

port of entry. This enables the FDA inspectors to facilitate clearance of products that are not on the watch list. During screening, inspectors go through hundreds of shipments that flash across computer screens each day, isolating those shipments that are on the watch list for further inspection. As the FDA relies heavily on information provided by importers and other regulators to isolate violative shipments, there are various ways for importers to escape the screening of their goods at the ports. A shipment can easily avoid inspection if its sender uses a name and address that is different from the one on the Import Alert. Importers can also circumvent inspection nets by importing products through third-party countries whose products are not on the Import Alert.[98] In 2008, the Associated Press (AP) published a finding that reviewed the effectiveness of an Import Alert issued to protect consumers from contaminated Chinese seafood. In their study of 4,300 manifests of seafood shipments from China, they found that by Spring 2008, 211 import shipments had arrived at U.S. ports of entry. This occurred after an Import Alert was issued in the fall of 2007. When contacted, the FDA was not willing to disclose which shipments had been inspected and which had not. The AP then contacted 15 companies responsible for 112 of the total 211 shipments received. Eleven of the companies confirmed that their products had undergone testing, and the remaining four denied that their products had undergone inspections or testing. According to the four companies that had not been inspected,

> *"the FDA did not bother to stop a total of 28 shipments weighing 1.1 million pounds. Virtually all the shipments entered through ports in the Southeast such as Tampa, FL; Savannah, GA; Norfolk, VA; and Miami, FL."*[99]

The importer with most cases of uninspected imports was the firm Tampa Bay Fisheries in Florida.[100] From such occurrences, it is clear that however diligently the regulatory authorities try to address food import safety concerns, many contaminated food products still find their way through to the tables of consumers.[101]

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[98] Elizabeth Weise, "GAO Study: Fraudulent Fish Easily Slip into Food Stream."

[99] Ibid.

[100] Associated Press, "Experts Question the Fda's Ability to Police Safety of Imported Food."

[101] G.A.O, "Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food," in *Food Safety* (Report to Congressional Committees, 2009).

In summary, this dissertation identifies several factors contributing to environmental and food safety problems in China's aquaculture industry. These factors included: (a) poor environmental and waste management practices by the wider industrial sector in China; (b) improper aquaculture farm management practices; (c) excessive application of agricultural chemicals and fertilizers, leading to contamination of water bodies used for aquaculture operations; (d) pervasive operation of counterfeiting enterprises, resulting in the frequent substitution of toxic chemicals and/or ineffective substances for genuine aquaculture chemicals (a problem further compounded by the inability of farmers to distinguish fake chemicals from genuine ones); (e) a lack of education regarding proper chemical application procedures for aquaculture farms; (f) lack of product liability laws; (g) laxity on the part of government and food safety regulators to develop and enforce food safety regulations and monitor regulatory compliance; and (h) a weak civil-society and judiciary system hindering the pursuit and prosecution of violators.

Meanwhile, the U.S. has pursued policies to protect itself from the stream of contaminated imports continuously showing up at its borders. The U.S. is currently pursuing new inspection approaches that involve "pushing the borders back" and establishing systems to prevent contaminated shipments from reaching U.S. ports. This inspection approach involves working with foreign countries' governments (including China's) to ensure that food products exported from those countries are inspected and certified before being shipped to the U.S. This inspection approach differs from traditional approaches in which products are only inspected, sampled, and tested at ports of entry.

In January 2009, the U.S. government made efforts to effectively manage inspection of imported products by revitalizing the process of deploying FDA inspectors in foreign countries. The inspectors were to provide training to foreign inspectors and assist with inspection of products destined for the U.S.[102] Under agreement with certain countries, the FDA is now authorized to require that producers of high-risk foods in those countries be certified and cleared to export to the U.S. The U.S. is also currently involved in a larger process of certifying foreign food manufacturers who comply with import regulations to be granted expedited clearance at U.S. ports of entry. Meanwhile, products from importers who continuously violate U.S. food safety regulations will receive more scrutiny from the FDA and customs officials before being admitted into the U.S. The

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[102] "Global Issues: FDA Opens Offices in China," *Journal of American Veterinary Medical Association*, January 1, 2009.

U.S. government is also considering information-sharing agreements (both amongst its own agencies as well as with foreign governments) that would facilitate the exchange of information such as recall data. Access to such information would enable U.S. Customs and Border Protection officials and other governmental agencies to obtain data on product safety, import transactions, et cetera. It would also enable inspectors to make timely decisions on whether to accept or reject imports, recall unsafe products, or advise consumers on certain products. The U.S. government is also considering providing incentives to importers who uphold higher safety practices for high-risk products. Finally, the U.S. government intends to publicize the names of certified producers and importers so as to increase transparency and consumer awareness.

Contaminants in Chinese Seafood

As mentioned earlier in this dissertation, the U.S. has been facing major SPS-related problems with Chinese food imports. In May 2007, the FDA issued an Import Alert on Chinese aquaculture imports. This was due to the presence of unapproved chemical contaminants in the imports. This dissertation focuses on risk assessment to determine if the contaminant exposure was within safe limits, given the current information from dietary studies conducted on the U.S. population. The results are focused on assessing the effectiveness of the risk management measures adopted by the U.S. government. Chemical contaminants detected in imports include:

- Malachite green,
- Leucomalachite green,
- Nitrofuran, and
- Gentian violet.

This section of the dissertation features a literature review of previous research done on these chemicals to establish their potential toxicity, carcinogenicity, or mutagenicity. The review examines previous scientific publications, lab tests, and data on the chemicals. It then assesses the extent of chemical contaminant exposure and discusses the regulatory agencies' reasons for banning them from human food.

Toxicity Tests

Chronic Toxicity Tests

Chronic toxicity tests are often done to establish if a chemical has the potential to cause cancer, mutation, or any other harm to an animal's body.[103] During the tests, physiological and biochemical parameters like body weights are recorded regularly and any "dose-related effects of the chemical are noted."[104] Physiological parameters are important because they indicate the general health conditions of the test animals. Reduction in physiological parameters such as food consumption and/or body weight can be an indicator of illnesses in the test animals. A post-mortem examination, accompanied by a comprehensive histopathological examination after the study, establishes any abnormality in tissues or cells of the test animals that are associated with the test chemical of interest.[105] Chronic toxicity tests help to determine whether the test chemical has the ability to cause cell mutations, which can result in uncontrolled cell growths (tumors) and the spread of those uncontrolled cell growths (cancer).[106] There are two forms of carcinogens: genotoxic carcinogens and non-genotoxic carcinogens. Genotoxic carcinogens are those which cause cancer through alteration of the DNA or the RNA of the cell, while non-genotoxic carcinogens cause cancer through mechanisms other than alteration of the nucleic acids of the cell. Non-genotoxic carcinogens give negative results for mutagenicity assays. Their effects can only be determined through chronic toxicity studies.[107]

The current concerns of food safety regulators and toxicologists have shifted more towards non-genotoxic carcinogens; this is due to their prevalence in food.[108] Suspected non-genotoxic carcinogens require full chronic toxicity testing to establish their effects on the human body before

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[103] Ian C Shaw and John Chadwick, "Environmental Toxicology," in *Principles of Environmental Toxicology* (Taylor and Francis Limited, 1998).

[104] Ibid.

[105] Ibid.

[106] R.E Taylor- Mayer F.K. Zimmermann, *Mutagenicity Testing in Environmental Control*, ed. R.A Chalmers and M .R. Masson (University of Aberdeen, West Sussex, England: Ellis Horwood Limited Chichester, John Wiley & Sons, 1985).

[107] Ian C Shaw and John Chadwick, "Environmental Toxicology." (1998)

[108] Ibid.

they can be used in food. Mutagenicity tests are done to establish if a test chemical causes abnormality in the DNA or RNA that can then be passed down to the daughter cell during mitosis.[109]

Malachite green

Malachite green (MG) is a toxic chemical used in the industrial production of silk, wool, jute, leather, and cotton. It is also used as a biological stain, a clinical reagent, a spot test reagent for detecting sulfurous and caesium, an acid-base indicator, and a paper dye. MG is used as a fungicide and pesticide in veterinary and aquaculture operations. It is also used as an antibiotic and antifungal to treat bacterial and fungal infections in fish and fish eggs.[110] In aquaculture operations, MG is famous in its chromatic form as a green dye. The figure below shows the structure of chromatic malachite green.

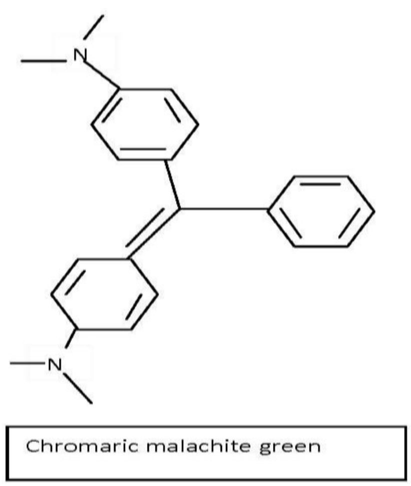

Figure 1.2 Chromatic form of malachite green

MG has a molecular formula of $C_{23}H_{25}N_2$ and a molecular weight of 329.46 mg. When used in an aquatic environment, the chemical enters the body of a fish and is metabolized into other forms such as leucomalachite green (LMG) and the carbinol form. The metabolite LMG is highly lipophilic; it is capable of penetrating fat, muscle tissue, and cellular membranes. MG is also highly soluble in water, ethanol, methanol, amyl alcohol, and other organic solvents.[111] The *Toxicity of Trimethylamine Dyes*, written by Werth, G. and A. Boiteux, profiles the detection of MG and LMG

[109] Ibid.

[110] Hazardous Substances Data Bank, "Malachite Green," http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+569-64-2.

[111] Ibid.

in the liver, heart, lungs, kidney, and muscle of rats 2 hours following their injection.[112] The chemical caused tumor cells 2 hours after intraperitoneal injection (injection of a substance into the peritoneum/body cavity). When used to treat fish diseases in aquatic environments, MG is absorbed in fish tissue and transformed into LMG, which persists in fish tissue for long time.[113] LMG is non-polar and has a half-life of 40 days in fish tissue.[114] Fish harvested from MG-contaminated aquatic environments have exhibited concentrations of LMG in their tissue that are higher than the concentration of MG in their surrounding environment.[115] This is due to the cumulative properties of LMG on fat tissues of living organisms.[116] Once a fish is harvested, the concentration of the chemical in the tissues does not change. This is because the metabolic functions responsible for eliminating chemical substances from the body stop after the fish dies. The figures below show other metabolic forms of malachite green.

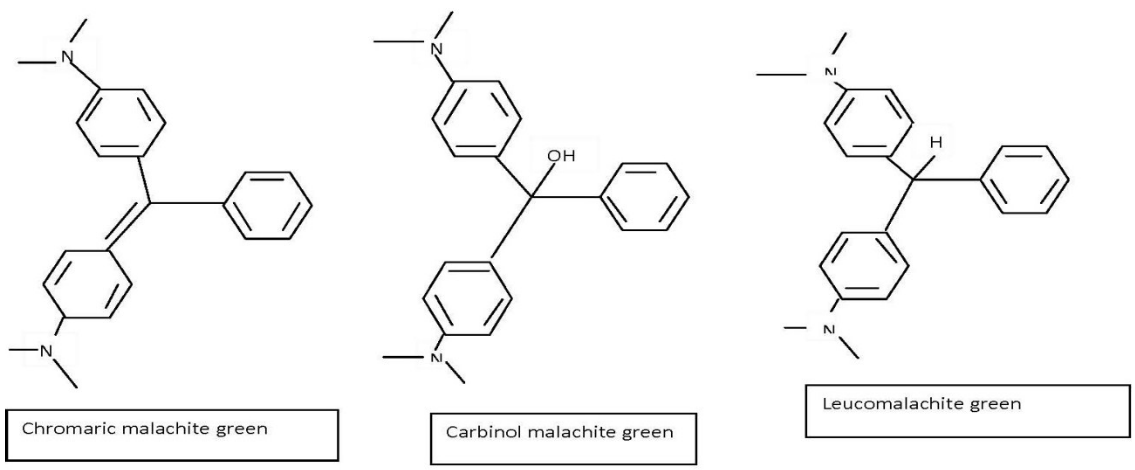

Figure 1.3 Metabolic forms of malachite green

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[112] G. Werth and A. Boiteux, "Toxicity of Triphenylmethane Dyes. Malachite Green as an Uncoupling Agent of Oxidative Phosphorylation in Vivo and in Vitro.," *Archive for Toxicology* 23, no. 2 (1968).

[113] National Toxicological Program, "Toxicology and Carcinogenesis Studies of Malachite Green Chloride and Leucomalachite Green. (Cas Nos. 569-64-2 and 129-73-7) in F344/N Rats and B6c3f1 Mice (Feed Studies)," in *The National Toxicological Program Technical Report Series* (2005).

[114] Ibid.

[115] D.R. Doerge, "Analysis of Malachite Green and Metabolites in Fish Using Liquid Chromatography Atmospheric Pressure Chemical Ionization Mass Spectrometry," *Rapid Communications in Mass Spectrometry* Vol. 12 (1998).

[116] Ibid.

Little is known about the effects of these chemicals on the human body, although previous studies done on other animal species indicate that the chemicals have carcinogenic properties.[117] Limited data is available on the effects of the chemicals on man. In 1993, the FDA nominated MG and LMG to the National Toxicological Program (NTP) for further studies. The NTP studies were done in 2002. The 104-week study focused on identifying possible toxicity or carcinogenicity of MG and its metabolite LMG. In the study, different concentrations of the chemicals were administered to lab animals through food. Concentrations of 0, 100, 300, and 600 parts per million (ppm) MG were administered to female rats, and 0, 100, 225, and 450ppm to female mice. 0, 91, 272, and 543ppm LMG were administered to female and male rats, and 0, 91, 204, and 408ppm LMG were given to male mice. A control group was set up to receive the same food, but without chemicals. At the end of the study, tissue biopsies from 40 different sites in each animal were conducted and differences between the animals exposed to the chemicals and the animals in the control groups were noted. A total of 48 animals were used in each test group. Results from the study indicated growth of cancer cells in mammary glands of female rats that were fed LMG. Similar growths occurred in the liver of entire group of male rats that were exposed to LMG, as well as the female rats that were exposed to 91 and 543ppm LMG. Male rats showed more cases of cancer than any other group of the test population. Cancer growths also occurred in the interstitial cells of male rats that were fed on LMG. The growths were significant in the groups that were fed on 543ppm—a relatively high concentration of the test chemicals. From this study, the final average body weight of female rats exposed to 300 or 600ppm MG or an equal concentration of LMG–227 and 543ppm was less than that of the control group.[118] A reduction in body weights of female rats that were fed on 91ppm of LMG was noted in the second year of study. Body weight serves as a good indicator of a test animal's health status. A reduction in body weight in test animals may indicate illnesses, negative effects of the test chemical(s) on the test animals, or negative effects of other extraneous factors.[119]

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[117] National Toxicological Program, "Toxicology and Carcinogenesis Studies of Malachite Green Chloride and Leucomalachite Green. (Cas Nos. 569-64-2 and 129-73-7) in F344/N Rats and B6c3f1 Mice (Feed Studies)."

[118] ———, "Toxicology and Carcinogenesis Studies of Malachite Green Chloride and Leucomalachite Green.," in *Toxicology and carcinogenesis studies of malachite green chloride and leucomalachite green. (CAS NOS. 569-64-2 and 129-73-7) in F344/N rats and B6C3F1 mice (feed studies)* (The National Toxicological Program, 2005).

[119] Ian C Shaw and John Chadwick, "Environmental Toxicology." (1998)

The chronic toxicity studies done on MG and LMG provided strong evidence of carcinogenicity and mutagenicity of the chemicals. No data is available on the effects of the chemicals on humans.[120]

LMG is persistent in tissues of fish; the chemical occurs at higher concentrations in fish tissues than does MG.[121] In a simultaneous analysis of concentrations of the two chemicals in fish tissues, Doerge (1998) found that LMG had a stronger tendency to accumulate in fish tissue than did MG.[122] Studies on the stability of MG and LMG under cooking processes indicate that processes such as boiling or baking can reduce concentrations of MG by 54 percent.[123] LMG, on the other hand, remains stable and does not undergo any degradation under baking or boiling processes.[124] Microwaving for 1 minute reduces the concentration of MG by 61 percent and that of LMG by 40 percent.[125] Microwaving is the only cooking process that reduces the levels of LMG in food. Heating at 150 degrees Celsius for 10 minutes reduces the concentration of MG by 49 percent; less than 3 percent of the original quantity of MG remains after 90 minutes heating at 150 degrees Celsius.[126] LMG, however, is stable and does not undergo any degradation even after heating at 150 degrees Celsius for 120 minutes.[127] At a holding temperature/time combination of 210°C/120 minutes, MG undergoes rapid degradation of 97 percent within 10 minutes, while only 18 percent of LMG reduces under these conditions.[128] LMG is very stable and remains in food even after undergoing the most severe cooking processes. The fact that LMG does not undergo any thermal degradation or destruction raises safety concerns over consumer exposure to residues of the chemical.

In a test for possible birth defects associated with MG and its metabolite, LMG, Meyer and Jogerson (1983) administered 0, 5, 10, and 20 milligrams of malachite green oxalate per kilogram

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[120] National Toxicological Program, "Toxicology and Carcinogenesis Studies of Malachite Green Chloride and Leucomalachite Green. (Cas Nos. 569-64-2 and 129-73-7) in F344/N Rats and B6c3f1 Mice (Feed Studies)."

[121] Doerge, "Analysis of Malachite Green and Metabolites in Fish Using Liquid Chromatography Atmospheric Pressure Chemical Ionization Mass Spectrometry."

[122] Ibid. (1998)

[123] K. Mitrowska, A. Posyniak, and J. Zmudzki, "The Effects of Cooking on Residues of Malachite Green and Leucomalachite Green in Carp Muscles," *Analytica Chimica Acta* 586, no. 1-2 (2007).

[124] Ibid.

[125] Ibid.

[126] Ibid.

[127] Ibid.

[128] Ibid.

body weight to New Zealand white rabbits. The study was done by force-feeding pregnant rabbits with food containing different concentrations of the test chemicals. The feeding was done on days 6 through 18 of the animals' gestation period. The test animals were then observed for any signs of toxicity from the test chemical. A similar study administered 13 daily doses of 50 milligrams malachite green oxalate per kilogram bodyweight to pregnant rabbits. The two studies recorded significant reduction in feed consumption in both groups of experimental animals; a consistent reduction in the average total body weights of the animals occurred after 29 days after the start of the study. Animals that were given 10 and 20mg/kg of the chemical in food lost 30g and 60g body weights respectively.[129] A reduction in the number of living fetuses was also observed; this shows possible reproductive or developmental toxicity of the test chemicals. A reduction in body weights of animals exposed to test chemicals, when compared with those of animals in the un-exposed group, serves as an indicator of possible illnesses resulting from the administered chemicals.[130]

Gentian violet

The other chemical contaminant that was found at high concentrations in Chinese seafood imports is gentian violet. Gentian violet is a water-soluble dye; it belongs to a group of chemicals called *di*- and *triaminophenyl methanes* used to control fungal diseases and intestinal parasites. It is also used in the staining of bacteria for bacterial identification.[131] The dye is not derived from gentians; rather, it was named after *Centarium gentiana* and *Centarium gentianella* due to its similarity to the pink-violet color of these organisms. Gentian violet is widely used in hospitals to treat serious heat burns and other injuries to the skin and gums. The chemical is also used to treat thrush, a fungal infection caused by the fungi *Candida albicans*, and yeast infections.[132] Like malachite green, gentian violet is readily absorbed by fish tissue. Once absorbed, it is metabolized into leucomoiety and leucocrystal violet (LCV).[133] Previous chronic carcinogenicity and

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[129] R.J. Salinas Jorgenson, C.F. Sujansky, E. Beierle, L.E., "Heterogeneity in the Trichorhinophalangeal Syndromes," *Birth Defects Original Article Series* 19, no. 1 (1983).

[130] Ian C Shaw and John Chadwick, "Environmental Toxicology." (1998)

[131] Lena Struwe, "Gentian Violet," Gentian Research Network, Rutgers University, U.S.A., http://gentian.rutgers.edu/GentianViolet.htm.

[132] Ibid.

[133] Ibid.

mutagenicity studies show the dye to have carcinogenic and mutagenic effects on rodents. Littlefield et al. (1985) found gentian violet to be associated with cancer of the bladder in humans.[134] Oral administration of the chemical in high doses caused irritation of the gastrointestinal tract, and its injection into the body caused a decrease in the body's white blood cell count.[135] In a sub chronic and chronic study involving 1440 animals, 720 male $B6C3F_1$ mice and $B6C3F_1$ female mice were given gentian violet doses of 0, 100, 300, and 600ppm to determine potential toxicity or carcinogenicity of the chemicals.[136,137] The animals were then terminated and autopsied after 12, 18, and 24 months of continuous dosing. Tissue biopsies showed that female animals were more susceptible to gentian violet than were their male counterparts. The study found gentian violet to be carcinogenic to different organs of the test animals. In male animals, the chemical caused an increase in liver neoplasm (abnormal multiplication of cells in the liver), while in females it caused atrophy (partial or complete wasting away) of the ovaries, cancer of connective and soft tissue in the urinary bladder, and cancer of the uterus, ovaries, and vagina.[138] An experimental virtual safe dose of 2ppm—the concentration at which the chemical is considered to have no effect on the animals—was established in mice. Other previous research on gentian violet has established that the chemical is capable of causing cell mutation, interference with the mitosis process during cell division, and breakage of chromosomes and consequent loss of genetic material during cell division.[139] In the liver, the chemical is demethylated by liver micromes, and then it is further reduced to leucocrystal violet by micro flora in the intestine. This reduction occurs under anaerobic conditions.[140] Leucocrystal violet is persistent in muscle tissue and can be detected in fish 79 days after exposure

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[134] N. A. Littlefield, "Chronic Toxicity and Carcinogenicity Studies of Gentian Violet in Mice," *Fundamental and Applied Toxicology* Issue 5 (1985).

[135] Lena Struwe, "Gentian Violet."

[136] W. Butler Au, M.A. Bloom, S.E. Matney, TS., "Further Study of the Genetic Toxicity of Gentian Violet," *Mutation Research* 66, no. 2 (1979).

[137] Littlefield, "Chronic Toxicity and Carcinogenicity Studies of Gentian Violet in Mice." (1985).

[138] W. Au et al., "Cytogenetic Toxicity of Gentian Violet and Crystal Violet on Mammalian Cells in Vitro," *Mutation Research* 58, no. 2-3 (1978).

[139]Ibid.

[140] J.J. McDonald and C.E. Cerniglia, "Biotransformation of Gentian Violet to Leucogentian Violet by Human, Rat, and Chicken Intestinal Microflora," *Drug Metabolism and Disposition* 12, no. 3 (1984).

to gentian violet.[141] Persistence of chemical residues in animal tissues is of great concern to public health officials; if animals are used as food before their bodies have a chance to completely metabolize and eliminate the chemicals, those chemicals can be transferred to consumers.[142] Another cause of concern for public health officials is the presence of antimicrobial contaminants in the environment. In low doses, these antimicrobials contribute to the development of microbial resistance.[143]

The Food Safety and Inspection Service (FSIS), a division of the U.S. Department of Agriculture (USDA), is responsible for ensuring that food products sold in interstate commerce are safe, wholesome, and properly labeled.[144] The FSIS conducts the National Residue Program (NRP), where products containing residues at levels beyond those set by the FDA and the EPA are sampled and tested. The purpose of testing is to inform the public of any potential exposure to residues in the food supply and to prevent food that violates maximum residue limits (MRL) from entering the country's food supply. The NRP also monitors the magnitude of hazards to public health and the probability of widespread human exposure to chemical residues. It ranks compounds using a risk assessment method—The Compound Evaluation System (CES)—in which compounds that are capable of leaving residues in food are ranked on a scale of 1 (likely) to 4 (unlikely) and Z (unknown), based on their toxicity and the probability of human exposure to the chemicals. As of 1991, gentian violet was ranked A-2.[145] Gentian violet was earlier permitted for use in poultry farms at concentrations of up to 8 parts per million to inhibit mold growth in animal feed; it was widely used because of its effectiveness in inhibiting a wide range of gram-positive bacteria.[146] Its potency on bacteria is affected by the pH of the solution. When used in a moderate pH, gentian violet

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[141] Jr. Thompson, "Persistence of Gentian Violet and Leucogentian Violet in Channel Catfish (Ictalurus Punctatus) Muscle after Water-Borne Exposure," *Journal of Chromatography. B, Biomedical Sciences and Applications* 723, no. 1-2 (1999).

[142] Ian C Shaw and John Chadwick, "Environmental Toxicology."

[143] Ibid. (1998).

[144] U.S. Department of Agriculture, Food Safety and Inspection Service, "National Residue Plan for 1998," Food Safety Inspection Service, http://www.fsis.usda.gov/OPHS/bluebook/hasect1.htm.

[145] Ibid.

[146] J.W. Moat Foster, A.G., "Mapping and Characterization of the Nad Genes in Salmonella Typhimurium Lt-2," *Journal of Bacteriology* 133, no. 2 (1978).

increases bacterial resistance to antibiotics.[147] The FDA's approval of gentian violet was withdrawn after its carcinogenic properties emerged following research by the National Toxicological Program (NTP).[148] The FDA recommended the use of propionic acid as a substitute for treating fungal and bacterial infections. Currently, gentian violet is not "generally regarded as safe" (GRAS) for use on food animals or as a food additive, and according to section 409 of the *Food, Drug and Cosmetic Act,* it is not permitted in human food.[149] Gentian violet, nitrofuran, malachite green, and leucomalachite green were detected in Chinese aquaculture imports in the sampling period between 2006 and 2007.[150] While these chemicals have been banned from human food in the U.S., several other countries continue to use them. This results in the continued exposure of U.S. consumers to chemical residues in food imports. According to data obtained from FDA lab-tests, gentian violet was found in levels ranging from 2.5ppb to 26.9ppb.[151] Consumer exposures to the chemicals over a long period of time could have serious public health consequences. Long-term consumer exposure to antimicrobials in food is known to cause the development of microbial resistance to antibiotics.[152] Microbial resistance is brought about when antimicrobials are washed away during the preparation of food and the drained water finds its way into water bodies such as rivers, lakes, water treatment plants/ponds etc. Antimicrobial residues in waste-contaminated bodies of water kill the vulnerable bacterial populations and other microbes, leaving only resistant ones—a phenomenon called selection. The surviving microbial populations grow and multiply, producing new generations of resistant microbial populations. If consumed with food, those microbes that have undergone selection can multiply and produce a generation of resistant microorganisms in the human body. Transfer of some resistant genes may also take place between those resistant microbial strains and

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[147] Ibid.

[148] The National Toxicological Program, "Teratologic Evaluation of Gentian Violet (Cas No. 584-62-9) in Cd Rats," Department of Health and Human Services, http://ntp.niehs.nih.gov/?objectid=072FDB21-F97F-372E-AAA7815272B76AE2.

[149] Food and Drug Administration, "U.S. Code of Federal Regulations: Subchapter E- Animal Drugs, Feeds, and Related Products " in *Title 21, Volume 6* (Department of Health and Human Services, 2007).

[150] ———, "FDA Detains Imports of Farm-Raised Chinese Seafood ".

[151] Murray M. Lumpkin, "Statement of Murray M. Lumpkin, M.D. Deputy Commissioner for International and Special Program before Committee on Commerce, Science, and Transportation; United States Senate."

[152] K. Kummerer, "Significance of Antibiotics in the Environment," *Journal of Antimicrobial Chemotherapy* 52. 5-7 (2003).

the microorganisms that are normal inhabitants of the human body.[153,154] Regional, national, and international trade in food and animal products can act as a vehicle for disseminating antibiotic-resistant microorganisms. This can occur if products come from areas with lax policies and regulations regarding the use of antimicrobials in food. Antibiotic resistance is a major concern for U.S. safety regulators in the food industry, particularly as increasing volumes of imports are seen in the international plant and animal trade.[155]

Nitrofuran

The fourth chemical contaminant that was found in Chinese aquaculture imports was nitrofuran.[156] Nitrofurans are a group of chemicals derived from furan; they are mostly used as antimicrobials to inhibit bacterial growth. Nitrofuran derivatives have a broad spectrum of activity against both gram-negative and gram-positive bacteria.[157] Their broad spectrum of activity makes them famous among veterinarians and farmers. The FDA banned the use of nitrofuran drugs in food animals and animal feed in 1991 due to their potential mutagenicity and carcinogenicity properties.[158] Mutagens are chemical or physical substances capable of modifying genetic information on the DNA molecule. The ban came into full effect on March 15, 2002.[159] Several studies have been done to establish potential toxicity of nitrofuran chemicals. In earlier studies of 27 nitrofuran derivatives by rapid microbial assay, 25 nitrofuran compounds were found to have the ability to modify the DNA of *E. coli*. 24 of the 27 nitrofuran compounds were capable of modifying the DNA of *Salmonella typhimurium,* and 15 of them were carcinogenic. Mutagenicity tests are fast

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[153] World Health Organization, "Medical Impact of Antimicrobial Use in Food Animals" (paper presented at the WHO Meeting, Berlin, Germany, 1997).

[154] ———, "Evaluation of Certain Veterinary Drug Residues in Food. Forty-Third Report of the Joint Fao/Who Expert Committee on Food Additives," in *World Health Organization Technical Report Series* (1995).

[155] ———, "Medical Impact of Antimicrobial Use in Food Animals".

[156] Food and Drug Administration, "FDA Detains Imports of Farm-Raised Chinese Seafood ".

[157] Farlex Clipart, "Medical Dictionary," Houghton Mifflin Company, http://www.thefreedictionary.com/nitrofuran.

[158] J.E. Morris et al., "The Carcinogenic Activity of Some 5-Nitrofuran Derivatives in Rat," *Journal of Cancer Research* Volume 29, no. 12 (1969).

[159] American Veterinary Medical Association, "Nitrofuran Ban in Effect," *Journal of American Veterinary Medical Association* (2002).

and reliable methods for determining potential carcinogenicity of various substances.[160] Some nitrofuran compounds induce phage development in lysogenic *E. coli,* while others are radiometric and have the ability to cause breakage in the DNA of bacteria.[161] Derivatives of nitrofuran have the ability to cause chromosome aberration in cultured human cells.[162]

The monitoring of food contamination is an important aspect of ensuring the safety of food supplies and managing food safety hazards associated with the regional and international food trade. Since 1976, the Global Environment Monitoring System's Food Contamination Monitoring and Assessment Program (GEMS/Food) has alerted standard-setting bodies—i.e., the Codex Alimentarius Commission, governments, regulatory authorities, public institutions, and other relevant authorities—of the trends and levels of contaminants in food. Such information is important for determining the average levels of consumer dietary exposure to various chemical contaminants, as well as for discerning the implications of those contaminants for public health and trade.[163] In an effort to monitor food consumption patterns, many governments have initiated dietary studies. In the U.S., dietary studies are conducted under the National Health and Nutrition Examination Surveys (NHANES) and the Continuous Survey of Food Intake by Individuals (CSFII). Similarly, in the UK, dietary studies are done under the National Diet and Nutrition Survey (NDNS).[164] The Irish food consumption survey (IUNA) carries out dietary studies in Ireland,[165] and China's food consumption

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160 T. Yahagi et al., "Relationships between the Carcinogenic and Mutagenic or DNA-Modifying Effects of Nitrofuran Derivatives, Including 2-(2-Furyl)-3-(5-Nitro-2-Furyl) Acrylamide, a Food Additive," *Cancer Research* Volume 34, no. 9 (1974).

161 D.E. Levin and B.N. Ames, "Classifying Mutagens as to Their Specificity in Causing the Six Possible Transitions and Transversions: A Simple Analysis Using the Salmonella Mutagenicity Assay," *Environmental Mutagenesis* 8, no. 1 (1986).

162 M.S. Sasaki and A. Tonomura, "A High Susceptibility of Fanconi's Anemia to Chromosome Breakage by DNA Cross-Linking Agents," *Cancer Research* 33, no. 8 (1973).

163 World Health Organization-Global Environment Monitoring System, "Food Contamination Monitoring and Assessment Program (Gems/Food)," http://www.who.int/foodsafety/chem/gems/en/.

164 National Diet and Nutrition Survey, "UK National Diet and Nutrition Survey: Adults Aged 19 to 64 Years, 2000-2001," in *Major studies: Consumer behavior-- Economics, General Health, and Nutrition Health* (Essex, UK: The Economic and Social Research Council (E.S.R.C.), 2000).

165 IUNA, "Research: Applied Nutrition and Food Safety " University College Cork, University of Ulster, and Trinity College Dublin, http://www.iuna.net/research.htm.

survey is responsible for collecting and maintaining such data in China. These surveys provide comprehensive demographic information and detailed food consumption patterns from the population. This information, provided from hundreds of thousands of subjects, ranges from subjects' habitual food and beverage consumption to their height, weight, body fat content, habitual physical activity levels, lifestyle characteristics (e.g., smoking), food and health attitudes, and socio-demographic characteristics.[166,167]

Quinolones

Quinonlones are a family of antimicrobial drugs consisting of ciprofloxacin, enrofloxacin, norfloxacin, oxolonic acid, perfloxacin, flumequin, sarafloxacin, and fluoroquinolone. Some of these antimicrobials are often used to treat bacterial infections and boost production in food animals.[168] Modern large-scale food production is increasingly characterized by the use of large amounts of antibiotics. Research has shown that continued use of antibiotics in food production, veterinary medicine, and human medicine can cause the development of microbial resistance against antibiotics that are important in treating human bacterial infections.[169] Some farmers in China and other Asian countries use quinolone and other groups of antibiotics to treat fish diseases in their aquaculture operations because the drugs are cheap and readily available.[170] Aquaculture farmers primarily use antibiotics to promote growth, prevent diseases, and treat bacterial infections in fish.[171] Excess use of quinolone drugs for therapeutic purposes in humans can cause serious health effects, such as damage to the central nervous system, serious harm to the brain, depression, paranoia, nervousness, dizziness, convulsive seizures, panic attacks, light-headedness, vertigo, insomnia, et cetera.[172]

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[166] Cronan Mc Namara, "Making the Most of Your Food Consumption Database," CREMe Research Network, www.cremesoftware.com.

[167] United States Department of Agriculture-Agricultural Research Service, "Information Collected in the 1994-96, 1998 Continuing Survey of Food Intakes by Individuals," http://www.ars.usda.gov/Services/docs.htm?docid=7764.

[168] World Health Organization, "Medical Impact of Antimicrobial Use in Food Animals".

[169] ———, "Use of Quinolones in Food Animals and Potential Impact on Human Health," in *World Health Organization Emerging and Other Communicable Diseases, Surveillance and Control* (1998).

[170] G.M. Marshall Duran, D.L., "Ready-to-Eat Shrimp as an International Vehicle of Antibiotic-Resistant Bacteria," *Journal of Food Protection* 68, no. 11 (2005).

[171] J. R. Arthur, *Use of Chemicals in Aquaculture in Asia* (2000).

[172] T. Boomer, "Toxicity of Quinolone Antibiotics on Normal and Healthy People," in *Patients Point of View* (2007).

Though not permitted for use in animals meant for human food in the U.S., farmers in some developing countries use sub-therapeutic levels of quinolone antibiotics to treat food animals.

The continuous use of quinolone antibiotics in human food in some developing countries is a cause of concern among food safety regulators and public health officials. The use of low levels of quinolone drugs in veterinary medicine and food production is concerning, because their use causes pathogenic bacteria to develop resistance to antimicrobials that are important to public health. Antibiotic-resistant pathogens pose serious health risks to humans since they can be transferred through the food chain.[173] The development of antimicrobial resistance in pathogenic bacteria can render current antibiotics ineffective for curing human bacterial infections.[174] Because few new antimicrobials are being introduced in the market, bacterial resistance to antibiotics can significantly increase human fatalities resulting from pathogenic bacteria. Medical experts have documented increasing cases of microbial resistance to quinolone drugs. For example, in 1992, the Minnesota Department of Health reported increasing cases of quinolone resistance in *Camphylobacter jejuni* infections in human.[175] *Camphylobacter jejuni* is a pathogenic bacterium commonly found in poultry and domestic animals.[176] The bacterial infection can result from consumption of contaminated meat or poultry products.

The misuse of antibiotics is not restricted to China and other Asian countries; it has been reported in both the developing and the developed world. Most farmers in the U.S. use antibiotics in food animals to increase the efficiency of food-muscle conversion in the animals; about 70 percent of antimicrobial use in food animals in the U.S. is intended to improve food-muscle conversion.[177] The U.S. government has strict regulations and guidelines regarding the use of antimicrobials in food animals. Most developing countries, on the other hand, have lax regulations regarding the use of antimicrobials. Weak regulations on the use of antimicrobials in developing countries provide room

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[174] World Health Organization, "Use of Quinolones in Food Animals and Potential Impact on Human Health."

[175] ———, "Medical Impact of Antimicrobial Use in Food Animals".

[176] K. E. Smith, "Quinolone-Resistant Campylobacter Jejuni Infections in Minnesota, 1992-1998," *The New England Journal of Medicine* 340, no. 20 (1999).

[177] Sabin Russell, "Fight to Curtail Antibiotics in Animal Feed," *San Francisco Chronicle*, no. Jan 28 (2008), http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2008/01/28/MNSTUGD8E.DTL.

for continuous development of microbial resistance against antibiotics. The infection of immunocompromised persons by antibiotic-resistant pathogenic bacteria can be fatal because infections cannot be treated with the antimicrobial drugs that are available on the market.[178] The FDA banned the use of antibiotics belonging to the family of Cipro—for example, fluoroquinolone—for use in poultry farming following increased cases of drug resistance in poultry among strains of *Campylobacter jejuni*.[179] Public health officials are becoming increasingly concerned over the development of bacterial resistance to antimicrobial drugs, especially because new antibiotics for treating human and animal bacterial infections are not being developed and approved as quickly as they once were.[180] For this reason, the FDA has banned certain antibiotics for use in food animals; however, U.S. food safety regulators have frequently detected violative levels of banned antibiotics in imported food. The FDA detected excessive levels of quinolone antibiotics in imported Chinese aquaculture products in the sampling period of October 2006 to May 2007. This prompted the FDA to issue an import alert against imported Chinese aquaculture products.

The National Health and Nutrition Examination Survey (NHANES)

The National Health and Examination Survey (NHANES) came into being in July of 1956 with the signing of the *National Health Survey Act* (NHS Act) by President Eisenhower. The NHS Act created a system for collecting population health and nutritional data in order to determine the health status of the entire U.S. population and specific sensitive subpopulations.[181] The National Center for Health Statistics (NCHS) under the Centers for Disease Control and Prevention (CDC) was assigned the responsibility for designing the survey and collecting data on population health status in the U.S. Since the signing of the NHS Act into law, eight separate health and nutritional surveys have been conducted.[182] The first health surveys were conducted for four consecutive years, with a break of at least one year between the surveys. The subsequent NHANES surveys that were

[178] H.C. Wegener, "The Consequences for Food Safety of the Use of Fluoroquinolones in Food Animals," *New England Journal of Medicine* 340, no. 20 (1999).

[179] Russell, "Fight to Curtail Antibiotics in Animal Feed."

[180] World Health Organization, "Medical Impact of Antimicrobial Use in Food Animals".

[181] Obe Met, "The National Health and Nutrition Examination Survey," http://www.faqs.org/nutrition/Met-Obe/National-Health-and-Nutrition-Examination-Survey-NHANES.html.

[182] Ibid.

conducted were continuous, with no breaks between the surveys. The NCHS uses a complex multistage sampling design in selecting participants in the study; the sampling design ensures that the selected participants are representative of the entire U.S. population.[183] Because the NHANES sample is representative of the U.S. population, the health and nutrition status resulting from NHANES survey is believed to be representative of that of the entire U.S. population. The results of the surveys are useful to government officials, public health officials, and researchers for making policy decisions, conducting research, et cetera. Public health officials use NHANES data in assessing the prevalence and trends of certain diseases, the distribution of risk factors for the diseases, and the success of intervention strategies for preventing or reducing the diseases.[184] Policy formulators use NHANES data in formulating public health policies; additionally, public health officials and epidemiologists use NHANES data in conducting research on emerging public health issues. The NHANES sampling includes a wide range of age groups to ensure that the results of the survey reflect the status of the entire U.S. population. In order to obtain a reliable sample, individuals from certain high risk groups, including infants, children, the elderly, and members certain ethnic groups, are more frequently sampled. Approximately 5000 people across the U.S. participate in NHANES studies annually. In order to ensure adequate ethnic and age representation, African-Americans, Mexican-Americans, infants, children, and those over sixty years of age are sampled more than other participants.[185]

NHANES surveys consist of two components—an interview and an examination. The interview component collects the participants' demographic, socioeconomic, and other health-related information that is not included in the examination component.[186] The examination component collects the participants' medical data such as dental measurements, physiological measurements, blood sugar levels, blood pressure levels, et cetera. Under the examination component, expert

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[183] National Centre for Health Statistics, Center for Disease Control and Prevention "The National Health and Nutrition Examination Survey, 2007-2008 " Center for Disease Control, http://www.cdc.gov/nchs/data/nhanes/nhanes_07_08/overviewbrochure_0708.pdf.

[184] Centers for Disease Control and Prevention, "The National Health and Nutrition Examination Survey,," The National Center for Health Statistics, , http://www.cdc.gov/nchs/about/major/nhanes/nhanesi.htm.

[185] National Centre for Health Statistics, "The National Health and Nutrition Examination Survey, 2007-2008 ".

[186] Katherine A. Beals, "National Health and Nutrition Examination Survey (Nhanes)," http://www.diet.com/g/national-health-and-nutrition-examination-survey-nhanes.

medical personnel conduct laboratory tests to determine the prevalence of certain diseases of interest among the participants.[187] The older NHANES participants are often subjected to more extensive physical and medical exams. The NCHS often makes the results of NHANES studies available to the public and researchers through publications and articles in scientific and technical journals. Data obtained from NHANES surveys is important for formulating policies that can protect the public; for example, policies which resulted in banning of production and sale of leaded products, fortifying of grain and other food products with folate and other vitamins, et cetera.

NHANES surveys use a complex, stratified, multistage probability-cluster sampling design to ensure that the participants selected are representative of the entire U.S. population.[188] The sampling does not include individuals in institutions such as nursing homes, college dormitories, prisons, et cetera. The NCHS, responsible for designing NHANES studies, adjusts for the unequal probability of sample selection when designing the studies.[189] The NCHS also adjusts for bias that may arise from non-response among the participants by assigning each participant a sample weight. The sample weight assigned to each participant also corresponds to the total number of people within the U.S. population that the participant represents.[190]

The data collected from NHANES is made public for scholars, researchers, public health officials, and policy formulators.[191] This dissertation takes advantage of the publicly available NHANES data on consumption patterns of the U.S. population to study the levels of exposure of consumers to contaminants in imported Chinese aquaculture.

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[187] Ibid.

[188] National Centre for Health Statistics, "The National Health and Nutrition Examination Survey, 2007-2008 ".

[189] Centers for Disease Control and Prevention, "The National Health and Nutrition Examination Survey,."

[190] National Centre for Health Statistics, "The National Health and Nutrition Examination Survey, 2007-2008 ".

[191] Katherine A. Beals, "National Health and Nutrition Examination Survey (Nhanes)."

CHAPTER 2 - Methodology

Introduction to Predictive Modeling and CREMe Software

Population food consumption patterns are complex, and diets vary among people from different geographic regions and demographic segments of society. As food consumption patterns vary among populations, so too do the levels of consumer exposure to contaminants in the food supply. The accurate, quantitative estimation of substances to which consumers are exposed is necessary for the formulation of policies to protect consumers. Processed foods are characterized by the use of food additives, flavoring agents, pesticides, food package migratory compounds, veterinary drugs, radioactive substances, heavy metals, dioxins, and other substances.[192] Predictive modeling can provide valuable data for policy formulators to use in making important public health decisions. Various methods can be used to estimate risks that are present in the food supply. These include:

a. Point estimates—also called deterministic modeling,
b. Simple distributions, and
c. Probabilistic distributions.

Deterministic Modeling

Deterministic modeling uses a single estimate of each variable within an exposure model to determine a model's outcome(s). In deterministic modeling, fixed values are used to calculate a population's exposure to contaminants in the food supply. In calculating chemical exposure levels in a particular food (e.g., aquaculture), the mean or maximum contaminant level present in the food is multiplied by the mean or maximum consumption rate to produce the food's contaminant exposure level. However, if different aquaculture products are contaminated by the same chemical, the value obtained from the calculation is summed up for all the different products under investigation. Deterministic modeling is often used as the first step in exposure assessment because the model is cheap, fast, and easy to do. Deterministic modeling is based on assumptions such as: (a) all

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[192] Lang, "The Complexities of Globalization: The UK as a Case Study of Tensions within the Food System and the Challenge to Food Policy."

individuals eat the specified food(s), (b) the specified food(s) are consumed in the same quantity by all consumers, and (c) the contaminant is always present in the foods at the specified mean or higher levels. This method does not provide detailed information on the range of possible exposures that may occur within a population, nor does it provide information on the main factors affecting exposure results; thus, it provides inadequate information for risk managers and public health officials. The method may significantly overestimate or underestimate actual exposure levels.[193] Using high values to estimate exposure to chemicals may overestimate chemical intake levels within a population. Deterministic models cannot provide accurate estimates of exposures within different demographic segments such as infants and children, women, and the immuno-compromised. Accurate predictive models are useful decision-making tools for food safety risk managers.

Probabilistic Modeling

The unpredictable nature of food contamination can make it difficult to estimate intakes of contaminants in food. In order to offset this unpredictability, the use of probabilistic logic is necessary. Probabilistic models involve the use of distributions instead of point estimates to describe model variables. This allows for all possible values of a variable to be considered in the calculation. Thus, each possible outcome of the event is weighted based on the likelihood of its occurrence. In an analysis, random samples are repeatedly selected on the basis of the presence probability from each input distribution. The selected samples are then factored into a deterministic analysis, and finally, the output of the analysis is stored. This process, known as *iteration*, is repeated a number of times until the required number of iterations are completed. A set of output samples is obtained. This method of risk assessment allows for assessment of the whole distribution of exposure from minimum to maximum, including all percentiles.[194] This provides useful information to the public in general and to risk managers in particular.

A probabilistic model provides the best estimate for consumer exposure to contaminants in the food supply. This is because it takes into account every possible value that each variable could have and weights each possible scenario by the probability of its occurrence. It also ensures that any variability and/or uncertainty (such as uncertainty regarding the presence of contaminants in the

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[193] K. Baert, et al., *Risk Assessment: A Quantitative Approach*, ed. Rui Costa & Kristberg Kristbergsson, Predictive Modeling and Risk Assessment (Portugal: Springer Science, 2009).

[194] Ibid.

food, uncertainty regarding the level of contamination present, variability on the level of contaminants present, etc.) is accounted for in the model. Variability in this context refers to variation in the input-variable of interest. Uncertainty, on the other hand, refers to lack of proper knowledge about aspects of the input-variable of interest.[195] The probabilistic approach for modeling contaminant exposure also has the advantage of allowing for cumulative assessment of multiple chemicals, which cannot be achieved using deterministic methods. The approach provides exposure levels with various confidence intervals, taking the model's uncertainties into account. This allows for accurate quantitative estimation of dietary exposure to food contaminants. Probabilistic assessment can also be used to carry out sensitivity analysis of results, allowing for independent assessment of various factors that influence exposure of consumers to contaminants. This provides room for regulatory authorities to formulate and implement policies that effectively protect public health.[196]

As mentioned earlier in this dissertation, numerous national food consumption surveys are done around the world: the NHANES, the NDNS, the IUNA, etc. This dissertation's study used data from NHANES food consumption surveys as an input variable to estimate consumer exposure to selected chemical residues in imported seafood. This was done in order to answer the following question:

3. Considering prevailing U.S. seafood consumption patterns amongst both the general population and specific sensitive sub-populations, would the dietary intake of specific chemicals from Chinese aquaculture imports be within safe levels (in a contrived scenario using actual consumption and contamination data)?

This study used data from different years; the study used data from the 2003-2004 U.S. seafood consumption pattern obtained from NHANES database, and the 2006-2007 FDA seafood contaminant sampling data.

Simulation: CREMe Exposure Assessment

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[195] D.R. Tennant, "Risk Analysis," in *Food Chemical Safety*, ed. David H. Watson (Brighton, East Sussex: Woodhead Publishing Limited, 2001).

[196] Cronan McNamara, "Pesticides and Contaminants in Food: The Safety Issue " CREMe Research Network, www.cremesoftware.com.

Developed in Dublin, Ireland, CREMe (Central Risk Exposure Modeling) is a computer program that uses high-performance computing to provide an accurate estimate of consumer exposure to various substances. It allows for exposure assessments on food additives, flavoring agents, pesticide residues, chemical contaminants, nutrients, food packaging migratory compounds, novel foods such as genetically modified foods, et cetera. CREMe relies on databases from the nationally run dietary surveys to assess exposure to various substances in the food supply. The software program is capable of running probabilistic exposure assessments based on the available consumption data—the U.S. NHANES, the UK NDNS, IUNA, et cetera.—to provide an accurate estimate of the general population's exposure to various substances in food. The exposure statistics for key demographic groups can also be obtained from CREMe analysis. This study is important because it provides information to those seeking to take the best course of action in protecting consumers from potential hazards in food. This is particularly necessary if exposure levels are likely to cause adverse health effects.

CREMe carries out probabilistic exposure assessments by running through each eating event in the food diaries of the subjects (consumers), identifying every eating occasion and food group. During CREMe's exposure analysis,

> *"the program looks up the chemical concentration for each eating event. Based on the presence probability, a random choice is made as to whether the chemical is present or not. If it is present, the concentration field is used to assign chemical concentration values for the eating event; if the concentration is probabilistic, a random value from the concentration probability function is generated."197*

Analysis of chemical intake continues through every eating event in the subject's diary file. Once complete, all eating events are calculated to produce the total daily intake for each subject. In order to accommodate probabilistic adjustments to the calculation, the whole process is repeated and a range of mean chemical intakes and percentiles (the 90^{th}, 95^{th}, 97.5^{th}, 99^{th}, and 99.9^{th}) is generated. The variances are the result of uncertainty and variability presented by the probabilistic input expressions. Standard deviations are also provided for the average chemical intake.[198] Exposure

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[197] Cronan Mc Namara, "Making the Most of Your Food Consumption Database." Pg. 2.

[198] ———, "Pesticides and Contaminants in Food- the Safety Issue " CREMe Research Network, www.cremesoftware.com.

results for each subject are given in terms of the daily contaminant concentration per kilogram of a consumer's body weight.

The following is a detailed description on how CREMe carries out an analysis of a population's exposure to contaminants. Within CREMe, there are different types of tables: a subjects' table, a diary table, a food group table, and a chemicals table. The subjects' table is used for entering demographic information on consumers. Subjects' tables have columns (fields) for subjects' code, body weight, and sex (in the form of 1 or 2, where 1 is for male and 2 is for female). The table below illustrates the structure of the subjects' table.

Table 2.1 Subjects table

Subject code	Weight	Sex
1	50	1
2	60	2
3	100	2

CREMe also contains a diary table where information on consumption (eating) patterns for each subject (collected during survey) is entered. The diary table contains information such as the subject's code, the day the meal was eaten, the type of meal eaten (i.e., breakfast, lunch, or supper), the food code for foods eaten, and the amount of food eaten during the meal. Below is an illustration of a food diary table.

Table 2.2 Diary table

Subject	Day	Meal	Food Code	Amount (g)
1	1	1	101	45
1	1	2	102	50
1	1	2	103	55
2	1	1	106	20
2	1	2	103	10
3	1	1	101	15
3	1	1	102	10

In the above illustration of the diary table, Subject 1 had two meals (Meal 1 and Meal 2) on the first day of the survey (Day 1). He had 45 grams of food 101 in the first meal on day 1 (Meal 1), and then he had 50 grams of food 102 and 55 grams of food 103 in the second meal of day 1 (Meal 2). Subject 2 had 20 grams of food 106 in the first meal of day 1, and 10 grams of food 103 in the second meal of day1. Subject 3 had different kinds of food in the same meal—15 grams of food 101 and 10 grams of food 102 in the same meal (Meal 1) of day 1.

The average quantity of food consumed by each subject is calculated, and a distribution of food intake from all consumers is generated. The distribution shows the mean food intake, as well as the 90th, 95th, 97.5th, 99th, and 99.9th percentiles for food consumption. A subject's food intake level depends on various factors such as body weight, sex, and availability of food. Thus, an accurate estimate of the quantity of food/chemical intake from a consumption pattern will consider the variables that are likely to affect an individual's food intake.

Table 2.3 Food intake model

Subject	Amount (g)	Amount (per kgbw)
1	(45+50+55)/1	150/50 = 3
2	(20 + 10)/1	30/60 = 0.2
3	(15 + 10)/1	25/100 = 0.25

Table 2.4 Food intake calculations

Statistic	Value
Mean	(3+0.2+0.25)/3= 1.15
Standard Deviation	1.602342

When food intake or chemical exposure of a segment of population (e.g., children or women) is to be considered, data on individual food consumption becomes important. This research made use of the publicly available 2003-2004 NHANES food consumption data on children, women, and adults to assess the extent of contaminant exposure from Chinese aquaculture imports. The term seafood is used to refer to edible fish and fishery products that are caught in natural water bodies such as the open sea, lakes, rivers, streams, et cetera. On the other hand, the term aquaculture is used to refer to edible farmed fish and fishery products; that is, edible fish and fishery that are produced under controlled marine or aquatic environment.

Safety of Chinese Aquaculture Imports

Based on the information in the literature review, this study used CREMe software to model the exposure of different demographic segments of the U.S. NHANES population to contaminants in imported Chinese aquaculture products (approximated using various FDA datasets, explained in this chapter). CREMe uses a standard statistical method called a Monte Carlo simulation, a method that involves the use of random numbers and probability statistics to investigate problems. The use of Monte Carlo models in food safety problems enables investigations of more complex systems than would otherwise be possible. Monte Carlo simulation helps examine the effects of various factors on consumer exposure by using individual distributions for the model variables such as food consumption patterns, chemical contaminant distribution patterns, and distributions of consumer body weight. In Monte Carlo distributions, single-point data is repeatedly generated from each input distribution. Monte Carlo looks at many different combinations of input data to give a frequency distribution exposure.[199]

This case study involves an exposure assessment of chemical contaminants in Chinese aquaculture imports in the U.S. The 2003-2004 U.S. NHANES food consumption pattern was combined with chemical concentration levels in aquaculture imports and consumer body weights. Both hypothetical and available (2006-2007) FDA seafood consumption sampling data was used to estimate the level of chemical exposure that would have occurred in different cohorts of 2003-2004 NHANES seafood consumers.

The following assumptions were made to best estimate chemical contaminant exposure in this study:

a. All seafood consumed in the U.S. is of Chinese aquaculture origin (a worst-case scenario);
b. The sampling distribution of NHANES 2003-2004 consumers is the same as that of the U.S. seafood consumers (a reasonable assumption that allows this study to take advantage of the NHANES data set);
c. There is a normal distribution of contaminants of interest in aquaculture imports (a commonly embraced assumption in studies of this kind);
d. The contamination data from 2006-2007 was used as a proxy for contamination data for 2003-2004; and
e. There is no other significant source of exposure to contaminants (a possibly unrealistic but nonetheless reasonable assumption).

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[199] K. Baert, *Risk Assessment: A Quantitative Approach*.

The first variable in the case study was chemical concentrations in Chinese aquaculture products; the concentrations of chemical residues in imported Chinese aquaculture were between 1.2-122ppm for malachite green, 2.5-26.9ppm for gentian violet, 1.9-6.9ppm for fluoroquinolone, and 0-1ppm nitrofuran.[200] These values were obtained from the FDA residue monitoring database and while from 2007-2007, provide realistic contamination data for this study. This database contains 21,295 chemicals found in imported and locally produced food; the database also contains the sampling design and the analytical procedures used.[201] The second variable in the model was food intake among NHANES 2003-2004 seafood consumers, and the third variable in the model was body weight of NHANES 2003-2004 seafood consumers. Food intake among consumers varies with body weight; these variations must be factored into the model if accurate exposure levels are to be obtained. Monte Carlo simulation allows for distributions from each model variable to be sampled in a number of multiple random configurations. Results are then combined and consumer exposure levels are generated from the simulation. The data generated helps to paint a picture of the overall consumer exposure to aquaculture chemical contaminants. 500 iterations were run in each exposure analysis, meaning that CREMe ran through the food diaries of NHANES seafood consumers 500 times. Each time, it picked up the levels of residues consumed in cases where contaminated seafood was part of the diet.

Food import shipments are subjected to inspections at U.S. ports of entry, and in the sampling period following an import alert, a number of Chinese aquaculture shipments to the U.S. were impounded. Although this action prevented many contaminated aquaculture imports from reaching consumers, some of the imported food did successfully make it to the market and eventually to consumers' tables. Monte Carlo simulations allow for the incorporation of uncertainties into the model through the use of probabilistic logic. During the study, several questions came to mind. These questions included:

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[200] Food and Drug Administration, "Pesticide Program: Pesticide Monitoring Database 2007," United States Department of Health and Human Services, http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/Pesticides/ResidueMonitoringReports/ucm172746.htm.

[201]. Ibid.

a. What is the probability that a contaminated shipment of aquaculture will make it through the FDA inspection nets?
b. What is the probability that aquaculture imports destined for further processing will pass the chemical screening tests in U.S. food processing facilities?
c. What is the probability that contaminated aquaculture products will end up on consumers' tables instead of being disposed of, as they should be?

CREMe was used for this study because of its ability to perform cumulative exposure assessments on multiple chemicals on different segments of the U.S. population, its ability to effectively account for multiple variables in the exposure model, and its ability to generate accurate exposure levels at different confidence intervals after factoring in all the variables that influence consumer exposure to contaminants.

The U.S. NHANES 2003-2004 database of subjects was used in this study. Preliminary analysis of all NHANES 2003-2004 consumers show that they can be divided into two distinct groups based on body weight and age. Figure 2.1 shows the distribution of the NHANES 2003-2004 seafood consumers based on body weight, while figure 2.2 shows their distribution based on age.

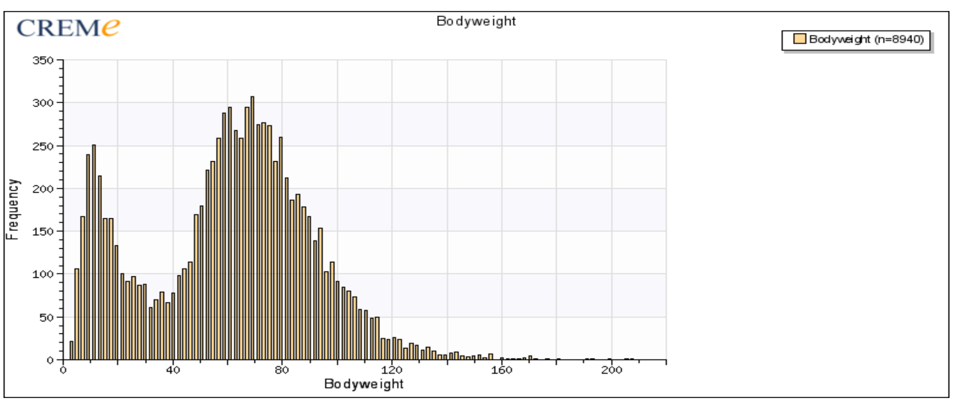

Figure 2.1 Distribution for NHANES 2003-2004 consumers' bodyweights

When the NHANES 2003-2004 seafood consumers were analyzed, clear distinctions emerged among the subjects. The distinctions among consumers were based on bodyweight and age. Figure 2.1 shows the distribution of NHANES 2003-2004 seafood consumers based on subjects' body weights. The distribution shows that NHANES 2003-2004 consumers who had body weights of less than 20 kg were sampled to a larger extent during the survey. Figure 2.2 below shows the distribution of NHANES 2003-2004 seafood consumers by age. The distribution also shows that

NHANES 2003-2004 consumers who were under the age of 20 years were sampled to a larger extent than were other NHANES 2003-2004 consumers.

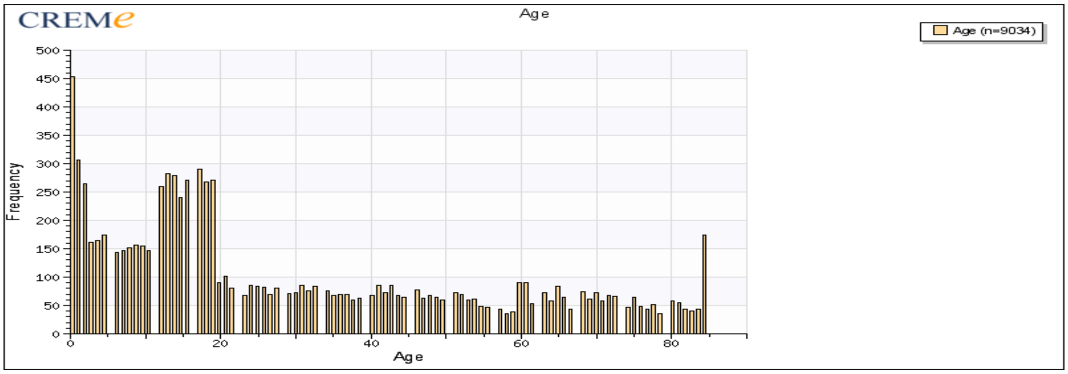

Figure 2.2 Distributions for NHANES 2003-2004 consumers' ages

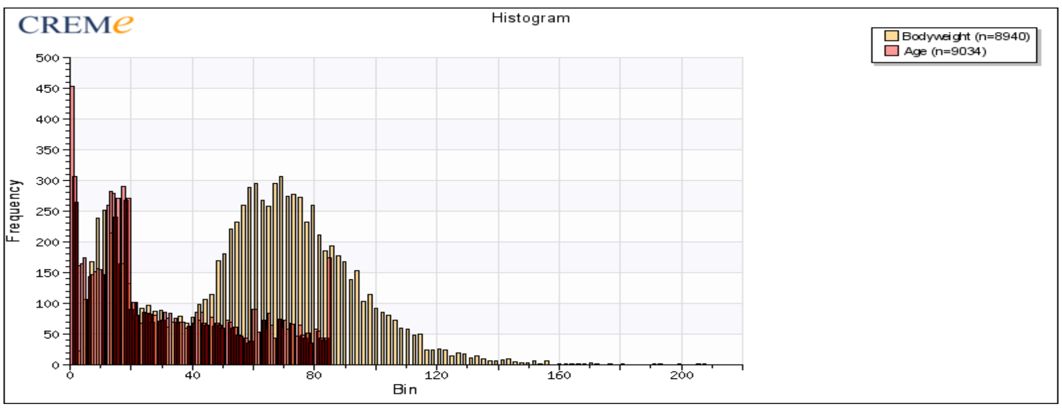

Figure 2.3 Distributions for NHANES 2003-2004 consumers' bodyweights and ages

To accurately evaluate the likely aquaculture contaminant exposures in consumers, NHANES 2003-2004 consumers (subjects) were divided into different groups based on ages. The distributions above—plotted from CREMe—show two distinct groups of consumers based on age and body weight. Two groups of consumers were sampled to a larger extent in the NHANES 2003-2004 survey: consumers who were under 18 years of age and consumers who were over 60 years of age. The exposure assessment in this study was based upon the two groups of consumers who are considered highly vulnerable to the effects of chemical contaminants in the food supply. Considering that children have higher rates of food consumption per kilogram body weight than adults, it is plausible that children would be exposed to higher levels of chemical contaminants in food.[202]

[202] Lynn R. Goldman, "Children Unique and Vulnerable. Environmental Risks Facing Children and Recommendations for Response," *Environmental Health Perspectives* 103 (Suppl 6) (1995).

Children form a vulnerable group of consumers because they easily succumb to illnesses resulting from food contamination, they have weak organs which are still under development thus prone to destruction from exposure to chemical contaminants, and their metabolic functions are still underdeveloped and thus unable to handle toxic contaminants in food.[203,204] Children who were under the age of 18 years formed the first group of consumers in this study.

Why Protect Children?

In 1993, the National Research Council (NRC) published a report entitled, *Pesticides in the Diets of Infants and Children.*[205] The report expressed serious concerns on equal treatment of adults and children when determining tolerances for chemical contaminants and pesticides in food. According to the NRC, children are unable to ward off dangers posed by chemicals in their diet due to their weak developing systems and their small physical size. The NRC proposed the use of additional safety margins when establishing tolerances in children's diets for adequate protection. According to the NRC, there are great differences in the physiological and biochemical activities of children's and adults' bodies, and these differences greatly influence the amount of contaminants absorbed and the effects of chemical contaminants on the body. Children consume larger proportional amounts of food and water, have higher metabolic rates, and tend to have less varied diets than adults. As a result, there is greater potential for short-term and long-term toxicity of chemical contaminants in children's bodies than in adults' bodies. These differences require the consideration of age in determining toxicity of chemical contaminants and their potential effects on consumers. Another report published by the World Resource Institute (WRI) in 1996 expressed similar concerns to those expressed by the NRC. According to WRI, chemical contaminants in children's diets can damage and/or suppress their immune systems. Children have immature immune systems and are thus predisposed to immune-suppression from chemical contaminants that enter their bodies through their diet.

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[203] National Research Council. Committee on Pesticides in the Diets of Infants and Children, *Pesticides in the Diets of Infants and Children* (1993).

[204] L. R. Goldman, "Children--Unique and Vulnerable. Environmental Risks Facing Children and Recommendations for Response," *Environmental Health Perspectives* 103, no. Suppl 6 (1995).

[205] National Research Council. Committee on Pesticides in the Diets of Infants and Children, *Pesticides in the Diets of Infants and Children*.

The *Food Quality Protection Act* (FQPA) was signed into law in 1996. The passage of this act was hailed as a major milestone in protecting consumers against chemical contaminants in the food supply; the act requires the Environmental Protection Agency (EPA) to determine limits of chemical residues in food, also known as tolerances. Tolerances are to be determined through quantitative risk assessment of the chemicals of concern. The FQPA has specific provisions to protect children from chemical contaminants in their diets. Before the implementation of the FQPA, the law permitted the EPA to determine risks posed by different chemicals in diets without considering the unique susceptibility of children and infants. The implementation of the FQPA brought changes in the manner in which the EPA carried out risk assessment on chemicals; consequently, the FQPA now requires the EPA to consider the unique susceptibility of children and infants in all of its future assessments of chemical contaminants and residues in diet.[206]

Why Protect Women?

In 2009, a report published by the *European Reproductive Journal* expressed concern that pregnant women and women of child bearing age in the U.S. were at high risk for developing reproductive problems (e.g., infertility). These problems are due, in part, to exposure to chemicals in the diet. According to the report, the presence of certain chemical contaminants in women's diets makes it difficult for conception to occur; this significantly increases the level of infertility among women. This is a source of concern, given that an individual's exposure to chemical contaminants through their diet is continuous. Exposure of pregnant and/or nursing mothers to certain chemical contaminants can also result in other serious reproductive health conditions that affect their children. Such conditions include childhood cancer, learning disabilities, asthma, heart disease, and other health problems. Exposure of women to hazardous chemicals can also interfere with hormones, immune systems, and fetal development.

Studies by the Environmental Working Group established that children's exposure to chemical contaminants begins in the womb. Analyses of umbilical cords have found more than 287 chemical contaminants in newborn children, indicating that exposure to chemicals begin and continue in the womb. The FDA affirms that the risk of severe and life threatening symptoms from

[206] Goldman, "Children--Unique and Vulnerable. Environmental Risks Facing Children and Recommendations for Response."

food-borne infections is higher for older adults, young children, pregnant women, and immuno-compromised persons; these groups make up about 20-25 percent of the U.S. population.[207] Protecting children and women from risks posed by chemical contaminants in food is vital if future generations are to be protected from the harmful effects of chemicals in the food supply and the environment.

Exposure Assessment in Seafood Consumers

This study assessed the level of chemical exposure that would have occurred among consumers who were over the age of 18 years but under the age of 60 years (the general adult population). The study compared the likely levels of contaminant intake in the various demographic segments of NHANES 2003-2004 consumers to determine the likely extent to which each group would be exposed. Exposure results were compared to the recommended safe exposure levels, or tolerances. The NHANES 2003-2004 subjects used in the study were divided into the following groups:

a. All seafood consumers,
b. Seafood consumers ages 18 years and below,
c. Seafood consumers between ages 18 years and 60 years, and
d. Female consumers of seafood.

The likely intake of aquaculture chemical contaminants that would have occurred in each of the groups was assessed and compared to the recommended safe exposure level—the Maximum Residue Limit (MRL). The aim was to determine whether there would be any difference between the likely levels of exposure from imported Chinese aquaculture products and the allowable safe exposure levels (MRL). Considering that many known and unknown shipments of Chinese aquaculture products were contaminated, the exposure assessment was done at various presence probabilities. This accounted for uncertainties and variability in the presence of unsafe contaminants in the imported shipments. Such variability includes facts such as: (a) not all seafood consumed in the U.S. is of aquaculture origin, and (b) not all aquaculture imports contain contaminants of concern.

[207] GAO, "The Fda's Food Protection Plan Proposes Positive First Steps but Capacity to Carry Them out Is Critical."

CREMe software was used in an effort to establish whether the dietary intake of chemicals in aquaculture imports was within safe levels. As mentioned earlier in this dissertation, the data on chemical concentrations used in this study was obtained from the FDA's residue monitoring database and, actually, featured data from 2006-2007.[208] The database contains 21,295 chemicals found in imported and locally produced food; it also contains the sampling design and the analytical procedures used during monitoring. The tests, which were performed on Chinese aquaculture imports from October 2006 to May 2007, specifically tested for contaminants in the imports through the use of targeted sampling. The second data set used in this study was that of NHANES 2003-2004 consumers. Data containing NHANES 2003-2004 dietary habits, food groups, and demographic information was a vital component of this study. These two sets of data were used in the CREMe analysis.

In the study, two CREMe simulations were run for each analysis and 500 iterations were run for each simulation. Exposure results for aquaculture chemical residues were generated and analyzed. The first simulation, done on NHANES 2003-2004 seafood consumers, was run using the actual range of concentration of chemical residues that were in Chinese aquaculture imports during the 2006-2007 sampling period. The second simulation on NHANES 2003-2004 seafood consumers was based on the fact that regulatory MRLs for related aquaculture contaminants are set at ≤ 0.2ppm; this is because tests done for chemical residues in food are run at detection levels that are slightly below 0.2ppm. The chemical contaminant exposure results from the two scenarios were analyzed and compared. The major reason for comparing the two scenarios was to determine the extent to which seafood consumers were exposed to unsafe levels of chemical contaminants in Chinese aquaculture imports. The analysis of contaminants in imports was run at presence probabilities of 0.1, 0.5, 0.8, and 1.0 for both scenarios. Similar groups of NHANES 2003-2004 seafood consumers were used for analysis in scenarios 1 and 2.

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[208] The Food and Drug Administration often monitors chemical residues in imported and locally produced food; food contaminant residue levels are also monitored based on the country of origin of the product being analyzed. Concentrations of chemical contaminants found in imports are listed against the country of origin. This is a valuable database given the diversity of chemicals and products analyzed. Seafood products are also classified based on whether they are farmed or caught in the open sea. Food and Drug Administration, "Pesticide Program: Pesticide Monitoring Database 2007."

Scenario 1: Exposure from Chinese aquaculture products in the sampling period of October 2006 to May 2007.

Table 2.5 Chemical concentrations (from the FDA)

Chemical	**Range (ppm)**
Malachite green	1.2-122
Gentian violet	2.5-26.9
Fluoroquinolone	1.9-6.9
Nitrofuran	1

Scenario 2: Exposure in a hypothetical scenario where all imports contain contaminants at levels that conform to the maximum residue limits (MRLs) of < 0.2ppm.

Table 2.6 Chemical concentrations (hypothetical, regulatory-compliant concentrations)

Chemical	**Range (ppm)**
Malachite green	0-0.2
Gentian violet	0-0.2
Fluoroquinolone	0-0.2
Nitrofuran	0-0.2

Note: Scenario 2 gives the hypothetical "safe levels" of the chemical contaminants in human food, while scenario 1 represents the range of chemical contaminants that were found in Chinese aquaculture imports in 2006-2007.

Chemical concentrations in the two scenarios were used to analyze for contaminant exposures in (a) all adult consumers in Chapter 3, (b) children consumers in Chapter 4, and (c) female consumers in Chapter 5. The next chapter—Chapter 3—seeks to answer the third research question by looking at the chemical exposures that occurred in all adult seafood consumers of imported Chinese aquaculture products.

CHAPTER 3 - Exposure in All Adult Seafood Consumers

Regulatory authorities often conduct sampling and testing for contaminants that they anticipate finding in imported products. The U.S. food safety regulators discovered certain unsafe chemicals such as gentian violet, malachite green, fluoroquinolone, and nitrofuran were present in imported Chinese aquaculture products; as a result, many U.S. consumers were probably exposed to harmful chemical contaminants in Chinese aquaculture imports. Food safety experts are unsure as to the duration of consumer exposure to the chemical contaminants before the situation was discovered and dealt with by the U.S. regulatory authorities. This section of the dissertation seeks to answer the following third research question:

3. Considering the prevailing U.S. seafood consumption patterns (amongst the entire population as well as specific sub-populations), would the dietary intake of specific chemicals from Chinese aquaculture imports be within safe levels (in a contrived scenario using actual consumption and contamination data)?

In order to best estimate the level of exposure to chemical contaminants that would have occurred among the U.S. consumers, the following assumptions were made:

a. All seafood consumed in the U.S. is of Chinese aquaculture origin (a conservative, worst-case scenario);
b. The sampling distribution of NHANES 2003-2004 consumers is the same as that of all the U.S. seafood consumers (a reasonable assumption that allows this study to take advantage of the NHANES data set);
c. There is a normal distribution of contaminants of interest in aquaculture imports (a commonly embraced assumption in studies of this kind);
d. The contamination data from 2006-2007 was used as a proxy for contamination data for 2003-2004; and
e. There is no other significant source of exposure to contaminants (a possibly unrealistic, but nonetheless appropriate assumption).

This study used the 2003-2004 U.S. seafood consumption data and the 2006-2007 FDA seafood contamination sampling data to estimate the probable chemical exposure levels among adult seafood consumers. In the analysis of the level of exposure to chemical contaminants that would have occurred among U.S. seafood consumers, 9,034 U.S. seafood consumers (also herein referred to as subjects) from the 2003-2004 NHANES subjects' database were used, and 252,035 food diaries containing the dietary habits of the same 9,034 U.S. NHANES consumers were used in CREMe. Food groups containing 201 different kinds of seafood were used in this assessment (Table 3.1). A total of 500 iterations were run for each analysis. CREMe gives exposure results in forms of the mean, standard deviation, minimum, and maximum chemical residue intakes. It also gives exposures for the 90th, 95th, 97.5th, and 99.9th percentiles of NHANES seafood consumers. Table 3.1 below is a summary of the data that was used in CREMe.

Table 3.1 CREMe data input

Table Type	Table Name	Number of Records
Subjects:	NHANES 2003-03 Subjects	9,034 distinct subjects
Diary:	NHANES 2003-2004 Diary	252035 for 9034 distinct subjects
Food Groups:	Fish 2003-2004	201

Fluoroquinolone Contaminant Exposure

Results and Discussion

Table 3.2a shows the likely fluoroquinolone contaminant intake in mg/day which, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, would have occurred among all adult NHANES seafood consumers. The table shows the likely exposure that would have occurred among upper 50th, 90th, 95th, 97.5th, and 99.9th percentiles of all adult U.S. NHANES 2003-2004 consumers. The exposure analysis was for all adult NHANES 2003-2004 consumers of imported Chinese aquaculture products. A total of 500 iterations were run for the analysis. The second similar simulation (results shown in Table 3.2b) was conducted to establish the probable residue intake levels that would have occurred among adult U.S. NHANES 2003-2004 seafood consumers. The second simulation (scenario 2) was based on the hypothetical assumption that all Chinese aquaculture imports contained contaminants at levels of 0.2 ppm or less (i.e., were MRL-compliant). Similar probability estimates were used for the two fluoroquinolone exposure scenarios. Results from the analysis show that NHANES 2003-2004 seafood consumers would have been exposed to 0.0285 mg/day fluoroquinolone residues. This would have been a higher exposure level than the 0.006 mg/day to which the subjects would have been exposed in a hypothetical scenario where all aquaculture imports contained fluoroquinolone residues within the maximum residue limit (MRL). The likely mean fluoroquinolone exposure that would have occurred among the upper 50th

percentile of adult NHANES 2003-2004 seafood consumers was 4.6 times more than the likely exposure that would have occurred in a hypothetical MRL-compliant scenario. The upper 50th percentile of NHANES 2003-2004 seafood consumers would have been exposed to 4.59 times more fluoroquinolone contaminants in scenario 1 than in scenario 2; consumers forming the upper 95th and 99.9th percentile of NHANES seafood consumers would have been exposed to 5.26 and 3.88 times more fluoroquinolone in scenario 1 than in scenario 2, respectively. Figure 3.1 below shows a comparison between the two exposure scenarios.

Table 3.2a Fluoroquinolone contaminant exposure (mg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0285	0.0208	0.2109	0.3791	1.2444
Standard Deviation	0.0008	0.0013	0.0087	0.0119	0.0978
Minimum	0.0261	0.0175	0.1834	0.3444	0.9839
Maximum	0.0308	0.0265	0.2347	0.4143	1.5961

Table 3.2b Fluoroquinolone contaminant exposure at MRL (mg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0062	0.000	0.0401	0.0888	0.3207
Standard Deviation	0.0002	0.000	0.0027	0.0038	0.0297
Minimum	0.005	0.000	0.034	0.078	0.254
Maximum	0.007	0.000	0.048	0.101	0.428

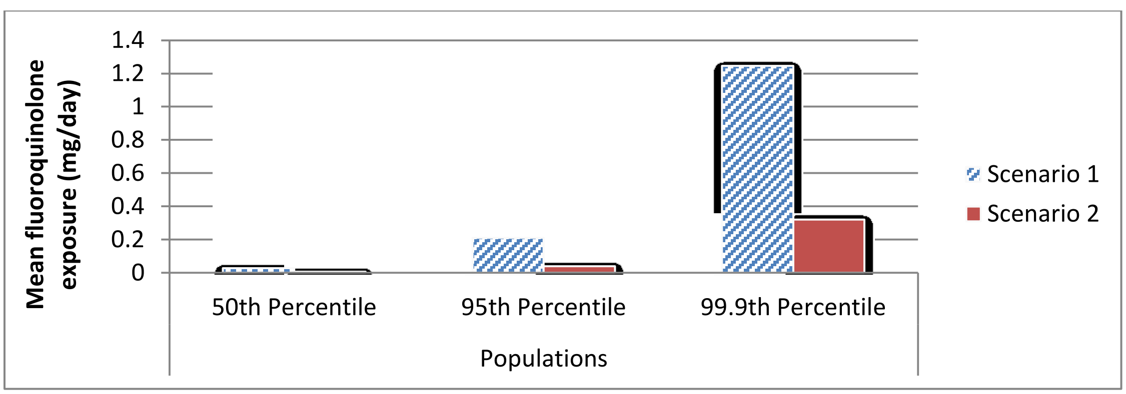

Figure 3.1. The likely mean fluoroquinolone exposure levels (in mg/day) among adult consumers. The exposure would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario) based on NHANES 2003-2004 data. The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of consumers.

Tables 3.3a and 3.3b are results for the likely exposure of aquaculture consumers to fluoroquinolone contaminant residues in milligrams per kilogram of body weight per day (mg/kg/day). The tables show the likely fluoroquinolone exposure which, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, would have resulted from Chinese aquaculture imports (Table 3.3a), and the likely exposure in the hypothetical MRL-compliant scenario (Table 3.3b). Table 3.3a shows the likely fluoroquinolone exposure that would have occurred for the upper 50th, 90th, 95th, 97.5th, and 99.9th percentiles of NHANES consumers of Chinese aquaculture products. Table 3.3b shows the likely exposure levels in mg/kg/day that would have resulted in a hypothetical MRL-compliant scenario where all imports have fluoroquinolone residues at or within the MRL. 500 iterations were run for each simulation.

Table 3.3a Fluoroquinolone contaminant intakes (mg/kg/day)

	Mean	P90	P95	P97.5	P 99.9
Mean	0.00049	0.00036	0.00034	0.00621	0.02624
Standard Deviation	0.00002	0.00003	0.00015	0.00022	0.00256
Minimum	0.00044	0.00003	0.00297	0.005623	0.01940
Maximum	0.00055	0.00047	0.00380	0.00689	0.03752

Table 3.3b Fluoroquinolone contaminant intakes at MRL (mg/kg/day)

	Mean	P90	P95	P97.5	P 99.9
Mean	0.0001	0.000	0.0007	0.0014	0.0067
Standard Deviation	0.000004	0.000	0.00004	0.00006	0.00066
Minimum	0.0001	0.000	0.0005	0.0013	0.0050
Maximum	0.0001	0.000	0.0008	0.0016	0.0098

Consumers whose diets included contaminated Chinese aquaculture products would have been exposed to mean fluoroquinolone residues of 0.00049 mg/kg body weight per day. The likely average maximum and minimum fluoroquinolone exposures would have been 0.00055 mg/kg/day and 0.00044 mg/kg/day, respectively. In the hypothetical scenario, consumers would have been exposed to a mean fluoroquinolone residue intake of 0.0001 mg/kg/day and average maximum and minimum residue exposure levels of 0.0001 mg/kg/day and 0.0001 mg/kg/day, respectively. The upper 50th percentile of NHANES 2003-2004 seafood consumers would have been exposed to 4.9 times more fluoroquinolone (per kilogram of consumer body weight per day) in scenario 1 than in scenario 2. Consumers in the upper 95th percentile and 99.9th percentile would have been exposed to

0.48 and 3.91 times more fluoroquinolone (per kilogram of consumer body weight per day) in scenario 1 than in scenario 2. Figure 3.2 below shows the comparison between the two exposure scenarios.

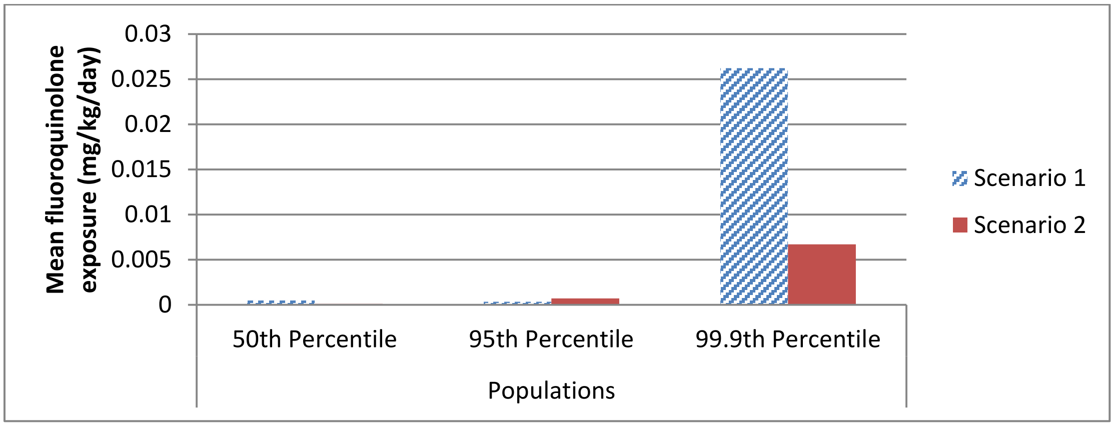

Figure 3.2. The likely mean fluoroquoquinolone exposure (in mg/kg/day) among adult consumers. The exposure would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario) based on NHANES 2003-2004 data. The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of consumers.

Gentian Violet Contaminant Exposure

Results and Discussion

Tables 3.4a and 3.4b show the likely levels of exposure of NHANES 2003-2004 consumers to gentian violet contaminant residues in milligrams per day (mg/day). The tables show the likely gentian violet exposure levels which would have occurred among the upper 50^{th}, 90^{th}, 95^{th}, 97.5^{th}, and 99.9^{th} percentiles of adult NHANES 2003-2004 seafood consumers. Table 3.4a shows the likely exposure levels that would have resulted from Chinese aquaculture imports, while table 3.4b shows the likely exposure levels that would have resulted from a hypothetical MRL- compliant scenario.

Table 3.4a Gentian violet contaminant intakes (mg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0923	0.0215	0.6405	1.2867	4.4572
Standard Deviation	0.0031	0.0015	0.0319	0.0439	0.4013
Minimum	0.0827	0.0173	0.5515	1.1662	3.5770
Maximum	0.1028	0.0281	0.7554	1.4130	5.8676

Table 3.4b Gentian violet contaminant intakes at MRL (mg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0062	0.0000	0.0408	0.0890	0.3210
Standard Deviation	0.0002	0.0000	0.0026	0.0038	0.028
Minimum	0.0055	0.0000	0.0322	0.0783	0.2407
Maximum	0.0068	0.0000	0.0491	0.1008	0.4214

The likely mean exposure that would have occurred among the upper 50th percentile of NHANES 2003-2004 seafood consumers was 14.8 times more in scenario 1 than in scenario 2 (that which would have occurred if the Chinese aquaculture imports had gentian violet at MRL-compliant levels). NHANES seafood consumers would have been exposed to high levels of gentian violet chemical residues in Chinese aquaculture imports. NHANES consumers forming the upper 99.9th percentile of all NHANES consumers would have been exposed to 13.8 times more gentian violet from imported Chinese aquaculture products (scenario 1) than in the hypothetical MRL-compliant scenario (scenario 2). Consumers forming the upper 95th percentile of NHANES 2003-2004 seafood consumers would have been exposed to 15.6 times more gentian violet from scenario 1 than from scenario 2. Figure 3.3 below shows comparison of the likely gentian violet exposure in the two scenarios.

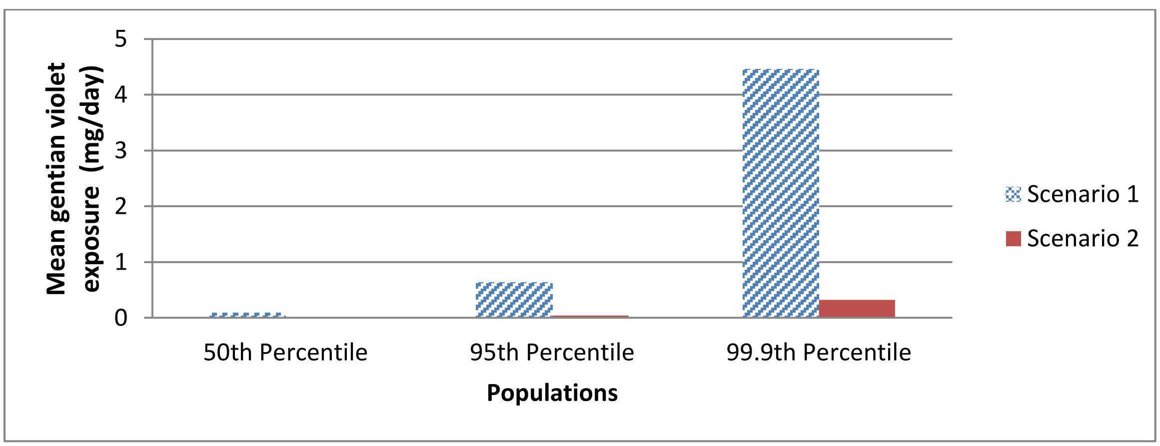

Figure 3.3. The likely mean gentian violet exposure levels (in mg/day) among adult seafood consumers. The exposure would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario) based on NHANES 2003-2004 data. The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of consumers.

Gentian violet is not "generally regarded as safe" (GRAS) for use on food animals or as a food additive. It is known to have carcinogenic and mutagenic effects on laboratory animals and humans, and is thus not permitted in food, based on section 409 of the *Food, Drug, and Cosmetic Act*. Exposure to its residues at a mean residue level of 0.0923 mg/day is a cause of concern for regulatory authorities—especially since the substance is classified as a mutagen and carcinogen. For the 95th percentile of NHANES 2003-2004 consumers, the mean gentian violet residue intake would have been 0.6405mg/day. In a hypothetical scenario in which all imports had contaminants at or below the MRLs, the likely mean residue intake for the upper 95th percentile of consumers would have been 0.0408 mg/day, while the average likely exposure resulting from contaminated imports would have been 0.6405 mg/day. A virtual experimental safe limit dose of 2.0ppm is normally used in lab experiments involving mice

Tables 3.5a and 3.5b show the results for the likely gentian violet contaminant exposure in milligrams per kilogram of consumer bodyweight per day. The tables show the likely levels of gentian violet exposure which would have occurred among the mean and the upper 50th, 90th, 95th, 97.5^{th,} and 99.9th percentiles of adult NHANES consumers. This was for all adult consumers whose diets included imported Chinese aquaculture products. Table 3.5a shows results for the likely exposure that would have resulted from Chinese aquaculture imports (scenario 1). Table 3.5b shows the likely gentian violet exposure levels that would have occurred in a hypothetical scenario where all imports contained contaminant residues at levels that conformed to the regulatory MRLs (scenario 1). A total of 500 iterations were run in each scenario.

Table 3.5a Gentian violet contaminant intakes (mg/kg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0016	0.0004	0.0103	0.0209	0.09431
Standard Deviation	0.00006	0.00003	0.00053	0.00075	0.00901
Minimum	0.0014	0.0003	0.0087	0.0188	0.0660
Maximum	0.0018	0.0005	0.0120	0.0236	0.1249

Table 3.5b Gentian violet contaminant intakes at MRL (mg/kg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0001	0.0000	0.0007	0.0014	0.0067
Standard Deviation	0.000004	0.0000	0.00004	0.00006	0.00064
Minimum	0.00009	0.0000	0.00052	0.00126	0.0048
Maximum	0.00012	0.0000	0.00080	0.00162	0.0086

A total of 8,910 seafood consumers, comprising 99.66 percent of NHANES 2003-2004 aquaculture consumers, were used in each exposure analysis. The results indicate that consumers would have been exposed to high levels of gentian violet contaminant residues per kilogram of body weight. The likely mean exposure to gentian violet contaminant from Chinese aquaculture imports would have been 0.0016 mg/kg/day, as compared to the likely hypothetical scenario exposure level of 0.0001 mg/kg/day. Considering the mean contaminant exposure among the upper 50th percentile of NHANES 2003-2004 consumers, gentian violet exposure would have been 16 times higher in imported Chinese aquaculture products (scenario 1) than in the hypothetical MRL-compliant scenario (scenario 2). Figure 3.4 below shows the comparison of gentian violet exposure in milligrams per kilogram of consumer body weight per day in the two scenarios.

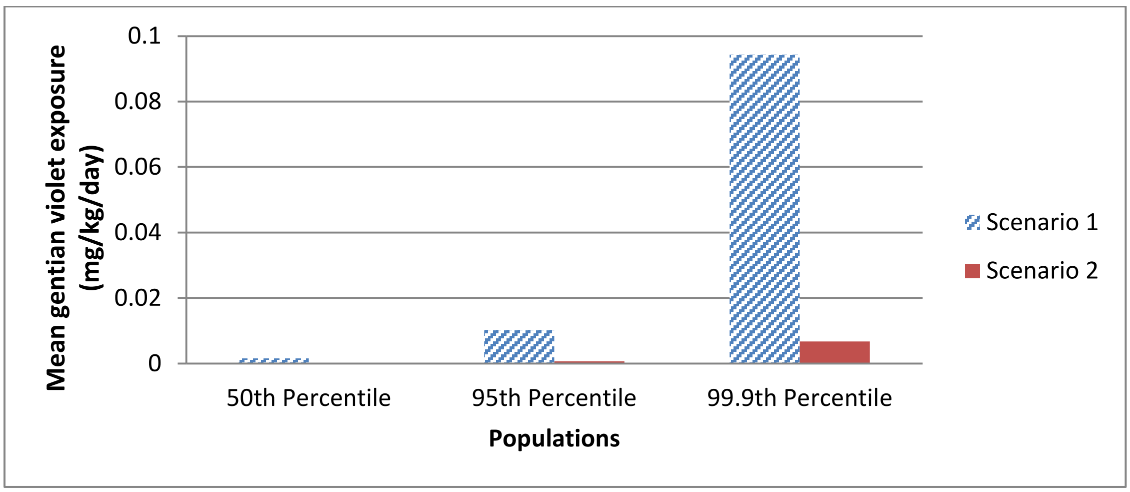

Figure 3.4. The likely mean gentian violet exposure levels (in mg/kg/day) among adult consumers. The exposure would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario) based on NHANES 2003-2004 data. The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of consumers.

Malachite Green Contaminant Exposure

Results and Discussion

Tables 3.6a and 3.6b show the likely malachite green (MG) residue intake in mg/day that would have occurred among the mean and the upper 90th, 95th, 97.5th, and 99.9th percentiles of all the 9,004 NHANES 2003-2004 adult seafood consumers. The tables show the likely MG intake which would have resulted from imported Chinese aquaculture products. 99.67 percent of all NHANES 2003-2004 adult seafood consumers were used in each analysis. Table 3.6a shows the likely levels of

MG exposure that would have resulted from imported Chinese aquaculture products (scenario 1). Table 3.6b shows the likely MG exposure that would have occurred in a hypothetical scenario where all aquaculture imports had MG contaminant residues at MRLs.

Table 3.6a Malachite green contaminant intakes (mg/day)

	Mean	P90	P95	P97.5	P 99.9
Mean	0.3840	0.0217	2.5405	5.4648	19.733
Standard Deviation	0.0143	0.0016	0.1525	0.2319	1.7317
Minimum	0.3451	0.0185	2.1593	4.7236	15.3181
Maximum	0.4285	0.0274	2.9623	6.2451	24.8725

Table 3.6b Malachite green contaminant intakes at MRL (mg/day)

	Mean	P90	P95	P97.5	P 99.9
Mean	0.0062	0.0000	0.0409	0.0891	0.3223
Standard Deviation	0.00024	0.0000	0.00256	0.00379	0.02733
Minimum	0.0055	0.0000	0.0340	0.0768	0.2598
Maximum	0.0070	0.0000	0.0497	0.1006	0.4421

Of the four contaminants studied in Chinese aquaculture imports, MG was present at much higher levels than the others. The likely mean MG exposure that would have occurred from imported Chinese aquaculture products (scenario 1) was 0.384 mg/day, the standard deviation was 0.0143, and the maximum and minimum MG exposure levels were 0.4285 mg/day and 0.3451mg/day, respectively. In a hypothetical MRL-compliant scenario (scenario 2), the likely mean MG exposure would have been 0.0062 mg/day with a standard deviation of 0.00024 and maximum and minimum levels of 0.007 mg/day and 0.0055mg/day, respectively. Figure 3.5 below shows comparison in the likely MG contaminant exposure that would have resulted from imported Chinese aquaculture imports (scenario 1) and the likely exposure that would have resulted in a hypothetical MRL-compliant scenario (scenario 2). NHANES consumers forming the upper 50th percentile of all NHANES seafood consumers would have been exposed to 61.9 times more MG per day in scenario 1 than in scenario 2. NHANES 2003-2004 consumers in the upper 95th percentile of all NHANES seafood consumers would have been exposed to 62 times more MG per day in scenario 1 than in scenario 2, while those in the upper 99.9th percentile would have been exposed to 61.2 times more MG. Figure 3.5 below shows comparisons of the likely MG exposure among the upper 50th, 95th, and 99.9th percentiles of NHANES 2003-2004 seafood consumers in scenario 1 and scenario 2.

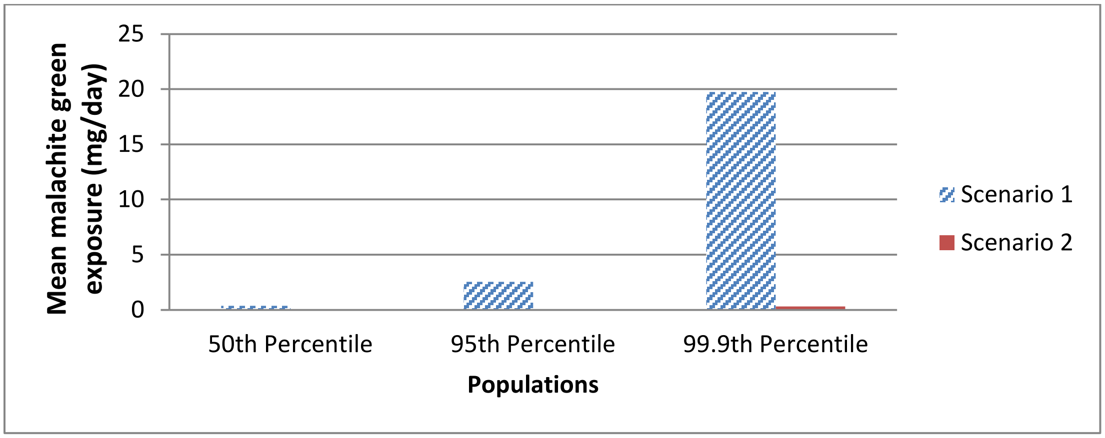

Figure 3.5. The likely mean malachite green exposure levels (in mg/day) among adult consumers. The exposure would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario) based on NHANES 2003-2004 data. The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of consumers.

Tables 3.7a and 3.7b show exposure results for the likely MG intakes in milligrams per kilogram body weight per day (mg/kg/day) that would have resulted among NHANES 2003-2004 seafood consumers. The tables show the likely MG exposure among the upper 50th, 90th, 95th, 97.5th, and 99.9th percentiles of adult NHANES seafood consumers. In total, 9,004 NHANES consumers—99.66 percent of all NHANES 2003-2004 seafood consumers whose diets included Chinese aquaculture products—were used in each analysis. Table 3.7a shows the results for the likely MG exposure that would have resulted from Chinese aquaculture imports between October 2006 and May 2007. Table 3.7b shows results for the likely MG exposure that would have occurred in a hypothetical scenario where all seafood imports contained MG residues at levels that conformed to the regulatory MRL. 500 iterations were run for each exposure scenario. Figure 3.6 below shows comparison between likely MG contaminant exposure that would have resulted from scenario 1 and scenario 2. NHANES 2003-2004 seafood consumers in the upper 50th percentile would have been exposed to 67 timed more MG from imported Chinese aquaculture products (scenario 1) than in the hypothetical MRL-compliant scenario (scenario 2). Meanwhile, consumers in the upper 95th percentile and 99.9th percentile of all seafood consumers would have been exposed to 58.7 and 61.98 times more MG respectively, in scenario 1 than in scenario 2. Figure 3.6 below shows comparisons for the likely MG exposure that would have resulted from the two scenarios.

Table 3.7a Malachite green contaminant intakes (mg/kg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0067	0.0004	0.0411	0.0889	0.4153
Standard Deviation	0.0003	0.00003	0.002	0.003	0.0403
Minimum	0.0059	0.0003	0.0340	0.0766	0.3154
Maximum	0.0075	0.0005	0.0497	0.1014	0.5559

Table 3.7b Malachite green contaminant intakes at MRL (mg/kg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0001	0.0000	0.0007	0.0014	0.0067
Standard Deviation	0.000005	0.0000	0.00004	0.00006	0.00071
Minimum	0.0001	0.0000	0.0005	0.0013	0.0051
Maximum	0.0001	0.0000	0.0008	0.0016	0.0096

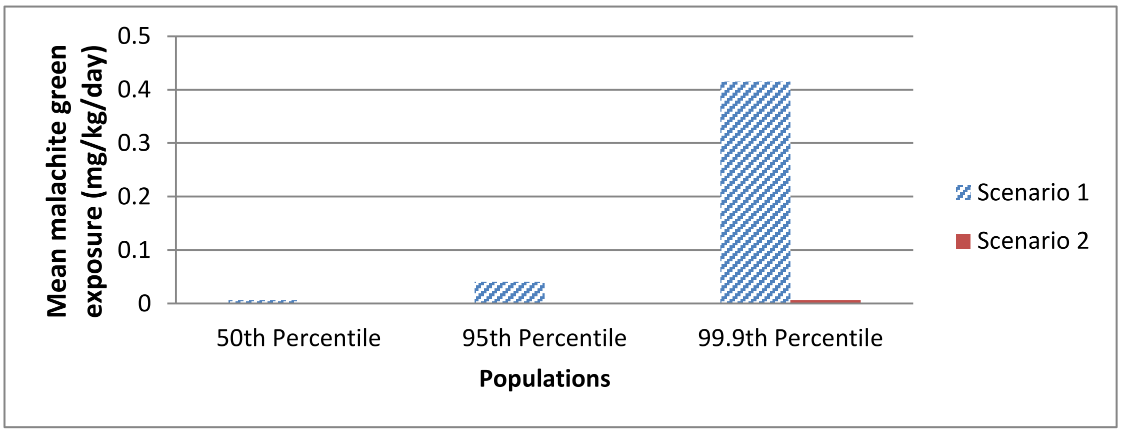

Figure 3.6. The likely mean malachite green exposure levels (in mg/kg/day) among adult consumers. The exposure would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario) based on NHANES 2003-2004 data. The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of consumers.

Nitrofuran Contaminant Exposure

Nitrofuran Contaminant Exposure (in mg/day) among All Adult Consumers

Results and Discussion

Tables 3.8a and 3.8b show the likely nitrofuran contaminant exposure in mg/day; this exposure would have occurred among the mean and the upper 90th, 95th, 97.5th, and 99.9th percentiles of all adult NHANES 2003-2004 seafood consumers. The tables show nitrofuran contaminant exposures which, in our contrived hypothetical scenario rooted in actual 2006-2007

FDA import data, would have resulted from imported Chinese aquaculture products. Table 3.8a shows the likely nitrofuran exposure that would have resulted from contaminated Chinese aquaculture imports (scenario 1). Table 3.8b shows the likely exposure that would have occurred in hypothetical scenario where all Chinese aquaculture imports had nitrofuran contaminant residues at the regulatory maximum residue limit (scenario 2). 500 iterations were run for each exposure scenario. A total of 9,004 adult NHANES 2003-2004 subjects, representing 99.66 percent of all adult NHANES 2003-2004 seafood consumers, were used in the analysis for each scenario. NHANES seafood consumers in the upper 50th percentile of seafood consumers would have been exposed to 72 times less nitrofuran contaminants from imported Chinese aquaculture products (scenario 1) than in the hypothetical MRL-compliant scenario (scenario 2). Meanwhile, NHANES seafood consumers in the upper 95th and 99.9th percentile of consumers would have been exposed to 67 and 50 times less nitrofuran contaminants from aquaculture imports, respectively. Figure 3.7 below shows comparison of the likely mean nitrofuran exposure that would have occurred between scenario 1 and scenario 2.

Table 3.8a Nitrofuran contaminant intakes (mg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0043	0.0127	0.0275	0.0482	0.1651
Standard Deviation	0.00009	0.00036	0.00081	0.00151	0.01329
Minimum	0.0039	0.0114	0.0249	0.0439	0.1328
Maximum	0.0046	0.0131	0.0300	0.0526	0.2137

Table 3.8b Nitrofuran contaminant intakes at MRL (mg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.006	0.000	0.041	0.089	0.324
Standard Deviation	0.0002	0.0000	0.0024	0.0037	0.0279
Minimum	0.0055	0.0000	0.0344	0.0783	0.2530
Maximum	0.0069	0.0000	0.0479	0.0989	0.425

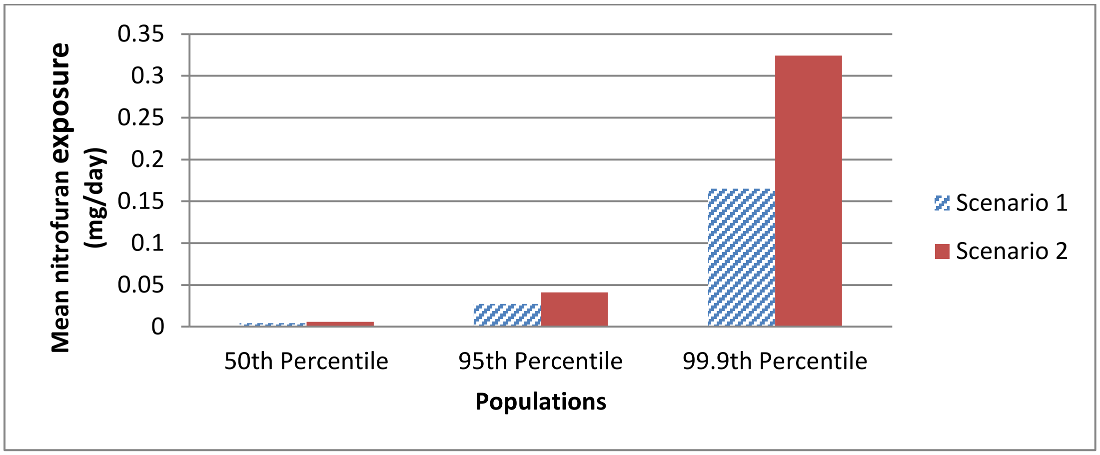

Figure 3.7. The likely mean nitrofuran exposure levels (in mg/day) among adult consumers. The exposure would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario) based on NHANES 2003-2004 data. The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of consumers.

Nitrofuran Contaminant Exposure (in mg/kg/day) among All Adult Consumers

Results and Discussion

Tables 3.9a and 3.9b are results for the likely nitrofuran contaminant residue intake in milligrams per kilogram body weight per day. The tables show the likely nitrofuran contaminant exposures which would have resulted from imported Chinese aquaculture products. This is for the upper 50th, 90th, 95th, 97.5th, and 99.9th percentiles of all NHANES 2003-2004 seafood consumers. Table 3.9a shows the results for the likely nitrofuran residue intake that would have resulted from imported Chinese aquaculture products. Table 3.9b shows the likely exposure in a hypothetical scenario where all imports contained nitrofuran residues at MRL. A total of 500 iterations were run for each scenario.

Table 3.9a Nitrofuran contaminant intakes (mg/kg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.00007	0.00019	0.00046	0.00081	0.00342
Standard Deviation	0.000001	0.000049	0.00001	0.00002	0.00032
Minimum	0.00007	0.00018	0.00041	0.00074	0.00266
Maximum	0.00008	0.00021	0.00050	0.00087	0.00455

Table 3.9b Nitrofuran contaminant intakes at MRL (mg/kg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0001	0.0000	0.0007	0.0014	0.0067
Standard Deviation	0.000004	0.00000	0.000040	0.000063	0.00063
Minimum	0.000098	0.00000	0.000535	0.001286	0.004928
Maximum	0.000122	0.00000	0.000768	0.001652	0.009103

The results in tables 3.9a and 3.9b show that the likely nitrofuran contaminants exposure that would have resulted from Chinese aquaculture imports was within safe levels. The likely mean nitrofuran intake from imports would have been 0.00007 mg/kg/day, with a standard deviation of 0.000001 and maximum and minimum intakes of 0.00008 mg/kg/day and 0.00007 mg/kg/day, respectively. The likely mean nitrofuran intake in the hypothetical scenario would have been slightly above the likely mean exposure from Chinese aquaculture imports. This shows that the likely consumers' exposure to nitrofuran contaminant residues from Chinese aquaculture imports would have been within regulatory safe levels. The likely mean nitrofuran residue exposure in the hypothetical scenario would have been 0.000108 mg/kg/day, with a standard deviation of 0.000004, and maximum and minimum average residue intake levels of 0.00012 mg/kg/day and 0.000098 mg/kg/day, respectively. Figure 3.8 below shows comparisons of the mean nitrofuran contaminant exposure that would have resulted from Chinese aquaculture imports (scenario 1), and the exposure that would have resulted in a hypothetical MRL-compliant scenario (scenario 2). The figure shows the likely exposures that would have occurred among the upper 50th 95th and 99.9th percentiles of consumers. NHANES consumers in the upper 99.9 percentile of consumers would have been exposed to 1.96 times less nitrofuran contaminants in scenario 1 than in scenario 2; the likely nitrofuran exposure among the upper 50th and 95th percentile would have been 1.4 and 1.5 times less in scenario 1 than in scenario 2, respectively. Figure 3.8 below shows comparisons of the likely nitrofuran exposure that would have occurred in scenario 1and in scenario 2.

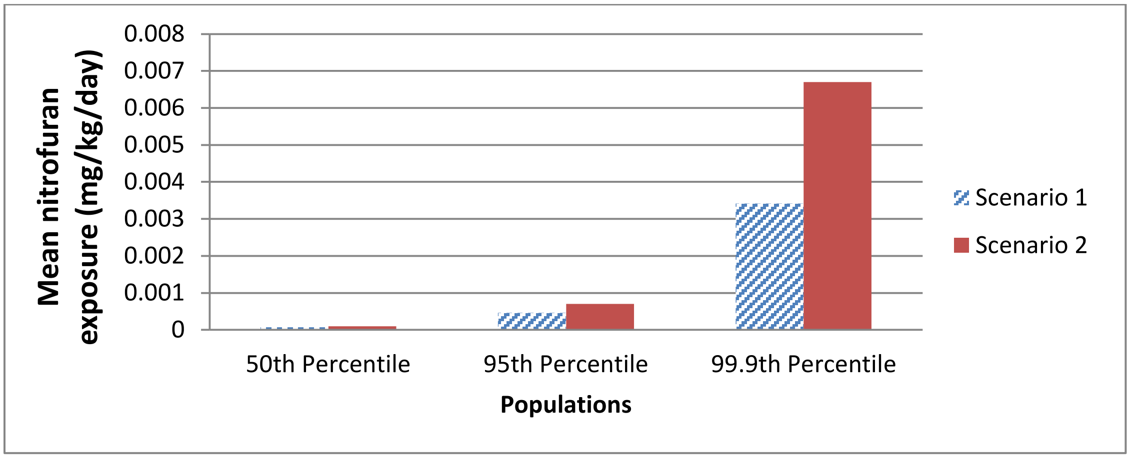

Figure 3.8. The likely mean nitrofuran exposure levels (in mg/kg/day) among adult consumers. The exposure would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario) based on NHANES 2003-2004 data. The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of consumers.

CHAPTER 4 - Exposure in Children Vs. Adult Consumers

Several factors account for variations in food intake among consumers. These include age, body weight, sex, physical activity, etc. The quantity of food consumed by adults is usually higher than that of children; however, food consumption per unit of body weight is higher in children than it is in adult consumers. This is because children have a higher index of surface area to body weight ratio than do their adult counterparts. Since children have a higher index of food consumption per unit of body weight, exposure to chemical contaminants in food has the potential to cause more serious problems in children's bodies than it would in adults' bodies. This section of the dissertation seeks to answer the following fourth research question with regard to NHANES 2003-2004 consumers who are under 18 years of age:

3. Considering the prevailing U.S. seafood consumption patterns (among the entire population as well as among specific sub-populations), would the dietary intake of specific chemicals from Chinese aquaculture imports be within safe levels (in a contrived scenario using actual consumption and contamination data)?

In order to best estimate the level of exposure to chemical contaminants among children who are under 18 years of age and adult U.S. consumers, the following assumptions were made:

a. All seafood consumed in the U.S. is of Chinese aquaculture origin (a conservative, worst-case scenario);
b. The sampling distribution of NHANES 2003-2004 consumers is the same as that of all the U.S. seafood consumers (a reasonable assumption that allows this study to take advantage of the NHANES data set);
c. There is a normal distribution of contaminants of interest in aquaculture imports (a commonly embraced assumption in studies of this kind);
d. The contamination data from 2006-2007 was used as a proxy for contamination data for 2003-2004; and
e. There is no other significant source of exposure to contaminants (a possibly unrealistic, but nonetheless appropriate assumption).

This study used the 2003-2004 U.S. seafood consumption data and the 2006-2007 FDA seafood contamination sampling data to estimate chemical exposure that would have occurred among children and adult consumers in a contrived scenario. This section specifically seeks to determine the extent of contaminant exposure that would have occurred among children less than 18 years of age. The analysis, which was done by comparing the likely levels of exposure that would have occurred in children with those in adults, helped to determine if NHANES 2003-2004 children would have been exposed to lower, equal, or higher levels of contamination than would their adult NHANES 2003-2004 counterparts. To address the research question, simulations were run on NHANES 2003-2004 seafood consumers who were under 18 years of age. A total of 252,035 food diaries, representing 4,315 NHANES consumers under the age of 18, were used in the analysis. An exposure analysis was done on four selected contaminants found in Chinese aquaculture imports: malachite green, gentian violet, nitrofuran, and fluoroquinolone. Below are tables showing summaries of the data used in the exposure analysis. Table 4.1 shows the number of subjects and the number of food diaries used in the analysis of probable contaminant exposure in children, while table 4.2 shows the number of subjects and food diaries used in the exposure analysis in adults.

Table 4.1 CREMe data input for NHANES 2003-2004 children

Table Type	Table Name	No. Records
Subjects	NHANES 2003-04 Subjects	4315 distinct subjects (Age < 18 yrs)
Diary	NHANES 2003-2004 Diary	252035 for 9034 distinct subjects
Food Groups	Fish 2003-2004	201

Table 4.2 CREMe data input for NHANES 2003-2004 adult consumers

Table Type	Table Name	No. Records
Subjects	NHANES 2003-04 Subjects	4986 distinct subjects (Age >18 yrs)
Diary	NHANES 2003-2004 Diary	252035 for 9034 distinct subjects
Food Groups	Fish 2003-2004	201

As mentioned earlier in this chapter, this study used the 2003-2004 U.S. seafood consumption data and the 2006-2007 FDA seafood contamination sampling data to estimate chemical exposure levels that would have occurred in children and adult seafood consumers in a contrived scenario.

Fluoroquinolone Contaminant Exposure in Children vs. Adults

Results and Discussion

The results below were obtained from a comparative exposure analysis that was conducted for NHANES 2003-2004 consumers less than 18 years of age and adult NHANES 2003-2004 consumers.

Table 4.3a Fluoroquinolone contaminants intakes in children (mg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0144	0.0000	0.0631	0.2181	0.8901
Standard Deviation	0.00081	0.0000	0.0124	0.0149	0.0934
Minimum	0.0122	0.0000	0.0243	0.1782	0.6284
Maximum	0.0165	0.0000	0.1079	0.2591	1.1860

Table 4.3a shows results for the likely fluoroquinolone exposure that would have occurred among consumers aged 18 years and under (children). About 50 percent of NHANES 2003-2004 children whose diets included imported Chinese aquaculture products would have been exposed to an average of 0.014 mg/day of fluoroquinolone contaminant in their diets. The upper 50-99.9 percentile of NHANES 2003-2004 children would have been exposed to average fluoroquinolone residue levels of 0.014-1.186 mg/day. The likely fluoroquinolone exposure levels in both NHANES 2003-2004 adults and NHANES 2003-2004 children would have been within the established acceptable daily intake (ADI) level of 0.03 mg/kg/day in food. Therefore, it is probable that fluoroquinolone contaminants in imported Chinese aquaculture products would have posed less risk to children.

Table 4.3b Fluoroquinolone contaminant intakes in adults (mg/day)

	Mean	P90	P95	P97.5	P99.9
Mean	0.0398	0.0973	0.3022	0.4621	1.3995
Standard Deviation	0.0014	0.0131	0.0125	0.0155	0.1384
Minimum	0.0359	0.0588	0.2616	0.4140	1.0220
Maximum	0.0449	0.1341	0.3442	0.5081	1.9512

Table 4.3b shows results for the likely fluoroquinolone contaminant exposure which would have resulted from imported Chinese aquaculture products. The likely exposure would have occurred among NHANES 2003-2004 adults. The upper 99.9th percentile of aquaculture-consuming NHANES adults would have been exposed to fluoroquinolone residues at levels above the ADI. Aquaculture consumer exposure to the fluoroquinolone contaminant would have been within acceptable levels. The upper 50th percentile of NHANES 2003-2004 adult seafood consumers would

have been exposed to an average level of 0.039 mg/day of fluoroquinolone contaminant. Meanwhile, adult consumers in the upper 50th, 95th, and 99.9th percentiles of NHANES 2003-2004 seafood consumers would have been exposed to 2.76, 4.79, and 1.57 times more fluoroquinolone residue, respectively, from imported Chinese aquaculture products than the corresponding children consumers. Figure 4.1 below shows a comparison for the likely exposure that would have occurred among NHANES 2003-2004 adult seafood consumers versus the exposure that would have occurred among children consumers.

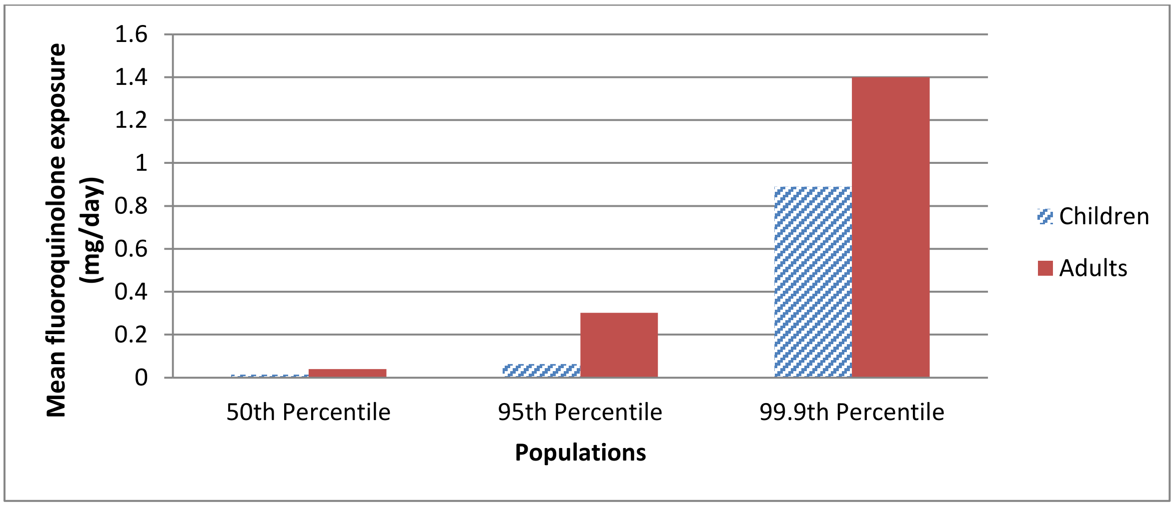

Figure 4.1. The likely mean fluoroquinolone exposure levels (in mg/day) among adults vs. children. The figure shows exposure that would have occurred among adult seafood consumers compared to that which would have occurred among children consumers based on NHANES 2003-2004 data. The figure shows the likely exposure that would have occurred among the upper 50th, 95th, and 99.9th percentiles of consumers.

Fluoroquinolone Exposure (mg/kg/day) among Adults vs. Children Consumers

Results and Discussion

The Joint FAO/ WHO Expert Committee on Food Additives established an ADI level of 0.03 mg/kg /day for fluoroquinolone residues in food.[209] Tables 4.4a and 4.4b show results for the likely fluoroquinolone exposures that would have occurred among the NHANES 2003-2004 seafood consumers. The likely fluoroquinolone exposure levels among the NHANES 2003-2004 children

[209] Erica Maharg Mary Bottari, Todd Tucker, Lori Wallach., "Trade Deficit in Food Safety: Proposed Nafta Expansions Contribute to Unsafe Food Imports," in *Public Citizen* (Washington, DC: Public Citizen's Global Trade Watch, 2007).

whose diets included imported Chinese aquaculture products would have been lower than exposure among adult seafood consumers. However, a small proportion of NHANES 2003-2004 consumers—approximately 0.1 percent (those at the upper end of the output distribution)—would have been exposed to high levels of fluoroquinolone residues in imported Chinese aquaculture products.

The exposure results on NHANES 2003-2004 adult consumers in table 4.4b shows that the likely adult exposure to fluoroquinolone residues that would have resulted from Chinese aquaculture imports would have been low. The upper 99.9th percentile of NHANES 2003-2004 children consumers would have been exposed to higher levels of fluoroquinolone contaminants than their adult counterparts. Figure 4.2 below shows comparison of the likely fluoroquinolone exposure levels that would have occurred between children and adult seafood consumers. The figure shows the likely exposures that would have occurred among the upper 50th, 95th, and 99.9th percentile of NHANES 2003-2004 children and adult seafood consumers of imported Chinese aquaculture products. The upper 50th and 95th percentile of NHANES 2003-2004 adult seafood consumers would have been exposed to 1.25 times and 2.05 times more fluoroquinolone per kilogram body weight, respectively, than their corresponding children consumers. Meanwhile, NHANES 2003-2004 children consumers in the upper 99.9th percentile of consumers would have been exposed to 1.68 times more fluoroquinolone per kilogram of body weight than their adult counterparts.

Table 4.4a Fluoroquinolone contaminant intakes in children (mg/kg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.0004	0.0000	0.0019	0.0061	0.0171	0.0322
Standard Deviation	0.0000	0.0000	0.0004	0.0004	0.0014	0.0044
Minimum	0.0004	0.0000	0.0008	0.0049	0.0132	0.0227
Maximum	0.0005	0.0000	0.0030	0.0073	0.0220	0.0502

Table 4.4b Fluoroquinolone contaminant intakes in adults (mg/kg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.0005	0.0012	0.0039	0.0062	0.0121	0.0191
Standard Deviation	0.00002	0.00002	0.00002	0.00022	0.0007	0.00177
Minimum	0.0005	0.0007	0.0033	0.0055	0.0099	0.0140
Maximum	0.0006	0.0017	0.0044	0.0067	0.0143	0.0251

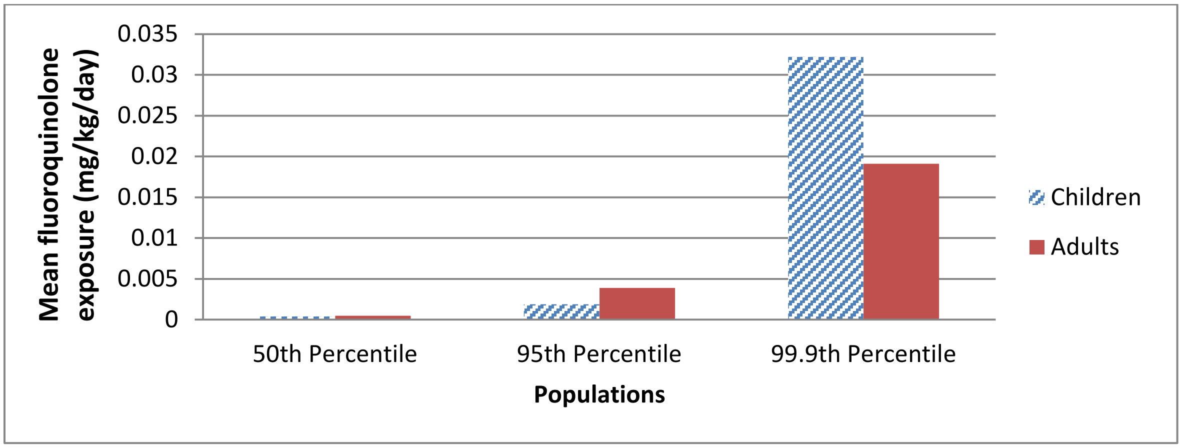

Figure 4.2. The likely mean fluoroquinolone exposure levels (in mg/kg/day) among adults vs. children. The figure shows exposure that would have occurred among adult seafood consumers compared to that which would have occurred among children consumers based on NHANES 2003-2004 data. The figure shows the likely exposure that would have occurred among the upper 50th, 95th, and 99.9th percentiles of consumers.

Gentian Violet Contaminant Exposure in Children vs. Adults

Results and Discussion

Table 3.14a shows the likely exposure for gentian violet contaminants which would have resulted from Chinese aquaculture imports. Gentian violet is currently listed under Part 589 of the *Code of Federal Regulations* (CFR). Drugs listed under Part 589 of the CFR are prohibited for use in animal food, subject to Subpart 589.1 of the CFR.[211] There are no established acceptable daily intake (ADI) levels for the drugs listed under Part 589 of the CFR; therefore, human food containing traces of the drug residues listed under this part are considered to be unsafe for consumption. Tables 4.5a and 4.5b show the likely levels of gentian violet exposure that would have resulted from consumption of imported Chinese aquaculture products. The exposure analysis was done using available data from different years; the study used data from the 2003-2004 U.S. NHANES food consumption pattern and the 2006-2007 FDA contaminant sampling data.

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[211] The EU has an established zero ppm maximum residue limit (MRL) for nitrofuran and chloramphenicol drug residues in milk, pork, and meat. The EU also has MRLs of 50-100ppm for most fluoroquinolones e.g. Flumequin, Marbofloxacine, Difloxacine, and Erythromycine: European Regulation n°2377/90/CEE. The U.S., on the other hand, has no established MRL or ADI for these chemical contaminants listed under Part 589 of the *U.S. Code of Federal Regulation.*

NHANES 2003-2004 children would have been exposed to high levels of gentian violet residues in imported Chinese aquaculture products. NHANES 2003-2004 children in the upper 95th percentile would have been exposed to excessive levels of gentian violet in the imported Chinese aquaculture products. The mean gentian violet exposure level among children would have been 0.0481 mg/day, while the highest exposure level—4.4559 mg/day—would have occurred among the upper 99.9th percentile of NHANES 2003-2004 children.

Table 4.5a Gentian violet contaminant intakes in children (mg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.0481	0.0000	0.1666	0.6951	1.9109	3.2478
Standard Deviation	0.0030	0.0000	0.0388	0.0579	0.1483	0.3477
Minimum	0.0365	0.0000	0.0000	0.4749	1.5483	2.3863
Maximum	0.0584	0.0000	0.2867	0.8967	2.5360	4.4559

Table 4.5b Gentian violet contaminant intakes in adults (mg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.1291	0.2390	0.9681	1.6131	3.1547	5.0633
Standard Deviation	0.0053	0.0369	0.0497	0.0646	0.1883	0.5346
Minimum	0.1148	0.1399	0.8327	1.3992	2.6405	3.8558
Maximum	0.1461	0.3435	1.1177	1.8167	3.7962	6.8979

Table 4.5a shows the likely daily intakes of gentian violet contaminants per kilogram of body weight which, in our contrived hypothetical scenario rooted in actual import data, would have occurred among NHANES 2003-2004 children. This exposure would have occurred among children whose diets included imported Chinese aquaculture products. As mentioned earlier in this dissertation, the index of food consumption per kilogram of body weight is usually higher than in children than it is in adults. This makes it plausible that children take in more chemical contaminants per unit body weight than do adult consumers. The results in tables 4.5a and 4.5b show the likely exposures that would have occurred in both children and adults. On average, NHANES 2003-2004 children would have been exposed to lower levels of gentian violet than their adult counterparts. NHANES 2003-2004 children at the upper end of the output distribution would have nevertheless been exposed to higher levels of cancerous chemical contaminants in food than would NHANES 2003-2004 adults. Table 4.5b shows the likely gentian violet exposures that would have occurred among adult seafood consumers. The average daily exposure level for this category of consumers would have been 0.1291 mg/day. Based on gentian violet's potential to cause cancer, these daily

exposure levels would have been extremely high. Adult NHANES 2003-2004 consumers would have been exposed to unsafe levels of gentian violet contaminants in the imported Chinese aquaculture products. NHANES 2003-2004 adult consumers at the upper 50th, 95th and 99.9th percentiles would have been exposed to 2.6, 5.8, and 1.5 times more gentian violet, respectively, than their corresponding NHANES children consumers.

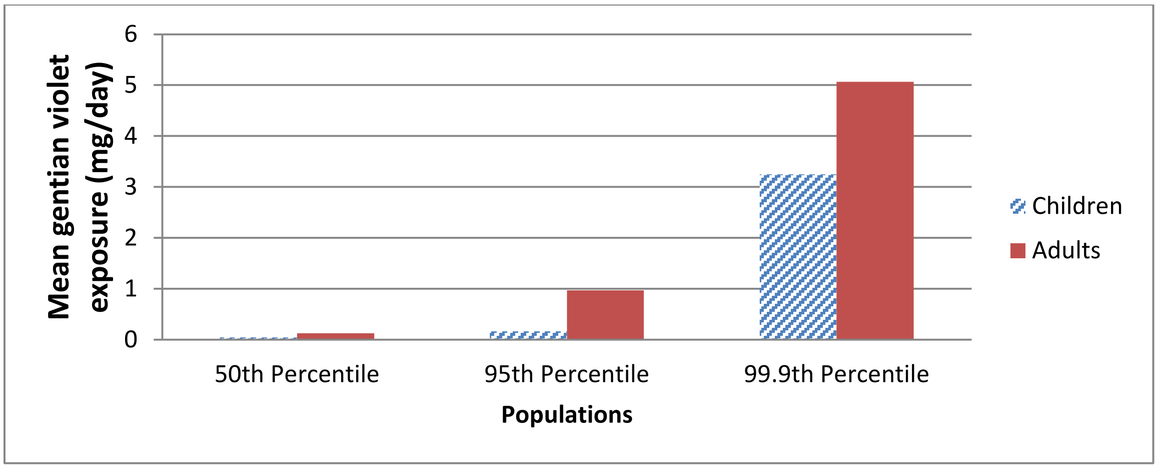

Figure 4.3. The likely mean gentian violet exposure levels (in mg/day) among adults vs. children. The figure shows exposure that would have occurred among adult seafood consumers compared to that which would have occurred among children consumers based on NHANES 2003-2004 data. The figure shows the likely exposure that would have occurred among the upper 50th, 95th, and 99.9th percentiles of consumers.

Tables 4.6a and 4.6b show the likely exposures for gentian violet in milligrams per kilogram body weight that would have occurred among NHANES 2003-2004 consumers. The results show the likely exposures which would have occurred among NHANES consumers whose diets included imported Chinese aquaculture products. This study used data from different years; the study used data from the 2003-2004 U.S. NHANES seafood consumption pattern and the 2006-2007 FDA contaminant sampling data. Table 4.6a shows the likely exposures that would have occurred among NHANES 2003-2004 children consumers, while Table 4.6b shows the likely exposures that would have occurred among NHANES 2003-2004 adult consumers. Adult NHANES seafood consumers in the upper 50th and 99.9th percentile would have been exposed to 1.13 and 2.53 times more gentian violet from imported Chinese aquaculture imports, respectively, than their corresponding NHANES children consumers. Meanwhile, NHANES children in the upper 99.9th percentile of NHANES seafood consumers would have been exposed to 1.6 times more gentian violet from imported Chinese aquaculture products than their adult counterparts.

Table 4.6a Gentian violet contaminant intakes in children (mg/kg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.0015	0.0000	0.0049	0.0198	0.0591	0.1130
Standard Deviation	0.0001	0.0000	0.0011	0.0016	0.0053	0.0171
Minimum	0.0011	0.0000	0.0000	0.0147	0.0456	0.0754
Maximum	0.0017	0.0000	0.0087	0.0244	0.0778	0.1904

Table 4.6b Gentian violet contaminant intakes in adults (mg/kg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.0017	0.0030	0.0124	0.0212	0.0433	0.0699
Standard Deviation	0.0000	0.0004	0.0006	0.0009	0.0026	0.0069
Minimum	0.0015	0.0016	0.0107	0.0187	0.0366	0.0511
Maximum	0.0019	0.0045	0.0143	0.0250	0.0515	0.0914

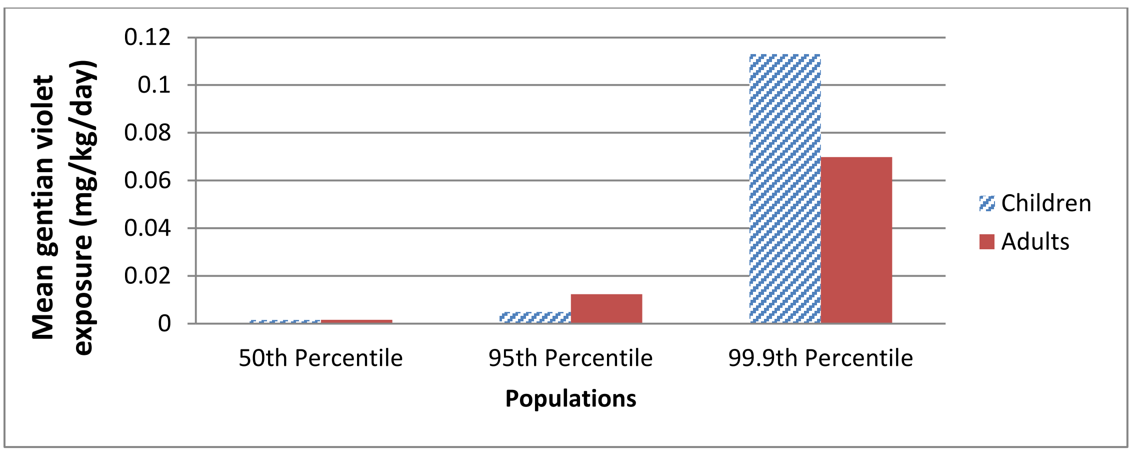

Figure 4.4. The likely mean gentian violet exposure levels (in mg/kg/day) among adults vs. children. The figure shows exposure that would have occurred among adult seafood consumers compared to that which would have occurred among children consumers based on NHANES 2003-2004 data. The figure shows the likely exposure that would have occurred among the upper 50th, 95th, and 99.9th percentiles of consumers.

Malachite Green Contaminant Exposure in Children vs. Adults

Results and Discussion

Results show that NHANES 2003-2004 consumers of imported Chinese aquaculture products would have been exposed to high levels of the malachite green (MG) contaminant. Of particular concern were those consumers at the upper end of the output distribution, who would have been exposed to as much as 20 mg/day in MG residues. The likely MG exposure level among the upper 99.9th percentile of NHANES 2003-2004 children whose diets included imported Chinese aquaculture products would have been 14.42 mg/day. Similarly, NHANES 2003-2004 adult consumers of Chinese aquaculture products would have been exposed to an average of 0.5379 mg/day of MG chemical residues. Consumers who are at the upper end of the output distribution would have been exposed to high levels of MG from the imported Chinese aquaculture products. The results obtained from this research can be of vital use in developing and implementing policies aimed at protecting vulnerable subpopulations from unapproved and dangerous chemicals that may be present in imported products. The exposure analysis gives a clear picture of the extent to which seafood consumers would have been exposed to malachite green contaminants from imported Chinese aquaculture products. The U.S. food safety regulators such as the FDA and the FSIS often test for contaminants that have, historically, been present in human food. However, changes in strategy may be necessary in order to achieve an increased level of consumer protection from chemical contaminants in imported products. Such changes may include adjustment of routine sampling and testing procedures to include occasional sampling and testing of all chemicals that have historically been in food. The changes may also entail random testing for chemicals that have no known history of use in human food.

In the results of the exposure analysis for MG contaminant intakes among NHANES 2003-2004 consumers, seafood consumers would have been exposed to high levels of MG contaminants from imported Chinese aquaculture products. This study used data from different years to analyze consumer exposure to MG; the study used the 2003-2004 U.S. NHANES seafood consumption data and the 2006-2007 FDA contaminant sampling data. Tables 4.7a and 4.7b show the likely MG intakes which, in our contrived hypothetical scenario rooted in actual import data, would have occurred among NHANES 2003-2004 seafood consumers.

Table 4.7a shows results for the likely MG exposure that would have occurred among NHANES 2003-2004 children, while table 4.7b shows the likely MG exposure that would have occurred among NHANES 2003-2004 adult consumers. Little is known about the effects of MG on the human body, but previous studies done on other animal species indicate that MG has carcinogenic effects. Limited data is available on the effects of the chemical on man. The use of MG is prohibited in human food; consequently, the presence of the chemical in food, particularly as a result of intentional use, is considered an adulteration of the food. Both the NHANES 2003-2004 children as well as the NAHANES 2003-2004 adults would have been exposed to extremely high levels of MG contaminant in imported Chinese aquaculture products.

Table 4.7a Malachite green contaminant intakes in children (mg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.2005	0.0000	0.5047	2.8468	0.0433	14.4189
Standard Deviation	0.0138	0.0000	0.1530	0.2529	0.0026	1.6883
Minimum	0.1595	0.0000	0.0957	2.1426	0.0366	9.1321
Maximum	0.2382	0.0000	0.9440	3.6083	0.052	20.1170

Table 4.7b Malachite green contaminant intakes in adults (mg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.5379	0.6961	3.9981	6.9610	10.6183	22.6567
Standard Deviation	0.0246	0.1619	0.2321	0.3084	0.5144	2.5071
Minimum	0.4695	0.2699	3.3897	5.8577	9.4388	16.9488
Maximum	0.6162	1.1822	4.7790	7.7731	12.9290	31.1886

Tables 4.7a and 4.7b show the likely average daily consumer exposure to malachite green in milligrams per day. Given that MG is prohibited in human food, the levels of the likely exposure that would have occurred in children (see Table 4.7a) were extremely high, particularly for NHANES 2003-2004 children. In the U.S., MG is considered to be a carcinogen and thus has no established ADI (acceptable daily intake). Its presence in human food is prohibited. Continued probable exposure of vulnerable subpopulations to carcinogenic contaminants in food imports raises serious public health concerns and calls for serious policy review. The likely mean level of exposures that would have occurred among the upper 99.9th percentile of NHANES 2003-2004 children was 14.4189 mg/day, with a standard deviation of 1.6883 and maximum and minimum exposure levels of 20.117 and 9.1321 mg/day, respectively. NHANES 2003-2004 adults would have been exposed to high levels of MG. The likely mean MG exposure among the upper 99.9th percentile of adult NHANES 2003-2004 consumers would have been 22.6567 mg/day, with a standard deviation of 2.5071 and maximum and minimum exposure levels of 31.1886 and 16.9488 mg/day, respectively.

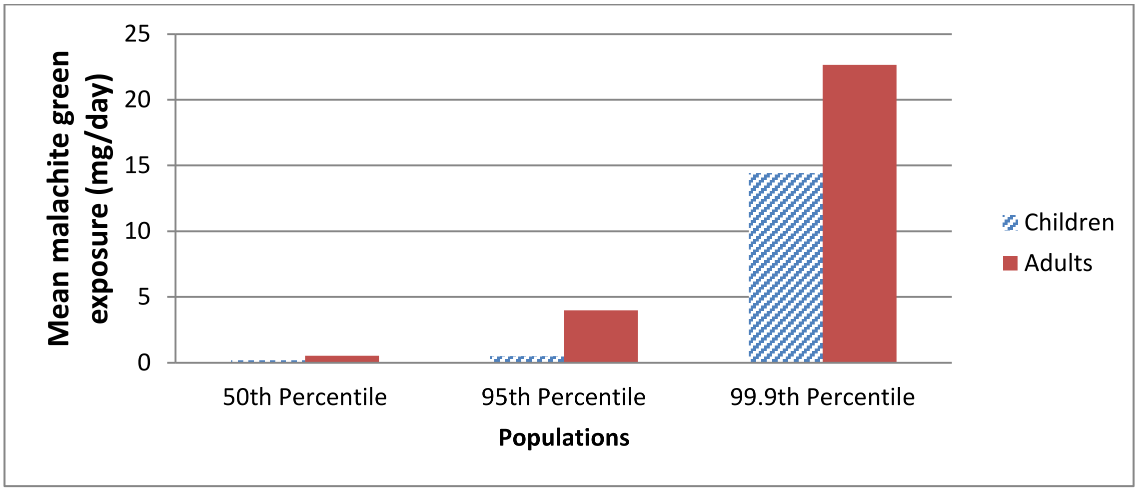

Figure 4.5. The likely mean malachite green exposure levels (in mg/day) among adults vs. children. The figure shows exposure that would have occurred among adult seafood consumers compared to that which would have occurred among children consumers based on NHANES 2003-2004 data. The figure shows the likely exposure that would have occurred among the upper 50th, 95th, and 99.9th percentiles of consumers.

Tables 4.8a and 4.8b show results for the likely MG exposures in milligrams per kilogram of NHANES 2003-2004 consumers' body weight. The tables show the likely MG exposures which would have occurred among NHANES seafood consumers. This study used the 2003-2004 U.S. NHANES seafood consumption data and the 2006-2007 FDA contaminant monitoring data. Table 4.8a shows the likely MG exposure results that would have occurred among the various percentiles of NHANES 2003-2004 children, while table 4.8b shows the likely MG exposures that would have occurred among the various percentiles of NHANES 2003-2004 adult seafood consumers.

Table 4.8a Malachite green contaminant intakes in children (mg/kg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.0061	0.0000	0.0148	0.0811	0.2572	0.5026
Standard Deviation	0.0004	0.0000	0.0046	0.0073	0.0244	0.0805
Minimum	0.0049	0.0000	0.0031	0.0614	0.1839	0.3099
Maximum	0.0075	0.0000	0.0309	0.1036	0.3398	0.8029

Table 4.8b Malachite green contaminant intakes in adults (mg/kg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.0071	0.0089	0.0514	0.0914	0.1902	0.3106
Standard Deviation	0.0003	0.0020	0.0029	0.0042	0.0126	0.0323
Minimum	0.0061	0.0033	0.0437	0.0781	0.1196	0.2177
Maximum	0.0081	0.0149	0.0615	0.1027	0.1524	0.4460

The likely MG exposure that would have occurred among NHANES 2003-2004 children was lower than the likely exposure that would have occurred among NHANES 2003-2004 adult consumers. The likely exposures which would have occurred in the upper 50th, and 95th percentiles of NHANES 2003-2004 children, were lower than the likely exposures that would have occurred among the corresponding adult consumers. Children in the upper 50th and 95th percentile would have been exposed to 1.16 and 3.47 times lower levels of malachite green than their adult counterparts. However, the likely exposure per kilogram body weight per day among children in the upper 99.9th percentile would have been 1.6 times higher than the exposure among the corresponding percentiles of NHANES 2003-2004 adult consumers.

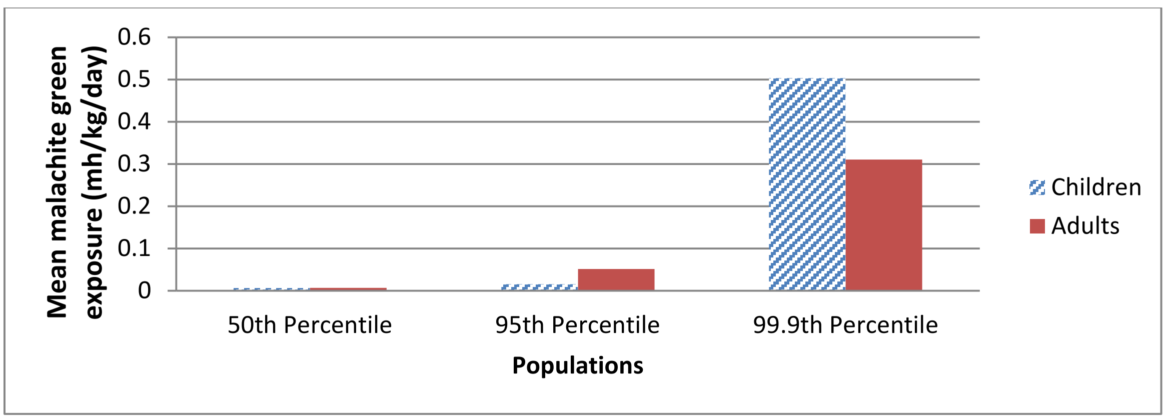

Figure 4.6. The likely mean malachite green exposure levels (in mg/kg/day) among adults vs. children. The figure shows exposure that would have occurred among adult seafood consumers compared to that which would have occurred among children consumers based on NHANES 2003-2004 data. The figure shows the likely exposure that would have occurred among the upper 50th, 95th, and 99.9th percentiles of consumers.

Nitrofuran Contaminant Exposure in Children vs. Adults

Results and Discussion

Tables 4.9a and 4.9b show results for the likely nitrofuran contaminant intakes in milligrams per day for the NHANES 2003-2004 children and adult consumers of imported Chinese aquaculture products. The tables show the likely nitrofuran contaminant exposures which, in our contrived hypothetical scenario rooted in actual import data, occurred in different percentiles of NHANES consumers. This study used the 2003-2004 U.S. NHANES food consumption data and the 2006-2007 FDA contaminant sampling data. Table 4.9a shows the likely exposure that occurred among NHANES 2003-2004 children, while table 4.9b shows the likely exposure that occurred among

NHANES 2003-2004 adult consumers. Exposure levels of the two groups were compared to determine whether exposure levels among children consumers were higher than those among adult consumers.

Table 4.9a Nitrofuran contaminant intakes in children (mg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.0016	0.0000	0.0039	0.0231	0.0681	0.1174
Standard Deviation	0.0001	0.0000	0.0014	0.0022	0.0052	0.0133
Minimum	0.0013	0.0000	0.0000	0.0169	0.0556	0.0816
Maximum	0.0019	0.0000	0.0083	0.0299	0.0847	0.1705

Table 4.9b Nitrofuran contaminant intakes in adults (mg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.0059	0.0186	0.0379	0.0601	0.0116	0.1872
Standard Deviation	0.0002	0.0006	0.0016	0.0023	0.0074	0.0184
Minimum	0.0056	0.0173	0.0334	0.0539	0.0922	0.1427
Maximum	0.0065	0.0204	0.0427	0.0677	0.1429	0.2549

The NHANES 2003-2004 adults would have been exposed to higher levels of nitrofuran chemical residues from imported Chinese aquaculture products than NHANES 2003-2004 children. There was a slight difference in the daily nitrofuran exposures between the would be exposure in NHANES 2003-2004 children and NHANES 2003-2004 adult consumers, as seen in table 4.9a and 4.9b.

The maximum residue limit (MRL) set by the U.S. and EU for the family of nitrofuran compounds is zero parts per million for milk, pork, meat, chicken, fish, and their products. The limits are set at zero because nitrofuran chemical contaminants that are in food pose a high risk to consumers.[212] NHANES 2003-2004 children would be exposed to 0.0016 mg/day of nitrofuran contaminants from imported Chinese aquaculture products. NHANES 2003-2004 consumers, who formed the upper end of the exposure distributions, would be exposed to high levels of nitrofuran residues in the imported Chinese aquaculture products. One possible explanation for the high level of exposure is that some individuals may have consumed larger amounts of seafood than others.

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[212] Food and Drug Administration, "Animal Drugs, Feeds, and Related Products," in *21 CFR 558*, ed. Department of Health and Human Services (Electronic Code of Federal Regulations: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=708082aaf4d65d2eb4441bbc7a3925f4&rgn=div8&view=text&node=21:6.0.1.1.18.1.1.5&idno=21).

Another possible explanation is that some individuals may have consumed seafood more frequently than others, resulting in increased exposure to chemical contaminants. The maximum nitrofuran exposure level among the upper 99.9th percentile of NHANES 2003-2004 children would be 0.1705 mg/day, while the minimum exposure level would be 0.0816 mg/day. On average, the upper 50th percentile of NHANES 2003-2004 children would be exposed to mean nitrofuran contaminant intake levels of 0.0016 mg/day. Adult consumers in the upper 50th, 95th, and 99.9th percentile would be exposed to 3.68, 9.72, and 1.59 times more nitrofuran contaminants, respectively, than the corresponding group of NHANES children.

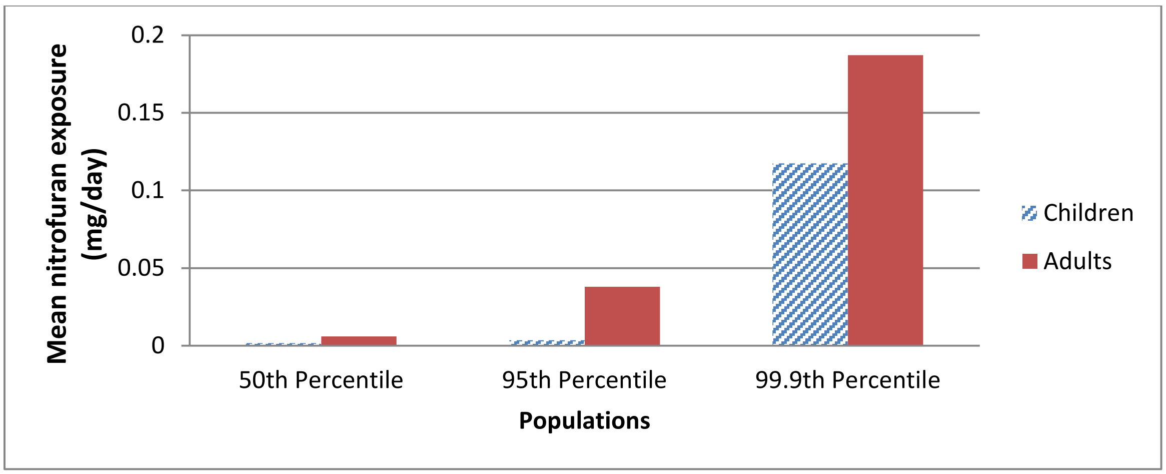

Figure 4.7 The likely mean nitrofuran exposure levels (in mg/day) among adults vs. children. The figure shows exposure that would have occurred among adult seafood consumers compared to that which would have occurred among children consumers based on NHANES 2003-2004 data. The figure shows the likely exposure that would have occurred among the upper 50th, 95th, and 99.9th percentiles of consumers.

Tables 4.10a and 4.10b show the likely nitrofuran exposure levels in milligrams per kilogram of NHANES 2003-2004 seafood consumer body weight. The tables show the likely nitrofuran exposures which, in our contrived hypothetical scenarios rooted in actual import data, would occur among NHANES 2003-2004 seafood consumers. This study used the 2003-2004 U.S. NHANES food consumption data and the 2006-2007 FDA contaminant sampling data. Table 4.10a shows the likely exposure levels that would have occurred among NHANES 2003-2004 children, while table 4.10b shows the likely exposure levels that would have occurred among the NHANES 2003-2004 adult consumers. The NHANES 2003-2004 children, who form the upper end of the output distribution (in the 99.9th percentile), would be exposed to higher levels of nitrofuran contaminants than all of the NHANES 2003-2004 adult consumers. Overall, aside from those consumers who form the upper end of the output distributions (97.5th-99.9th percentiles), there would be negligible exposures among NHANES 2003-2004 children and adult consumers.

Table 4.10a Nitrofuran contaminant intakes in children (mg/kg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.00005	0.0000	0.0001	0.0006	0.0021	0.0040
Standard Deviation	0.000003	0.0000	0.0000	0.0000	0.0002	0.0006
Minimum	0.00003	0.0000	0.0000	0.0004	0.0016	0.0026
Maximum	0.00006	0.0000	0.0003	0.0008	0.0028	0.0066

Table 4.10b Nitrofuran contaminant intakes in adults (mg/kg/day)

	Mean	P90	P95	P97.5	P99.5	P99.9
Mean	0.000079	0.0002	0.0004	0.0007	0.00160	0.0026
Standard Deviation	0.000002	0.0000	0.0000	0.0000	0.00009	0.0000
Minimum	0.000073	0.0000	0.0004	0.0007	0.00132	0.0020
Maximum	0.0000866	0.0003	0.0006	0.0008	0.00193	0.0034

While the amount of food consumed by adults is normally higher that that consumed by children, the index of the amount food consumed per kilogram of an individual's body weight is often higher for children than it is for adults. The high surface area to body weight ratio in children accounts for this difference. Since children consume more food per kilogram of body weight, their relative exposure to contaminants is likely to be higher than that of adults. There would be higher levels of exposure among NHANES 2003-2004 children who form the upper end of the output distribution than there would be among the corresponding NHANES 2003-2004 adult consumers. The likely exposures among the 99.5th-99.9th percentiles of NHANES 2003-2004 consumers would be higher in NHANES 2003-2004 children than in their NHANES 2003-2004 adult counterparts. NHANES 2003-2004 adult consumers in the upper 50th and 95th percentile would be exposed to 1.58 and 4 times more nitrofuran per kilogram body weight, respectively, than their corresponding adult counterparts. Meanwhile, the upper 99.9th percentile of NHANES children consumers would be exposed to 1.5 times more nitrofuran contaminants than their corresponding adult counterparts.

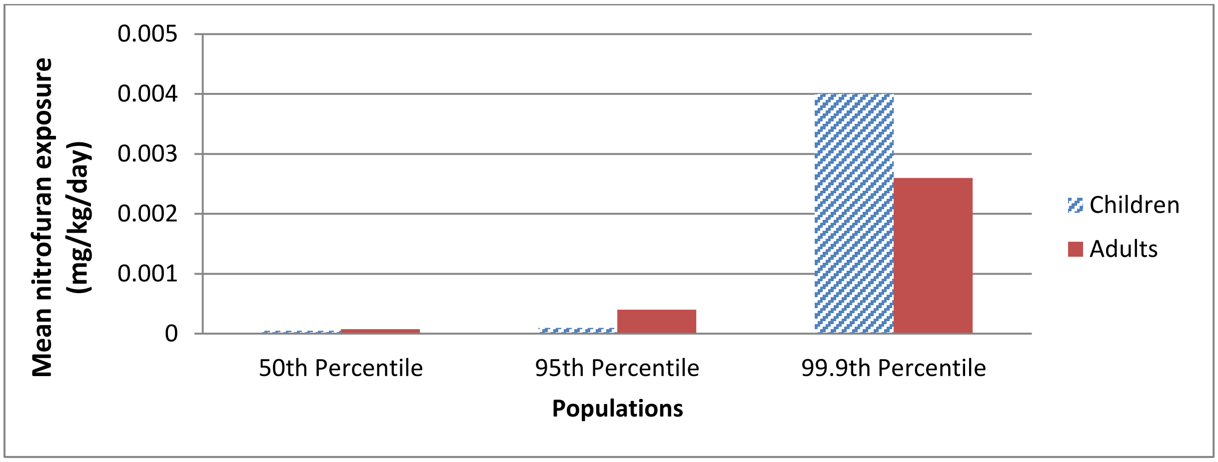

Figure 4.8. The likely mean nitrofuran exposure levels (in mg/kg/day) among adults vs. children. The figure shows exposure that would have occurred among adult seafood consumers compared to that which would have occurred among children consumers based on NHANES 2003-2004 data. The figure shows the likely exposure that would have occurred among the upper 50th, 95th, and 99.9th percentiles of consumers.

CHAPTER 5 - Exposure among Vulnerable Adult Sub-populations: Females and the Elderly

Female NHANES Consumers Aged 18 and Older

Adult females are considered to be a physiologically vulnerable subsection of the U.S. population.[213] As adult females' bodies are biologically designed to carry large amounts of body fat, their susceptibility to toxic chemicals that accumulate in body fat is greater than that of their male counterparts. Additionally, adult females undergo rapid physiological changes during certain stages of life that increase their susceptibility to chemical contaminants in the food supply.[214] Adult female exposure to certain chemical contaminants has been known to result in problems such as infertility, susceptibility to certain diseases and cancers, and other health issues. This chapter of the dissertation assesses the contaminant levels to which adult female NHANES consumers of Chinese aquaculture imports would have been exposed in a contrived scenario. The major objective of this section is to answer the following research questions:

1. What would be the likely exposure level of adult female consumers to chemical contaminants Chinese aquaculture imports?
3. Considering the total dietary intake among U.S. NHANES adult female consumers, would the dietary intake of chemicals from aquaculture imports be within safe levels (in a contrived scenario using actual consumption and contamination data)?

This study used the 2003-2004 U.S. NHANES food consumption data and the available 2006-2007 FDA seafood contamination sampling data. In order to best estimate the likely level of exposure to chemical contaminants that would have occurred among U.S. adult female consumers, the following assumptions were made:

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[213] E. J. Calabrese, "Sex Differences in Susceptibility to Toxic Industrial Chemicals," *Occupational and environmental medicine* 43, no. 9 (1986).

[214] United Nations Development Program (UNDP), "Chemical Management: The Why and How of Mainstreaming Gender in Chemicals Management," in *Gender Mainstreaming: A key Driver of Development in Environment and Energy*.

a. All seafood consumed in the U.S. is of Chinese aquaculture origin (a conservative, worst-case scenario);
b. The sampling distribution of NHANES 2003-2004 adult female consumers is the same as that of all the U.S. adult female seafood consumers (a reasonable assumption that allows this study to take advantage of the NHANES data set);
c. There is a normal distribution of contaminants of interest in aquaculture imports (a commonly embraced assumption in studies of this kind);
d. The contamination data from 2006-2007 was used as a proxy for contamination data for 2003-2004; and
e. There is no other significant source of exposure to contaminants (a possibly unrealistic but nonetheless appropriate assumption).

The assessment was done to determine the likely exposure levels that would have occurred among NHANES 2003-2004 adult female consumers whose diets included imported Chinese aquaculture products. The analysis was done for the four major contaminants—fluoroquinolone, gentian violet, nitrofuran, and malachite green—which were found in Chinese aquaculture imports. The output for the analysis was obtained on different percentiles of NHANES seafood consumers. The tables below show the different input data sets used in the exposure analysis.

Table 5.1 Population data sets

Table Type	Table Name	Records	Selection Criteria/Filter
Subjects:	NHANES 2003-04 SUBJECTS	4601(4601 distinct Subjects)	Gender=2(Age>18)
Diary:	NHANES 2003-04 DIARY	252035 (9034 distinct Subject)	
Food Groups:	Raw Fish 2003-2004	20	

Table 5.2 Chemical data sets

Table Type	Table Name	Records	Targets	Filter
Chemicals:	Seafood contaminants	4	Fluoroquinolone, Gentian violet, Malachite green, Nitrofuran	

Fluoroquinolone Contaminant Exposure in NHANES 2003-2004 Adult Female Consumers

Results and Discussion

Table 5.3 below shows the probable level of fluoroquinolone exposure that would have occurred among the various percentiles of NHANES 2003-2004 adult female seafood consumers. These were the likely exposures that, in our contrived hypothetical scenario rooted in actual chemical data, would have occurred among NHANES 2003-2004 adult female consumers of imported Chinese aquaculture products. Table 5.4 shows the level of the likely fluoroquinolone exposures that would have occurred in milligrams per kilogram body weight of NHANES 2003-2004 adult female seafood consumers. From the exposure analysis, NHANES adult female consumers who form the upper end of the output distribution would be exposed to higher levels of fluoroquinolone contaminants than they ought to be (in a hypothetical MRL-compliant scenario). NHANES 2003-2004 adult females who form the upper 95th, 90th, and 50th percentiles would be exposed to lower levels of fluoroquinolone contaminants than those in the upper 97.5th, 99th, 99.5th, and 99.9th percentiles. The highest fluoroquinolone exposure level would be 1.5702 mg/day, which would have occurred among the 99.9th percentile of NHANES 2003-2004 adult female consumers. The upper 50th, 95th, and 99.9th percentile of adult female seafood consumers would be exposed to 4.47, 5.20, and 3.52 times more fluoroquinolone from imported products (scenario 1) than in the hypothetical MRL-compliant scenario (scenario 2), respectively.

Table 5.3 Fluoroquinolone intakes in NHANES adult females (mg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.02776	0.02191	0.20862	0.36410	0.55177	0.70992	1.13007
Standard Deviation	0.00118	0.00246	0.01150	0.01466	0.02784	0.04442	0.12059
Minimum	0.02414	0.01730	0.17099	0.31930	0.48464	0.57933	0.81892
Maximum	0.03302	0.03179	0.25970	0.41491	0.65115	0.86553	1.57028

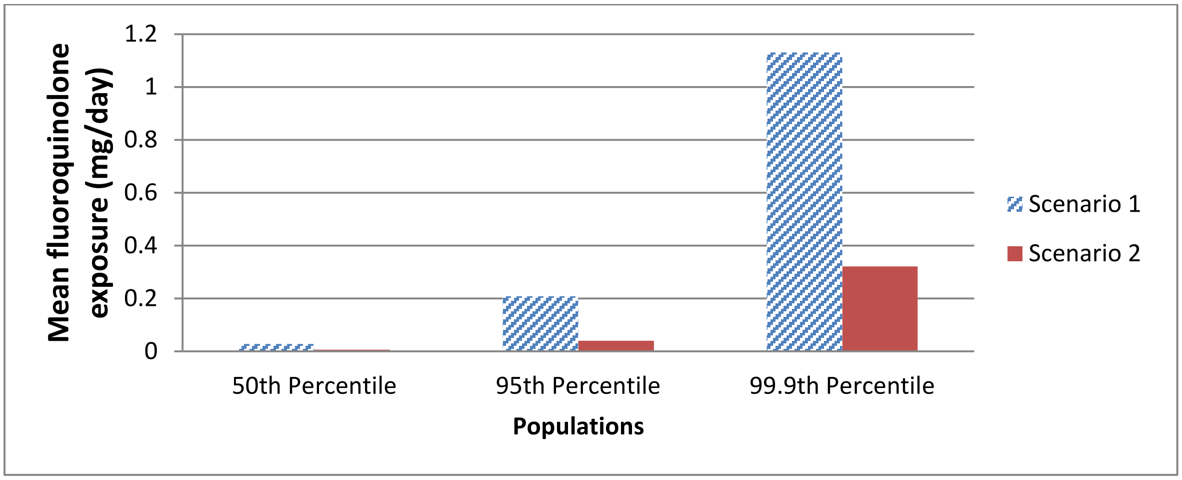

Figure 5.1. The likely mean fluoroquoroquinolone exposure (in mg/day) among adult female. The figure shows exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Table 5.4 below shows the likely fluoroquinolone exposure that would have occurred among the various percentiles of NHANES 2003-2004 adult female consumers. The exposures would have occurred among adult female consumers whose diets included imported Chinese aquaculture products in our contrived hypothetical scenario. Table 5.4 shows the likely exposure levels that would have occurred in milligrams of fluoroquinolone per kilograms of adult female consumer body weight per day. The 50th, 95th, and 99.9th percentile of female seafood consumers would be exposed to 0.2, 4.9, and 3.8 times more fluoroquinolone, respectively, than they ought to be in a hypothetical MRL-compliant scenario.

Table 5.4 Fluoroquinolone intakes in NHANES adult females (mg/kg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00049	0.00041	0.00342	0.00616	0.01004	0.01376	0.02549
Standard Deviation	0.00002	0.00005	0.00020	0.00028	0.00057	0.00097	0.00367
Minimum	0.00042	0.00028	0.00277	0.00538	0.00829	0.01020	0.01786
Maximum	0.00060	0.00062	0.00412	0.00740	0.01190	0.01648	0.03731

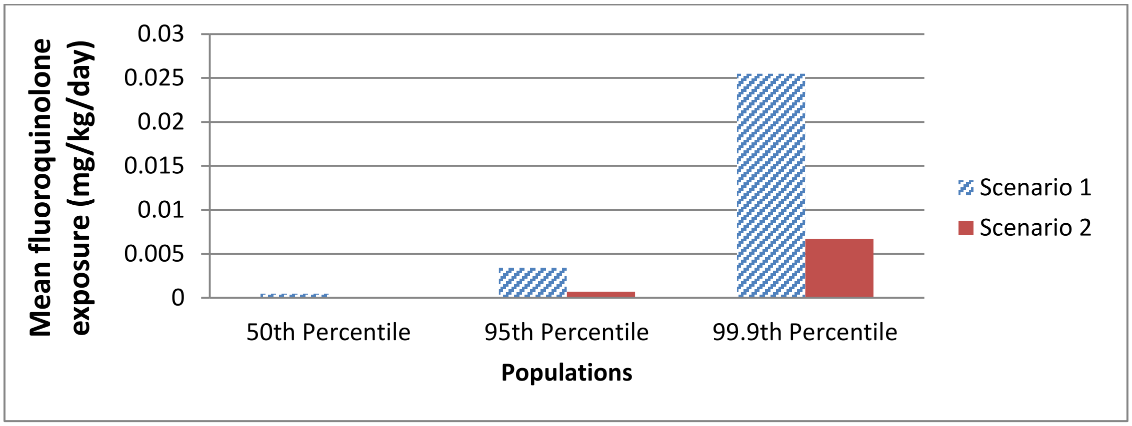

Figure 5.2. The likely mean fluoroquoroquinolone exposure levels (in mg/kg/day) among adult female. The figure shows exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Gentian Violet Contaminant Exposure in NHANES 2003-2004 Adult Female Consumers

Results and Discussion

Table 5.5 below shows the likely gentian violet exposure levels that would have occurred among the various percentiles of female NHANES seafood consumers. Table 5.6 shows the likely gentian violet contaminant exposure in milligrams per kilogram body weight per day among adult female NHANES seafood consumers. The use of gentian violet in human food is prohibited, according to Title 21 of the *Code of Federal Regulations* Subchapter E Sec. 589.1000.[215] The presence of any traces of the chemical in human food renders it unfit for human consumption. Gentian violet, considered to be a carcinogenic substance, is one of the chemicals for which the FDA has not established tolerance. The results below show the likely gentian violet exposure levels which, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, would occur among NHANES 2003-2004 adult female consumers of imported Chinese aquaculture products. The NHANES women in the upper 95th percentile of all NHANES 2003-2004 adult female seafood consumers would be exposed to high levels of gentian violet; the highest exposure level,

[215] U.S. Food and Drug Administration, "Food, Drug, and Cosmetic Act: 21 Cfr 589.1000," ed. Department of Health and Human Services (2010). The use of gentian violet in animal feed renders the feed adulterated and in violation of the *Food, Drug, and Cosmetic Act*

which would have occurred among the upper 99.9th percentile of NHANES 2003-2004 female consumers, would be 6.1638 mg/day. The upper 50th, 95th, and 99.9th percentile of female consumers would be exposed to 14.5, 15.67, and 12.8 times more fluoroquinolone, respectively, than they ought to be in a hypothetical MRL-compliant scenario (scenario 2).

Table 5.5 Gentian violet intakes in NHANES adult females (mg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.08992	0.02302	0.63947	1.23655	1.94480	2.53950	4.12312
Standard Deviation	0.00453	0.00335	0.04511	0.06254	0.10445	0.16221	0.43888
Minimum	0.07684	0.01700	0.49712	1.05185	1.68582	2.13402	3.17189
Maximum	0.10696	0.05999	0.82445	1.42155	2.22745	3.15221	6.16382

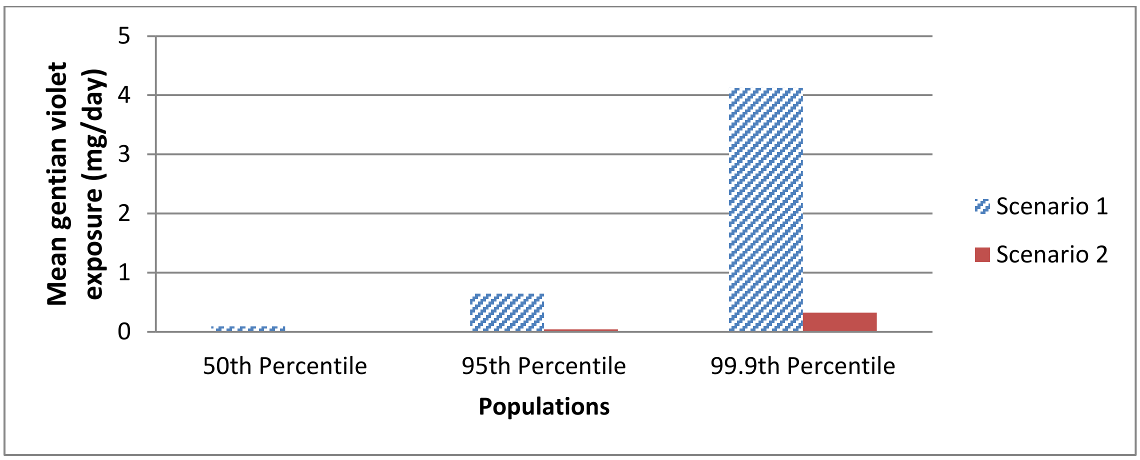

Figure 5.3. The likely mean gentian violet exposure levels (in mg/day) among adult female. The figure shows exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Table 5.6 below shows the likely gentian violet exposure that would occur among various percentiles of NHANES 2003-2004 adult female seafood consumers. The table shows the likely gentian violet exposures that would have occurred from imported Chinese aquaculture products. The likely exposures are in milligrams per kilogram of consumer body weight per day. This study used the 2003-2004 NHANES food consumption data and the available 2006-2007 FDA contaminant sampling data for aquaculture imports. NHANES female consumers in the upper 50th percentile of NHANES seafood consumers would be exposed to 16.2 times more gentian violet from imported Chinese aquaculture products (scenario 1) than in the hypothetical MRL-scenario (scenario 2);

meanwhile, the upper 95th and 99.9th percentile of consumers would be exposed to 15.08 and 13.61 times more gentian violet from imported products, respectively. Figure 5.4 below shows a comparison for the likely exposure that would have occurred in scenario 1 and scenario 2.

Table 5.6 Gentian violet intakes in NHANES adult females (mg/kg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00162	0.00043	0.01056	0.02077	0.03510	0.04859	0.09121
Standard Deviation	0.00009	0.00007	0.00077	0.00116	0.00223	0.00410	0.01370
Minimum	0.00138	0.00029	0.00779	0.01708	0.02898	0.03722	0.06395
Maximum	0.00194	0.00110	0.01422	0.02447	0.04397	0.06430	0.14645

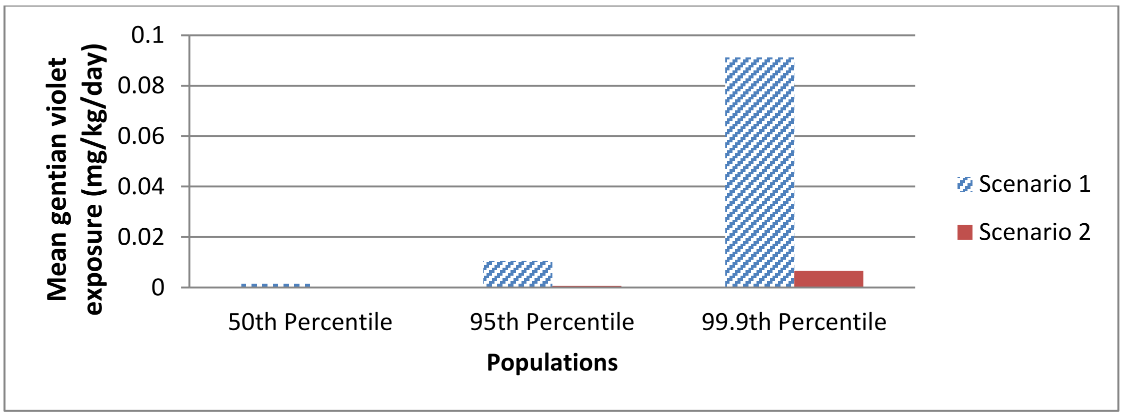

Figure 5.4. The likely mean gentian violet exposure levels (in mg/kg/day) among adult female. The figure shows exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Malachite Green Contaminant Exposure in NHANES 2003-2004 Adult Female Consumers

Results and Discussion

Tables 5.7 and 5.8 show the likely malachite green (MG) exposure levels that would have occurred among the NHANES 2003-2004 adult female seafood consumers. The tables show the likely MG contaminant exposure which, in our contrived hypothetical scenario rooted in actual import data, would have occurred from imported Chinese aquaculture imports (scenario 1). Table 5.7 shows the likely exposure levels in milligrams per day, while table 5.8 shows the likely exposure levels in milligrams of the contaminant per kilogram of consumer body weight per day. Although

MG is not approved for use in human food, the chemical was found in high amounts in imported Chinese aquaculture products. Human exposure to MG over an extended period of time can cause the development of cancer in various organs of the body; moreover, research by the National Toxicological Council established that MG exhibits reproductive and developmental toxicity.[216,217] The upper 95th percent of NHANES adult female seafood consumers would be exposed to levels exceeding 2.5614 mg/day. This high level of exposure would pose a great risk to female seafood consumers. The likely maximum exposure level among the upper 99.9th percentile of NHANES adult female consumers would be 28.12 mg/day. Female consumers who were in the upper 95th percentile of all NHANES adult female seafood consumers would be exposed to high levels of MG residues. This study used the publicly available 2003-2004 NHANES food consumption data and the 2006-2007 FDA contaminant sampling data. Table 5.8 shows the likely MG exposures that would have occurred in milligrams per kilogram of consumer body weight per day for female consumers whose diets contain imported Chinese aquaculture products. The likely mean MG exposure per kilogram body weight for NHANES adult female seafood consumers would be between 0.0067 and 0.3921 mg/kg/day. The likely maximum exposure levels would be between 0.008 and 0.5934 mg/kg/day while the likely minimum exposure levels would be between 0.0056 and 0.2574 mg/kg/day. The U.S. prohibits the use of MG in human and animal food; therefore, the presence of any residues of the chemical in human food or animal feed is considered violative.[218] The level of the likely MG exposure per kilogram of body weight among NHANES women would be higher than it would have been if the imported Chinese aquaculture products contained levels of MG that conformed to MRL standards. NHANES consumers in the upper 50th percentile would be exposed to 60.2 times more MG from imported Chinese aquaculture products (scenario 1) than they ought to be in a hypothetical MRL-compliant scenario (scenario 2). The upper 95th and 99.9th percentile of consumers would be exposed to 62.2 and 56.1 times more MG, respectively, than they ought to be.

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[216] National Toxicological Program, "Toxicology and Carcinogenesis Studies of Malachite Green Chloride and Leucomalachite Green. (Cas Nos. 569-64-2 and 129-73-7) in F344/N Rats and B6c3f1 Mice (Feed Studies)."

[217] S. Jensen Clemmensen, J.C. Jensen, N.J. Meyer, O. Olsen, P. Wurtzen, G., "Toxicological Studies on Malachite Green: A Triphenylmethane Dye," *Archives of Toxicology* 56, no. 1 (1984).

[218] Andrew C. von Eschenbach, "Enhanced Aquaculture and Seafood Inspection - Report to Congress," (2008).

Table 5.7 Malachite green intakes in NHANES adult females (mg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.37343	0.02337	2.56138	5.27094	8.47451	11.04685	18.06824
Standard Deviation	0.01999	0.00355	0.21458	0.30083	0.45950	0.74222	1.99718
Minimum	0.32779	0.01722	1.99101	4.55147	7.27415	9.09246	13.46006
Maximum	0.44134	0.04550	3.13403	6.22307	9.86628	13.81735	28.12491

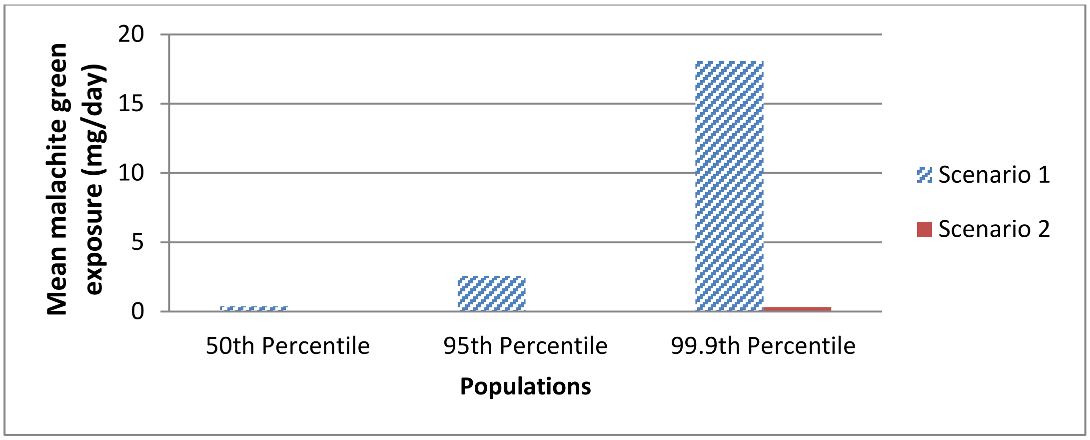

Figure 5.5. The likely mean malachite green exposure levels (in mg/day) among adult female. The figure shows exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Table 5.8 below shows the likely malachite green contaminant exposure which, in the contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, would occur among NHANES 2003-2004 adult female seafood consumers. The likely exposures that would have occurred among the NHANES 2003-2004 adult female consumers whose diets included imported Chinese aquaculture products. The table shows the likely daily exposures that would have occurred in milligrams of MG contaminant per kilogram of consumer body weight. This study used the publicly available U.S. NHANES food consumption data and the 2006-2007 FDA contaminant sampling data for Chinese aquaculture imports. Adult female seafood consumers in the upper 50th percentile of NHANES seafood consumers would be exposed to 67.2 times more MG per kilogram body weight from imported Chinese aquaculture products (scenario 1) than in the hypothetical MRL-compliant scenario (scenario 2). Meanwhile, adult female consumers in the upper 95th and 99.9th percentile would be exposed to 60.3 and 58.53 times more MG, respectively, from imported

Chinese aquaculture products than they ought to be. Figure 5.6 below shows a comparison of exposure that would have occurred in scenario 1 and scenario 2.

Table 5.8 Malachite green intakes in NHANES adult females (mg/kg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00672	0.00044	0.04227	0.08832	0.15234	0.21072	0.39212
Standard Deviation	0.00040	0.00007	0.00357	0.00535	0.01013	0.01717	0.05572
Minimum	0.00564	0.00029	0.03360	0.07379	0.12882	0.16814	0.25740
Maximum	0.00806	0.00108	0.05267	0.10230	0.19347	0.26616	0.59344

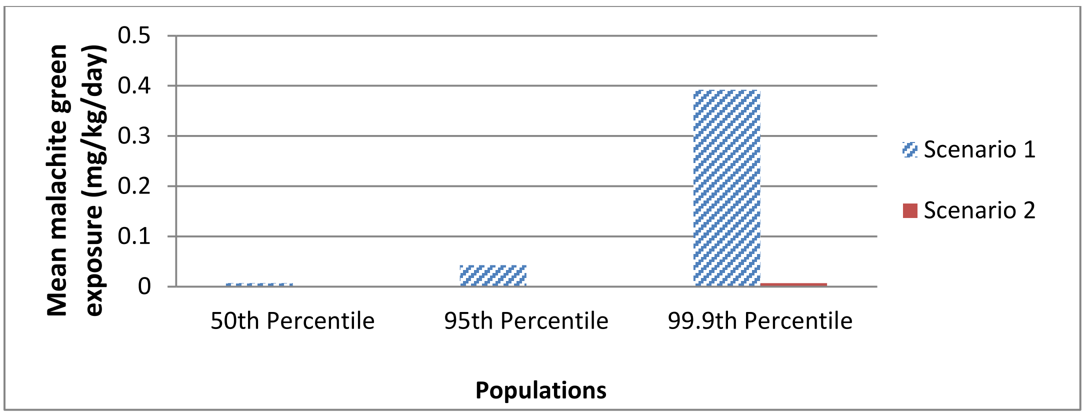

Figure 5.6. The likely mean malachite green exposure levels (in mg/kg/day) among adult female. The figure shows exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Nitrofuran Contaminant Exposures in NHANES 2003-2004 Adult Female Consumers

Results and Discussion

Table 5.9 shows the likely exposures for nitrofuran contaminants that would have occurred among NHANES adult female seafood consumers in milligrams per day. Table 5.10 shows the likely exposures in milligrams of nitrofuran contaminant per kilogram of body weight among NHANES adult female seafood consumers. Nitrofuran is prohibited from human food because of its carcinogenic properties.[219] Tables 5.9 and 5.10 show the likely nitrofuran contaminant exposures

219 Yahagi et al., "Relationships between the Carcinogenic and Mutagenic or DNA-Modifying Effects of Nitrofuran Derivatives, Including 2-(2-Furyl)-3-(5-Nitro-2-Furyl) Acrylamide, a Food Additive."

which, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, would result from Chinese aquaculture imports. The exposure analysis found that NHANES adult female seafood consumers of childbearing age would probably exposed to high amounts of nitrofuran in imported Chinese aquaculture products. NHANES adult female seafood consumers would likely exposed to mean nitrofuran contaminants levels ranging between 0.0041 and 0.1534 mg/day; the range of likely maximum exposures would be between 0.0045 and 0.2387 mg/day, and the range of likely minimum exposures would be between 0.0038 and 0.1081 mg/day. The likely nitrofuran contaminant exposure that would have occurred among NHANES adult female consumers would be higher than it would be if the imported Chinese aquaculture products contain contaminants at the permitted MRL. The likely mean of nitrofuran contaminant exposure per kilogram body weight among NHANES adult female seafood consumers would be between 0.00007 and 0.00329 mg/kg/day. The likely maximum nitrofuran exposure would be between 0.00008 and 0.00546 mg/kg/day, while the likely minimum nitrofuran contaminant exposure would be between 0.00006 and 0.00222 mg/kg/day. Tables 5.9 and 5.10 show the likely nitrofuran exposures that would have occurred among different percentiles of the NHANES 2003-2004 adult female seafood consumers. Adult female seafood consumers in the upper 50th percentile of all NHANES seafood consumers would be exposed to 1.49 times less nitrofuran from imported Chinese aquaculture products (scenario 1) than they would be in a hypothetical MRL-compliant scenario (scenario 2). Meanwhile, adult female consumers in the upper 95th and 99.9th percentile would be exposed to 1.54 and 2.11 times less nitrofuran contaminants, respectively, in scenario 1 than in scenario 2. Figure 5.7 below shows comparisons for nitrofuran exposure in scenario 1 and scenario 2.

Table 5.9 Nitrofuran intakes in NHANES adult females (mg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00414	0.01246	0.02651	0.04587	0.07248	0.09379	0.15349
Standard Deviation	0.00012	0.00055	0.00102	0.00218	0.00386	0.00591	0.01662
Minimum	0.00381	0.01114	0.02276	0.04031	0.06433	0.07827	0.10814
Maximum	0.00456	0.01360	0.03022	0.05431	0.08514	0.11152	0.23876

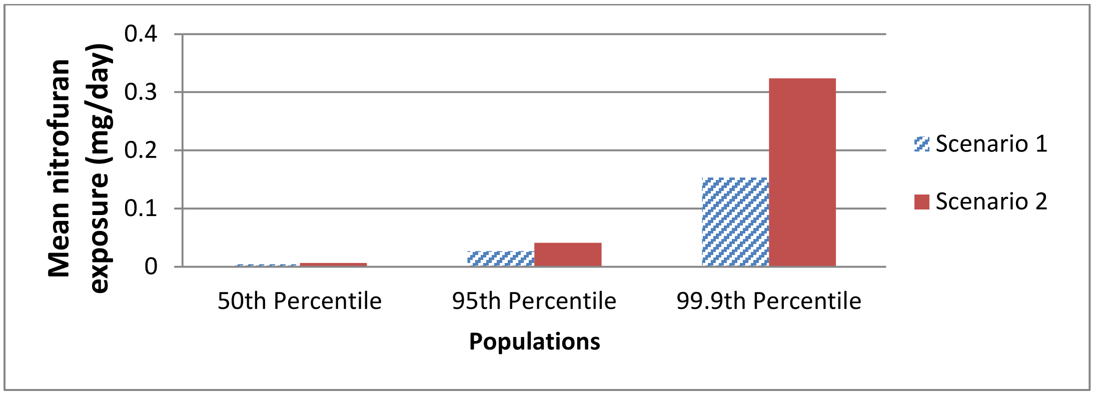

Figure 5.7. The likely mean nitrofuran exposure levels (in mg/day) among adult female. The figure shows exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Table 5.10 below shows the possible nitrofuran contaminant exposure that would have occurred among NHANES 2003-2004 adult female seafood consumers who consumed imported Chinese aquaculture products. The table shows the likely daily exposures that would have occurred in milligrams of nitrofuran contaminant per kilogram of consumer body weight for NHANES 2003-2004 adult female consumers. The table shows the likely exposures that would have occurred among different percentiles of NHANES 2003-2004 adult female seafood consumers of imported Chinese aquaculture products. Data from different years—the 2003-2004 U.S. NHANES food consumption data and the 2006-2007 FDA contaminant sampling data were used in this study. The upper 50th percentile of adult female seafood consumers would be exposed to 1.43 times less nitrofuran from imported Chinese aquaculture products (scenario 1) than they ought to in a hypothetical MRL-compliant scenario (scenario 2). Meanwhile the upper 95th and 99.9th percentile of NHANES seafood consumers would be exposed to 1.52 and 2.03 times less nitrofuran, respectively, in scenario 1 than in scenario 2. Figure 5.8 below shows comparison for exposure in scenario 1 and scenario 2.

Table 5.10 Nitrofuran intakes in NHANES adult females (mg/kg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00007	0.00020	0.00046	0.00079	0.00131	0.00179	0.00329
Standard Deviation	0.00000	0.00000	0.00001	0.00003	0.00007	0.00013	0.00051
Minimum	0.00006	0.00017	0.00039	0.00069	0.00112	0.00148	0.00222
Maximum	0.00008	0.00022	0.00052	0.00092	0.00156	0.00240	0.00546

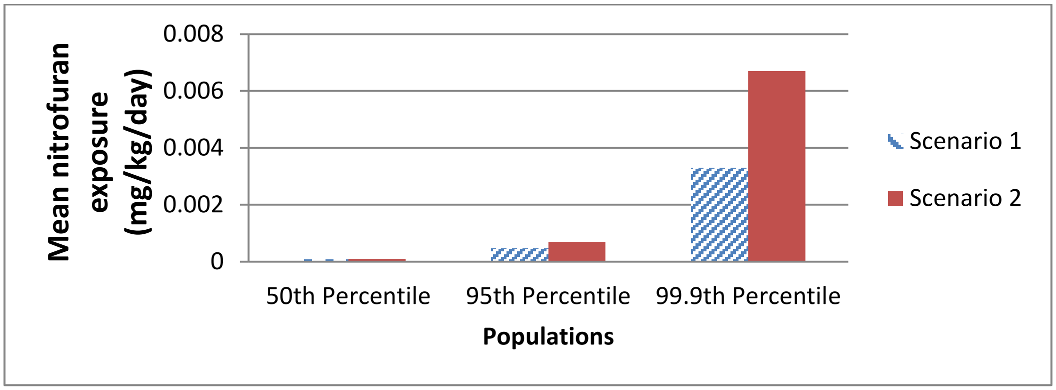

Figure 5.8. The likely mean nitrofuran exposure levels (in mg/kg/day) among adult female. The figure shows exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Chemical Contaminant Exposure in NHANES 2003-2004 Consumers Aged 60 and Older

Chemical contaminants in the food supply can cause serious adverse health effects in consumers who have weak immune systems. The elderly are often considered to have weakened immune systems and are thus vulnerable to the effects of contaminants in food or the environment. The exposure of the elderly to high levels of food or environmental contaminants can result in serious health effects. This study seeks to determine the level of contaminant exposure that would have occurred among NHANES 2003-2004 consumers aged 60 years and older in a contrived scenario; therefore, this section of the dissertation seeks to answer the following research questions:

1. What would be the likely exposure level of elderly seafood consumers aged 60 and older to chemicals in Chinese aquaculture imports?
3. Considering the total dietary intake among U.S. NHANES seafood consumers aged 60 and older, would the dietary intake of chemicals from Chinese aquaculture imports be within safe levels?

In order to estimate the level of exposure to chemical contaminants among U.S. seafood consumers aged 60 and older, the following assumptions were made:

a. All seafood consumed in the U.S. is of Chinese aquaculture origin (a conservative worst-case scenario);

b. The sampling distribution of NHANES 2003-2004 seafood consumers ages 60 and older is the same as that of all the U.S. seafood consumers of ages 60 and older (a reasonable assumption that allows this study to take advantage of NHANES data set);
c. There is a normal distribution of contaminants of interest in Chinese aquaculture imports (a commonly embraced assumption in studies of this kind);
d. The contamination data from 2006-2007 was used as a proxy for contamination data for 2003-2004; and
e. There is no other significant source of exposure to contaminants (a possibly unrealistic but nonetheless appropriate, assumption).

This study combined the 2003-2004 U.S. NHANES food consumption data and the 2006-2007 FDA contaminant sampling data to determine the likely level of contaminant exposure that would have occurred among NHANES seafood consumers aged 60 and older. The analysis was done on four major contaminants that were found in Chinese aquaculture imports: fluoroquinolone, gentian violet, malachite green, and nitrofuran. The results for the analysis were obtained for different percentiles of NHANES 2003-2004 seafood consumers aged 60 and older. Tables 5.11 and 5.12 below show the different input data sets used in the analysis.

Table 5.11 shows the population data used in the exposure analysis for chemical contaminant intakes that, in our contrived hypothetical scenario rooted in actual import data, would have occurred among NHANES 2003-2004 elderly consumers of imported Chinese aquaculture products. A total of 1,901 elderly consumers aged 60 and older were used in the exposure analysis. Table 5.12 shows the chemical contaminants that were found in imported Chinese aquaculture products, as well as the chemicals for which the exposure analysis was done.

Table 5.11 CREMe data sets

Table Type	Table Name	Number of Records	Selection Criteria
Subjects:	NHANES 2003-04 SUBJECTS	1901 (1901 distinct Subjects)	(`Age` >= 60)
Diary:	NHANES 2003-04 DIARY	252035(9034 distinct Subjects)	
Food Groups:	Raw Fish 2003-2004	201	

Table 5.12 Chemical data sets

Table Type	Table Name	No. Records	Targets
Chemicals:	Seafood contaminants	4	Fluoroquinolone, Gentian violet, Malachite green, Nitrofuran

Fluoroquinolone Exposure in the Elderly

Results and Discussion

Table 5.13 below shows the level of the likely fluoroquinolone contaminant exposure that, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, would have resulted from imported Chinese aquaculture products. The exposures would have occurred among NHANES 2003-2004 consumers aged 60 and older whose diets included imported Chinese aquaculture products. The table shows the likely exposures that would have occurred in milligrams per day for the various percentiles of NHANES 2003-2004 consumers aged 60 and older. The elderly seafood consumers in the upper 50th percentile of all NHANES seafood consumers would have been exposed to 8.49 times more fluoroquinolone from Chinese aquaculture imports (scenario 1) than they would be in a hypothetical MEL-compliant scenario (scenario 2). Elderly seafood consumers in the upper 95th and 99.9th percentile of consumers would be exposed to 9.31 and 4.57 times more fluoroquinolone in scenario 1 than in scenario 2. Figure 5.9 below shows comparison for fluoroquinolone exposures in scenario 1 and scenario 2.

Table 5.13 Fluoroquinolone contaminant intakes in the elderly (mg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.05268	0.19988	0.37345	0.52952	0.75257	0.93692	1.4646
Standard Deviation	0.00295	0.01488	0.01883	0.02932	0.05691	0.08174	0.24540
Minimum	0.04367	0.14866	0.31650	0.44043	0.61212	0.70118	0.99870
Maximum	0.06426	0.25313	0.43240	0.62421	0.94212	1.20435	2.30067

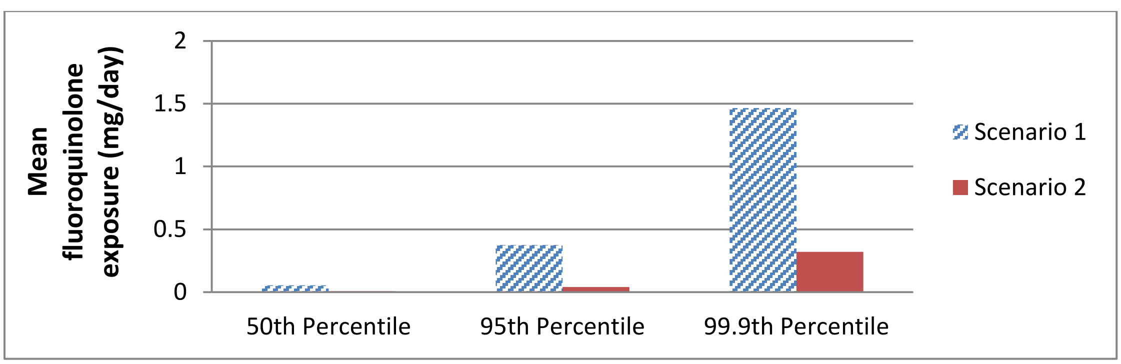

Figure 5.9 The likely mean fluoroquinolone exposure levels (in mg/day) among the elderly. The figure shows the likely exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Table 5.14 below shows the level of the likely fluoroquinolone contaminant intakes that would have resulted from imported Chinese aquaculture products (scenario 2). The likely exposure would have occurred among NHANES 2003-2004 seafood consumers aged 60 and older. The table shows the likely exposures that would have occurred in milligrams of fluoroquinolone contaminant per kilograms of elderly consumers' body weights per day. The exposures would have occurred among NHANES 2003-2004 elderly consumers whose diets included imported Chinese aquaculture products. The table shows the likely fluoroquinolone exposures that would have occurred among the mean, 90th, 95th, 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 consumers aged 60 and older. Elderly seafood consumers in the upper 50th percentile of the elderly NHANES seafood consumers would have been exposed to 7.1 times more fluoroquinolone from imported Chinese aquaculture products (scenario 1) than they would be in a hypothetical MRL-compliant scenario (scenario 2). The elderly consumers in the upper 95th and 99.9th percentile would be exposed to 7.1 and 3.0 times more fluoroquinolone per kilogram of consumer body weight in scenario 1 than in scenario 2. Figure 5.10 shows comparison of exposure in scenario 1 and 2.

Table 5.14 Fluoroquinolone contaminant intakes in the elderly (mg/kg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00071	0.00261	0.00499	0.00722	0.01045	0.01304	0.02023
Standard Deviation	0.00004	0.00020	0.00027	0.00040	0.00078	0.00120	0.00321
Minimum	0.00058	0.00186	0.00418	0.00607	0.00827	0.00991	0.01402
Maximum	0.00086	0.00328	0.00587	0.00865	0.01403	0.01649	0.03132

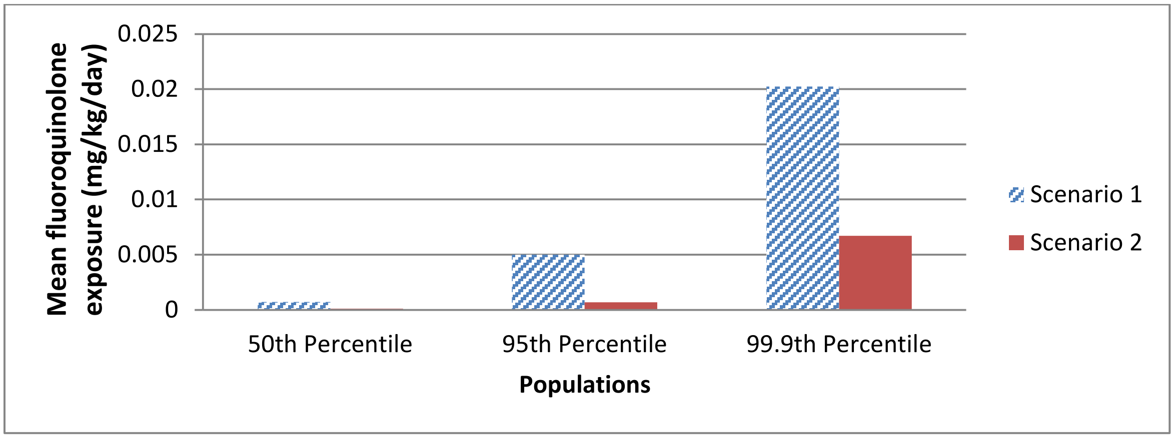

Figure 5.10. The likely mean fluoroquinolone exposure levels (in mg/kg/day) among the elderly. The figure shows the likely exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Gentian Violet Exposure in the Elderly

Results and Discussion

Table 5.15 shows the likely gentian violet contaminant exposure that, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, would have occurred among NHANES 2003-2004 seafood consumers aged 60 and older. The table shows the likely gentian violet exposures in milligrams per day among the various percentiles of NHANES 2003-2004 seafood consumers whose diets included imported Chinese aquaculture products. Gentian violet is a carcinogen, and thus is not permitted in human food; consumers aged 60 and older would be exposed to considerably high levels of gentian violet in imported Chinese aquaculture products. This study combined two sets of data from different years—the 2003-2004 U.S. NHANES food consumption data and the 2006-2007 FDA contaminant sampling data to determine consumer exposure to Chinese aquaculture contaminants. The upper 50th percentile of elderly NHANES seafood consumers would be exposed to 28.3 times more gentian violet from imported Chinese aquaculture products (scenario 1) than they would be in a hypothetical MRL-compliant scenario (scenario 2). The elderly consumers in the upper 95th and 99.5th percentile would be exposed to 31.5 and 16.4 times more gentian violet, respectively, in scenario 1 than in scenario 2. Figure 5.11 below shows comparison for gentian violet exposure among elderly NHANES seafood consumers in scenario 1 and 2.

Table 5.15 Gentian violet contaminant intakes in the elderly (mg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.17535	0.60015	1.26349	1.83836	2.67559	3.37297	5.27431
Standard Deviation	0.01145	0.06243	0.08289	0.11022	0.21869	0.32554	0.91577
Minimum	0.13829	0.38967	1.04350	1.49201	2.05002	2.53478	3.45336
Maximum	0.20582	0.80250	1.48323	2.15845	3.41140	4.45079	8.84198

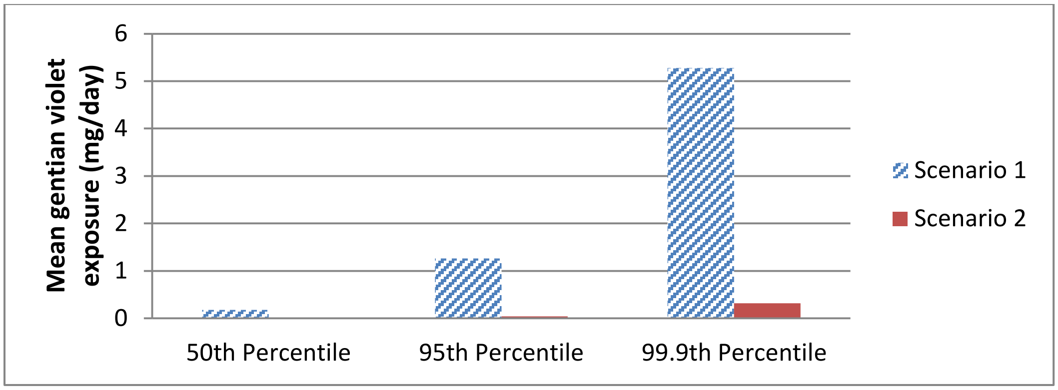

Figure 5.11. The likely mean gentian violet exposure levels (in mg/day) among the elderly. The figure shows the likely exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Table 5.16 below shows the level of the likely gentian violet contaminant exposure that would result from imported Chinese aquaculture products. The exposures would have occurred among NHANES 2003-2004 adult seafood consumers whose diets include imported Chinese aquaculture products. The table shows the likely gentian violet exposure levels in milligrams of gentian violet per kilogram of consumer body weight. The table shows the likely exposures that would have occurred among the 50th, 90th, 95th, 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 consumers aged 60 and older. The upper 50th percentile of elderly NHANES seafood consumers would be exposed to 23.6 times more gentian violet from imported aquaculture products (scenario 1) than they would be in a hypothetical MRL-compliant scenario (scenario 2). Meanwhile, elderly seafood consumers in the upper 95th and 99.9th percentile of NHANES consumers would be exposed to 23.9 and 10.96 times more gentian violet in scenario 1 than they would be in scenario 2. Figure 5.12 shows comparison for the likely gentian violet exposures in scenario 1 and 2.

Table 5.16 Gentian violet contaminant intakes in the elderly (mg/kg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00236	0.00786	0.01673	0.02498	0.03686	0.04678	0.07344
Standard Deviation	0.00015	0.00081	0.00115	0.00160	0.00307	0.00481	0.01254
Minimum	0.00181	0.00533	0.01262	0.01994	0.02885	0.03546	0.04491
Maximum	0.00279	0.01077	0.02035	0.02932	0.04768	0.06382	0.11690

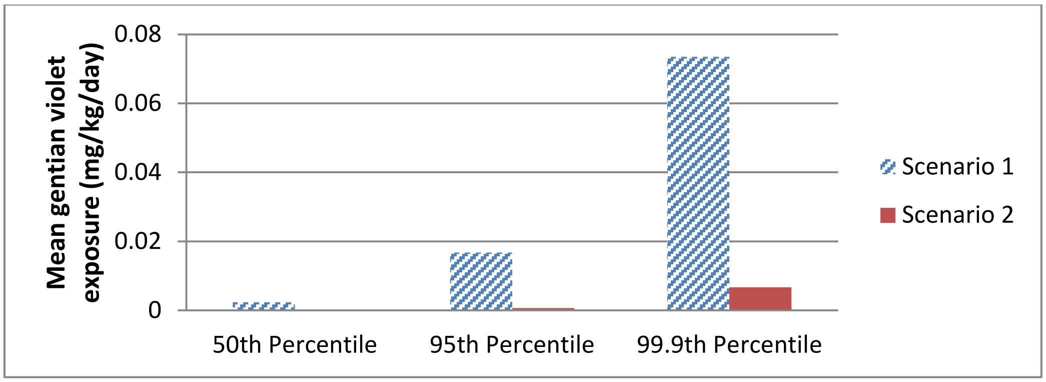

Figure 5.12. The likely mean gentian violet exposure levels (in mg/kg/day) among the elderly. The figure shows the likely exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES consumers.

Malachite Green Exposure in the Elderly

Results and Discussion

Table 5.17 below shows the likely malachite green (MG) contaminant intakes that, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, resulted from imported Chinese aquaculture products. The table shows the likely MG contaminant exposures in milligrams per day that occurred among NHANES 2003-2004 seafood consumers aged 60 and older. The exposures occurred among NHANES consumers whose diets included imported Chinese aquaculture products. The table shows the likely exposures for the mean, 90th, 95th, 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 consumers aged 60 and older. Overall, seafood consumers were exposed to significantly high levels of MG contaminant from imported Chinese aquaculture products. This study used the 2003-2004 U.S. NHANES food consumption data and the 2006-2007 FDA contaminant sampling data to determine the level of consumer exposure to MG contaminants.

Table 5.17 Malachite green contaminant intakes in the elderly (mg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.73507	2.34906	5.33687	8.01029	11.64587	14.74612	23.10074
Standard Deviation	0.04658	0.27110	0.36231	0.47022	0.88382	1.40193	4.29433
Minimum	0.60929	1.63909	4.45906	6.75897	9.26576	11.67334	14.97812
Maximum	0.89342	3.03423	6.65894	9.49373	14.67503	21.29558	37.42859

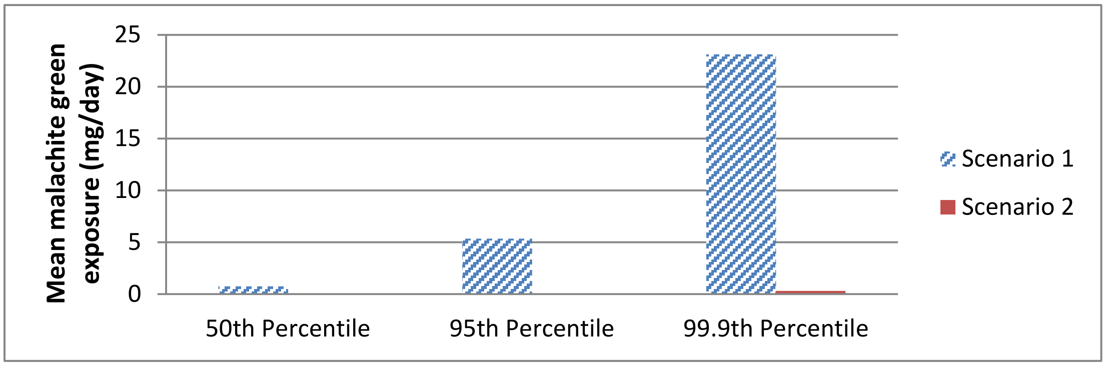

Figure 5.13. The likely mean malachite green exposure levels (in mg/day) among the elderly. The figure shows the likely exposures that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Table 5.18 below shows the likely MG contaminant exposure that, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, resulted from consumption of contaminated Chinese aquaculture products. The exposures occurred among NHANES 2003-2004 adult seafood consumers whose diets included imported Chinese aquaculture products. The table shows the likely malachite green exposure levels in milligrams per kilogram of consumer body weight per day. The table shows the likely MG exposures for the mean, 90th, 95th, 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 consumers aged 60 and older. This study exploited the publicly available U.S. NHANES 2003-2004 food consumption data and the 2006-2007 FDA contaminant sampling data to determine the likely extent of MG exposure.

Table 5.18 Malachite green contaminant intakes in the elderly (mg/kg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00991	0.03075	0.07058	0.10864	0.16092	0.20375	0.32403
Standard Deviation	0.00063	0.00353	0.00500	0.00681	0.01230	0.02062	0.05465
Minimum	0.00825	0.02095	0.05935	0.09026	0.12348	0.15022	0.20942
Maximum	0.01217	0.04073	0.08721	0.13229	0.20228	0.29173	0.50224

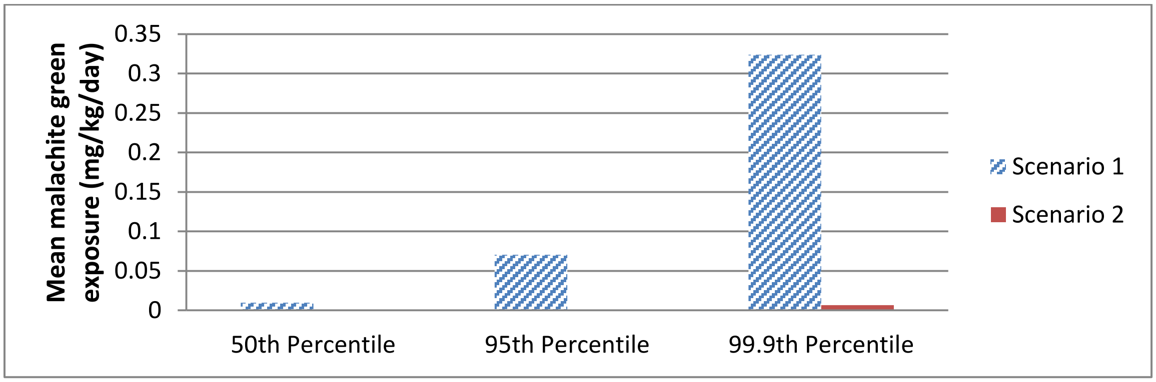

Figure 5.14. The likely mean malachite green exposure levels (in mg/kg/day) among the elderly. The figure shows the likely exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES seafood consumers.

Nitrofuran Exposure in the Elderly

Results and Discussion

Table 5.19 shows the likely nitrofuran contaminant exposures that, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, would result from consumption of imported Chinese aquaculture products. The table shows the likely nitrofuran exposures in milligrams per day that would have occurred among NHANES 2003-2004 seafood consumers aged 60 and older. The exposures would have occurred among consumers whose diets contain imported Chinese aquaculture products. The table shows the likely nitrofuran exposures for the mean and the upper 90th, 95th, 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 consumers aged 60 and older. Seafood consumers would be exposed to high levels of nitrofuran contaminants from imported Chinese aquaculture products. The upper 50th percentile of elderly consumers would be exposed to 1.04 times lower levels of nitrofuran contaminants from imported Chinese aquaculture products (scenario 1) than they would be in a hypothetical MRL-compliant scenario (scenario 2). The level of exposure among the upper 95th percentile would be the same as the level of exposure in the hypothetical MRL-compliant scenario. The upper 99.9th percentile of elderly consumers would be exposed to 1.69 times lower levels of nitrofuran contaminants in scenario 1 than in scenario 2.

Table 5.19 Nitrofuran contaminant intakes in elderly consumers (mg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00596	0.01884	0.04360	0.06545	0.09506	0.12057	0.18870
Standard Deviation	0.00041	0.00221	0.00319	0.00411	0.00764	0.01168	0.03534
Minimum	0.00466	0.01295	0.03495	0.05213	0.07491	0.09118	0.12339
Maximum	0.00705	0.02612	0.05188	0.07789	0.12666	0.14999	0.34028

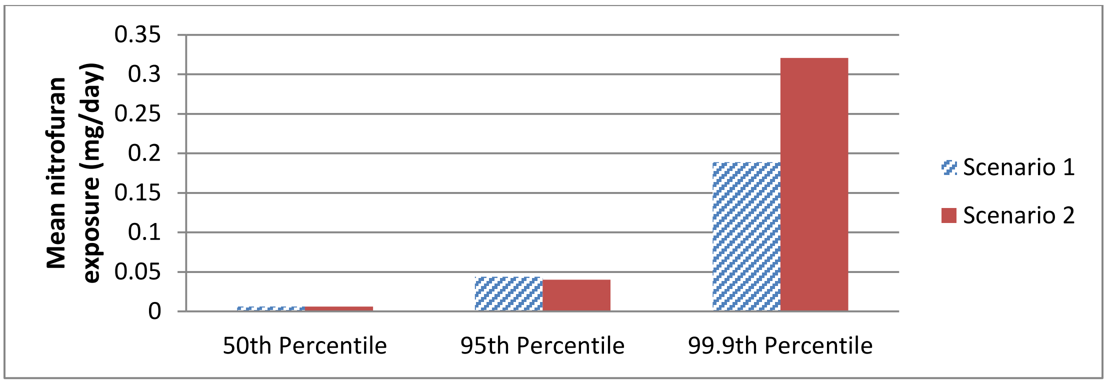

Figure 5.15. The likely mean nitrofuran exposure levels (in mg/day) among the elderly. The figure shows the likely exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES consumers.

Table 5.20 shows the likely nitrofuran contaminant exposures that would result from consumption of imported Chinese aquaculture products. The likely exposures would have occurred among NHANES 2003-2004 elderly seafood consumers whose diets include imported Chinese aquaculture products. The table shows the likely nitrofuran exposure levels in milligrams per kilogram of consumer body weight per day. The table shows the likely nitrofuran exposure levels for the mean and the upper 90th, 95th, 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 consumers aged 60 and older. The upper 50th percentile of elderly seafood consumers would be exposed to 1.25 times less nitrofuran from imported Chinese aquaculture products (scenario 1) that they would be in a hypothetical MRL-compliant scenario (scenario 2). The upper 95th and 99.9th percentiles elderly seafood consumers would be exposed to 1.23 and 2.56 times less nitrofuran in scenario 1 than in scenario 2.

Table 5.20 Nitrofuran contaminant intakes in elderly consumers (mg/kg/day)

	Mean	P90	P95	P97.5	P99	P99.5	P99.9
Mean	0.00008	0.00024	0.00057	0.00088	0.00131	0.00166	0.00262
Standard Deviation	0.00000	0.00002	0.00004	0.00005	0.00010	0.00016	0.00045
Minimum	0.00006	0.00016	0.00045	0.00072	0.00104	0.00127	0.00162
Maximum	0.00009	0.00034	0.00069	0.00107	0.00163	0.00228	0.00449

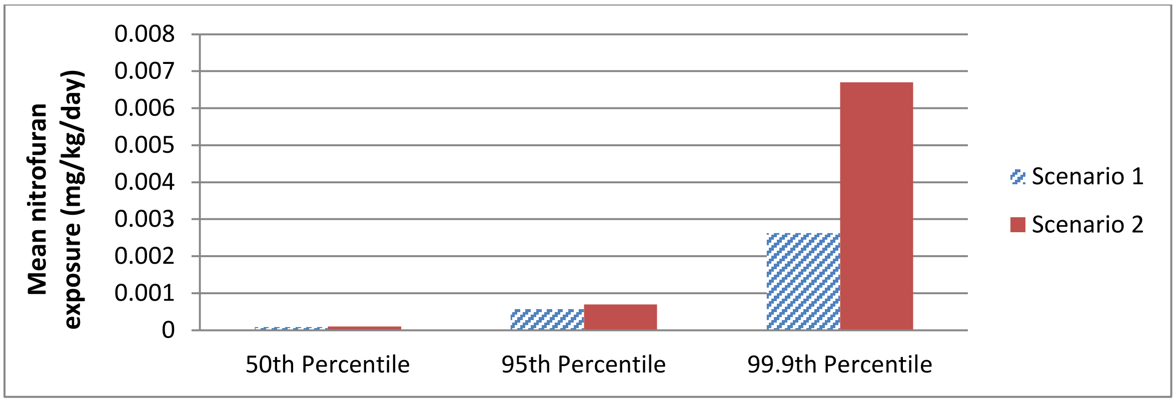

Figure 5.16. The likely mean nitrofuran exposure levels (in mg/kg/day) among the elderly. The figure shows the likely exposure that would have resulted from scenario 1 (a hypothetical scenario based on actual 2006-2007 FDA contaminant sampling data) compared to the likely exposure levels that would have resulted from scenario 2 (a contrived hypothetical MRL-compliant scenario). The figure shows the likely exposure in the upper 50th, 95th, and 99.9th percentiles of NHANES consumers.

CHAPTER 6 - Protecting Vulnerable Subpopulations from Hazards

Exposure analyses conducted in the previous chapters focused on children, women, and the elderly who were considered physiologically vulnerable to chemical contaminants in the food supply. The objective of the exposure analyses was to determine the extent to which the sensitive U.S. subpopulations of children, women, and the elderly were exposed to selected chemical contaminants from imported Chinese aquaculture products. The exposure analysis covered by the previous chapters focused on the level of consumer exposure to chemical contaminants which, in our contrived hypothetical scenario rooted in actual 2006-2007 FDA import data, resulted from Chinese aquaculture imports. This chapter focuses on the novel findings of this research, as well as its implications for import security, social justice, and the dietary practices of American consumers, all of which have been affected by the globalization of the U.S. food supply. Therefore, this chapter seeks to answer the fourth research question:

4. What should the U.S. and Chinese governments do to address aquaculture safety?

In addition to the addressing the above research question, this chapter provides a summary of the findings to the other three research questions:

1. What is the origin of food safety and environmental health problems in the aquaculture industry in China?
2. How effective are the U.S. and Chinese governments' regulations in protecting consumers from hazards in Chinese aquaculture products?
3. Considering the prevailing U.S. seafood consumption patterns (amongst the entire population as well as within specific sensitive sub-populations), was the dietary intake of specific chemicals from Chinese aquaculture imports within safe levels (in a contrived scenario based on actual consumption and contamination data)?

What should be done to address aquaculture safety

Members of every professional society are expected to exhibit certain moral standards by which they "surpass the stage in which [they] are directed by traditional rules and reach the stage in which [they] think for [them]selves in critical terms and in general terms."[220] Food science

[220] Paul Newall, "An Introduction to Ethics," http://www.galilean-library.org/manuscript.php?postid=43789.

professionals need to adopt autonomy, an action that requires normative thinking. Normative thinking involves asking questions about what is right, good, or obligatory with regard to protecting mankind, and particularly vulnerable subpopulations, from harm. Vulnerable subpopulations consist of those who are physiologically weak and thus susceptible to the effects of chemical contaminants in the food supply and the environment. These vulnerable subpopulations include children, the elderly, pregnant women, individuals who have undergone strenuous medical procedures (such as chemotherapy or organ transplants), and those who suffer from certain diseases (such as human immunodeficiency virus, cancer, etc.). These groups collectively represent about 20 percent of the U.S. population.[221]

Many countries and international organizations recognize the importance of protecting their vulnerable subpopulations. The WHO, for example, has programs that specifically focus on women, children, and the elderly.[222] The WHO's vision for children contains a strong statement in support of promoting children's health. UNICEF also seeks to advance this cause, proclaiming, "For every child: health, education, equality, and protection advance humanity."[223] Meanwhile, the U.S. Centers for Disease Control and Prevention (CDC) recognizes the close relationship between environmental health and quality of life. The CDC, therefore, seeks "to promote health and quality of life by preventing and controlling those diseases or deaths that result from infections between people and environment."[224] Every Woman Every Child—a WHO program—sets out a collaborative initiative aimed at saving the lives of women and children around the world,[225] while The Partnership for Maternal, Newborn, and Child Health—also a WHO global collaborative program—sets out strategies for protecting life and improving health among women and children around the world.

As discussed in the first chapter, the continued globalization of food supplies has increased food safety risks faced by U.S. consumers and has created challenges for the food safety regulators attempting to protect them. While numerous challenges continue to emerge as a result of the

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[221] P. Kendall, "Food Handling Behaviors of Special Importance for Pregnant Women, Infants and Young Children, the Elderly, and Immune-Compromised People," *Journal of the American Dietetic Association* 103, no. 12 (2003).

[222] World Health Organization, "Global Strategy for Women's and Children's Health," http://www.who.int/pmnch/activities/jointactionplan/en/.

[223] UNICEF, "Environment: Children Need a Clean Environment " http://www.unicef.org/wash/index_43103.html.

[224] CDC, "Child Development and Public Health," http://www.cdc.gov/ncbddd/child/development.htm.

[225] World Health Organization, "Every Woman Every Child," http://www.everywomaneverychild.org/pages?pageid=1.

continued consolidation of world food markets, it is vital for scientists, risk assessors, and public health officials to not only identify new and emerging challenges, but also to devise strategies for minimizing emerging risks in order to better protect consumers, especially the vulnerable subpopulations. The exposure data from the research shows that, in our contrived scenario using actual consumption and contamination data: (a) vulnerable U.S. seafood consumers were exposed to unsafe levels of chemical contaminants in imported Chinese aquaculture products between October 2006 and May 2007, and (b) children who consumed imported Chinese aquaculture products were more at risk from chemical contaminants than other subpopulations. The exposure results paint a clear picture of the hazards associated with imported food for food safety regulators, the public, and public health officials.

Exposed? So What?

Research is important because it increases our understanding of the world around us, enabling us to learn from the past and present in order to develop solutions for current and future problems. In order to effectively protect vulnerable subpopulations from hazards, it is important that food safety officials continuously update their knowledge of issues within the food safety profession; this enables them to introduce better laws and regulations, evaluate all possible options, listen closely to all positions, research issues thoroughly, better understand the big picture, and ultimately make better decisions.[226] There is an ethical call for food safety professionals to establish a debate amongst themselves and with others regarding the "good" and/or "right" way to protect vulnerable subpopulations from hazards in the food supply. They must use their knowledge to assert normative judgments and then be prepared to defend the positions they adopt and the decisions they make. New discoveries often result in paradigm shifts in science and society, consequently changing the manner in which humans respond to the world around them. The advent of better technology for monitoring food contaminants has increased the availability of data, both on the levels of chemicals in the food supply as well as on the toxic effects of chemicals and other contaminants on consumers. This increased information sets the stage for rethinking strategies to regulate toxic chemical contaminants in food. There is an increased presence of large amounts of different toxic man-made chemicals in

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[226] Neal D. Fortin, *Food Regulation: Law, Science, Policy, and Practice* (John Wiley & Sons, Inc, 2009).

the bodies of U.S. consumers.[227] A recent CDC report on biomonitoring (released Summer 2008) shows that the average U.S. consumer has at least 207 different man-made substances in his/her body. For food science and public health professionals, ethical questions arise regarding the safety of these levels of exposure, particularly for vulnerable subpopulations. Such ethical questions include:

(a) Is it good or right to do nothing about the exposure of vulnerable subpopulation to chemicals in the food supply, despite having knowledge of unsafe chemical levels?

(b) Whose moral obligation is it to protect the vulnerable members of society from contaminants in the food supply?

Understanding the "big picture" (i.e., the complexity of issues) requires a multidisciplinary approach that involves looking at issues from both a historical and a contemporary perspective. The ethics of protecting the unborn is one such complex issue which requires examination from a historical perspective. Historically, people believed that the womb was a sheltered, capsule-like environment that was safe from intrusions and dangers of the external environment. The womb was viewed as a time capsule with a short lease, relatively impermeable to circulating drug toxicants.[228] The woman's body was considered an altruistic reservoir prepared to sacrifice itself for the survival of the fetus, and the layer of biological material–the placenta—was once called "the placental barrier" because it was believed to provide great protection to the embryo and fetus.[229] Scientists now know that the degree of fetal protection provided by the womb is modest, and that the placental membrane, once thought to be protective, is actually more like an ultra-filter.[230] The passage of a given substance through the placental membrane depends on a variety of factors, including: (a) the molecular size of the particles (smaller particles diffuse easily), (b) the charge of the particle (uncharged particles diffuse more readily), (c) the fat-solubility of the particle (the more fat-soluble,

[227] CDC, "Third National Report on Human Exposure to Environmental Chemicals " (Department of Health and Human Service, 2005).

[228] T. Takahashi, *Taking Life and Death Seriously - Bioethics from Japan : Bioethics from Japan* (2005).

[229] The first experience of fetal damage occurred as a result of atomic bombing at Hiroshima and Nagasaki: Ibid. Pg. 300-301

[230] Carl F. Cranor, "Do You Want to Bet Your Children's Health on Post-Market Harm Principles? An Argument for a Trespass or Permission Model for Regulating Toxicants," *Villanova Environmental Law Journal,* 19 (2008).

the more likely to diffuse), (d) the degree of ionization (the less ionized, the more likely to diffuse), and (e) the molecular complexity (the less complex, the more likely to diffuse).

Toxicologists classify effects of chemicals on consumers into four categories: (a) death, (b) malformation, (c) growth retardation, and (d) functional deficit. Deaths and malformations are often clearly seen, although the cause may not be obvious; growth retardation and functional deficit, on the other hand, are more hidden and thus more difficult to detect and attribute causation. Protecting female consumers of childbearing age from contaminants in the food supply is vital if unborn children are to be protected. Such protection must extend after the birth of the child as well, as breastfeeding infants and children can still be exposed to chemical contaminants through their mothers' diets. Fetuses, infants, and children need more protection than any other group of consumers. This is because (a) they have no control over what they are exposed to, (b) the mother's body's chemical burden is often shared with the fetus or breastfeeding infant/child, (c) fetuses, infants, and children are often exposed to larger chemical doses relative to body weights, (d) they are susceptible to wide range of adverse effects of chemical contaminants, a condition which increases during development, and (e) the exposure to toxic contaminants during development may result in life-long functional deficit and manifestation of increased disease risks.[231]

The next important question that food scientists need to ask is: whose moral obligation is it to protect the vulnerable members of society? Scientists have more knowledge than ever about the effects of most chemical contaminants on consumer health. Although gaps still exist in scientific studies, the available toxicological and epidemiological data provide an important basis for making rational policy decisions for protecting the health of consumers. The availability of "information comes with ethical and societal responsibilities"[232] Such responsibilities include a readiness to formulate policies to protect vulnerable subpopulations in the presence or absence of sufficient scientific evidence. The ethical and social effects of science can be considered in a variety of frameworks. One framework—biomedical ethics—is rooted in four principles: (a) respect for autonomy, (b) nonmaleficence (do no harm), (c) beneficence (do good), and (d) justice (be fair).[233] This framework forms the basis for a richly philosophical approach to medical issues, serving as a

[231] Grandjean Philippe et al, "The Faroes Statement: Human Health Effects of Developmental Exposure to Chemicals in Our Environment," *Nordic Pharmacological Society. Basic & Clinical Pharmacology & Toxicology* (2007).

[232] Steven G. Gilbert, "Ethical, Legal, and Social Issues: Our Children's Future," *NeuroToxicology* 26 (2005).

[233] Ibid.

guideline for physicians. The biomedical approach can be borrowed as a model for addressing social and ethical issues in society, including issues such as the exposure of vulnerable subpopulations to chemical contaminants in the food supply. The principle of “respect for autonomy” supports the need to protect the vulnerable subpopulation. Fetuses, infants, and children, for example, have no control over what is in the environment and in the food supply; therefore, it is the responsibility of adults and the society to ensure that the environment and the food supply are safe. In addition, it is the ethical responsibility of professionals to share their knowledge with decision makers and then engage them in using that knowledge to better protect vulnerable subpopulations. In this regard, scientists and public health officials occupy a unique position in society. Since policy makers may not have enough knowledge to make informed decisions about certain issues, it is the moral and ethical duty of scientists and health professionals to share their knowledge with decision makers and to advocate for the protection of society’s vulnerable members.[234] It is also important for scientists to explain why a certain amount of regulation is necessary. Many tragic lessons have been learned from the failure of public health officials to make informed decisions, particularly when the solutions to the prevailing problems required policy-based decisions such as prevention, public education, stringent regulation, etc.[235] Numerous gaps exist in the body of scientific evidence surrounding the toxicity (specifically for humans) of chemical contaminants, largely because the studies necessary to prove the effects of those chemicals on humans are nearly impossible to ethically conduct in a laboratory setting. The existing gaps in scientific evidence may include, but are not limited to, lack of data on the long-term or short-term harmful effects of certain chemicals on humans. Unfortunately, these gaps in scientific data introduce a measure of uncertainty about conclusions, thus providing an opportunity for adversaries to argue that some substances may not cause health problems in humans as they do in many other biological systems. Gaps also open up the possibility

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[234] If scientists do not open their doors and improve communication and sharing of knowledge and research findings, they can pose a greater danger to the society. Takahashi, *Taking Life and Death Seriously - Bioethics from Japan : Bioethics from Japan*. Pg 331

[235] Lessons should be drawn from tragedies such as *the Minamata tragedy* named after Minamata Bay in Japan, which also affected Kumamoto, Agano River, and Niigata Prefecture in Japan. The tragedy resulted in “Minamata disease” that claimed the lives of more than 1700 people and severely affected another 2,900 persons in Japan. K. Eto, "Minamata Disease," *Neuropathology* 20, no. s1 (2000), P. P. Powell, "Minamata Disease: A Story of Mercury's Malevolence," *Southern medical journal* 84, no. 11 (1991).

for scientific doubt, something that can be exploited by those who argue that some substances are less worrisome than data may suggest. The repercussions of failure to respond in the face of limited scientific data, however, can be serious, as demonstrated by a number of incidents throughout history. One such incident is the tragedy of Minamata Bay in Japan. This catastrophe, which took place from 1958 to 1968, was the result of methylmercury discharging into lakes and rivers where local residents fished, causing a number of neurological diseases among the Minamata inhabitants. While Japanese scientists worked hard to identify the etiological agents of the disease, the residents of Minamata Bay were not informed of their findings, no steps were taken to arrest continued food poisoning of the residents, public health officials were not familiar with regulations and thus did not act to protect the public, and the government failed to respond (citing lack of sufficient scientific data as the primary excuse for not acting).[236] While studies of historical tragedies are often characterized by the easy assignment of blame and the prescription of what ought to have been done, it is nevertheless important to appreciate lessons that can be drawn from them.

The tragedy of the Minamata incident "had great influence not only in medicine, but also on natural science, sociology, politics, law, public policy, and ethics."[237] One lesson from the Minamata tragedy was that members of a society must be ready to accept the undesirable and unanticipated consequences of their collective judgments. We may not choose individually to endorse certain practices in society, but we cannot personally abdicate social responsibility for the consequences of practices taking place in the society in which we live. The case of the Minamata outbreak, which involved consumer exposure to chemical contaminants in the food supply, is similar to the situation being discussed in this dissertation; both follow the "classical form of tragedy… a tragic choice, followed by unforeseen consequences."[238] Nobody wants to consume contaminated food; however, the realities of globalization mean that the poor regulation of hazardous chemicals in a few countries can negatively affect the entire global village. Countries that no longer permit the use of certain unsafe chemicals within their own territories can still experience the effects of those chemicals when they import chemically contaminated food. As developed countries enforce stricter environmental

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[236] T. Tsuda et al., "Minamata Disease: Catastrophic Poisoning Due to a Failed Public Health Response," *Journal of Public Health Policy* 30, no. 1 (2009).

[237] Takahashi, *Taking Life and Death Seriously - Bioethics from Japan : Bioethics from Japan*. Pg 331.

[238] Douglas Allchin, "The Tragedy & Triumph of Minamata: A Paradigm for Understanding Ecological, Human-Environment & Culture-Technology Interactions," *The American Biology Teacher* 61, no. 6 (1999).

regulations and approval procedures for veterinary and agricultural chemicals, more chemical industries are relocating to developing countries to take advantage of weak regulations and lax chemical approval procedures.[239] Although many chemical industries are relocating to countries with less stringent laws and regulations, no one can foretell the long-term undesirable consequences that their continued production and use might have in countries where they are banned; therefore, we must learn to cope with their consequences as they emerge.

The use of hazardous chemicals in agriculture and animal production in countries with less stringent regulations and enforcement has returned to haunt countries where such chemicals are prohibited. This is partly due to the globalization of food supplies and the resulting practice of sourcing food from many countries, including those with weak regulation and enforcement of food safety laws in food production. Developing countries with weak regulations experience serious environmental pollution from the reckless use of hazardous industrial chemicals, agricultural chemicals, and veterinary drugs in food production.[240] While the first step in solving a global issue is to deal with it locally, some issues in the current globalized world require both local and global approaches. Education, training, and regulation improvement (namely, the strengthening of chemical use and approval procedures) among the primary suppliers of U.S. food imports may prove to be the best way for the U.S. to avoid exposing its population to unsafe, chemically contaminated food imports. Children are often the first ones to suffer from the effects of food and environment contamination; this is because their weak physiological states, their close contact with the environment, and their high ratio of food consumption per unit of body weight.[241,242] It is sad to note that most people become aware of chemical exposure through food or the environment only when

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[239] B. I. Castleman, "International Mobility of Hazardous Products, Industries, and Wastes," *International Journal of Health Services* 17, no. 4 (1995).

[240] For this reason, banning the use of certain hazardous chemicals in developed countries is not enough to assure safety from the hazardous chemicals if their production and use continue in other countries. The “not-in-my-backyard” philosophy does not assure safety because the hazards deposited in someone’s backyard can still return in food –well packaged and presented on the shelves in supermarkets—to haunt consumers.

[241] Takahashi, *Taking Life and Death Seriously - Bioethics from Japan : Bioethics from Japan*.

[242] Liz Creel, "Children's Environmental Health: Risks and Remedies," Population Reference Bureau, http://www.prb.org/pdf/ChildrensEnvironHlth_Eng.pdf

the side effects become visible in the exposed vulnerable population.[243] Those who are the first to suffer the consequences of food or environmental pollution are those with low social status --for example, unborn fetuses, infants, children, and the elderly, who are generally unable to express their opinions or demand their rights from society.[244] Therefore, it is important for studies to be conducted on behalf of the weak; the studies should seek to bring justice where there is injustice and to bring equality where there is inequality.

Since 1993, there have been sustained campaigns within the national and international policy cycles for the recognition of vulnerabilities in children, women, the elderly, and the immuno-compromised. The difference in the vulnerabilities of subpopulations calls for a new approach to conducting risk assessment for chemical contaminants; it also calls for new approaches to protecting vulnerable subpopulations. Despite advancement in science, uncertainties still exist regarding the extent to which chemical contaminants in food and the environment influence the health of vulnerable subpopulations. In the case of developmental disabilities, for example, it is known that chemicals such as lead, methylmercury, and polychlorinated biphenyls exert harmful effects on the developing brains of fetuses, infants, and children. Variation exists between men and women in their physiological susceptibility to chemical exposure. Children are predisposed to increased health damage from exposure to chemicals in the food supply because of their high rate of development (with which chemical exposure can interfere); this increases their physiological sensitivity.[245] Negative effects of exposure to chemical contaminants in the food supply are further exacerbated by children's small size (relative to amount of chemical exposure) and their greater proportional intake of chemical contaminants in food, water, and the environment (relative to their body size).[246,247] Women are also considered to be physiologically vulnerable to chemical contaminants in the food supply. Women's reproductive cycle increases their susceptibility to chemicals in the food supply.

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[243] M. Harada, "Environmental Contamination and Human Rightsâ Case of Minamata Disease," *Organization & environment* 8, no. 2 (1994).

[244] This is why there is an ethical need to protect this group of consumers at all costs. Takahashi, *Taking Life and Death Seriously - Bioethics from Japan : Bioethics from Japan*. Pg 303

[245] United Nations Development Program (UNDP), "Chemical Management: The Why and How of Mainstreaming Gender in Chemicals Management."

[246] Ibid.

[247] Philip Landrigan, "Children's Environmental Health," (Population Reference Bureau, 2001).

Women's bodies also undergo rapid physiological changes during certain stages of their lives (such as pregnancy, lactation, and menopause), a phenomenon that increases their susceptibility to chemical contaminants in food and the environment. Women's exposure to chemicals can also cause miscarriages, premature births, birth defects, and low birth weights (as evidenced in the tragedy of Minamata Bay in Japan); a significant proportion of women's chemical body burden can be passed through the placenta to their children during gestation and breastfeeding. Finally, due to their special reproductive roles, women's bodies are biologically designed to retain high reserves of fatty tissues throughout their life cycles; this increases their vulnerability to fat-soluble chemical contaminants in the food supply.[248,249] Fat-soluble chemicals have a tendency to accumulate in the fat tissues of the body, and their effects can be seen after long periods of time. Uncertainties exist regarding the correlation between food and environmental contamination and rising cancer rates among children, women, the elderly, and those with compromised immune systems.

As mentioned earlier in this chapter, the past is often the first place people look for future guidance. *The Delaney Clause* of 1958, an amendment to the 1939 *Food, Drug and Cosmetic Act*, was one of the first laws passed to control hazardous or carcinogenic chemical substances in the U.S. food supply. The formulation of the *Delaney Clause* was triggered by the discovery of an herbicide—aminotriazole (a suspected carcinogen)—in cranberry plants in Oregon and Washington. The law was intended to protect consumers from chemical contaminants in the food supply. The law not only prohibited the use of potentially carcinogenic chemicals in human food, but also prohibited the use of chemicals that, when used during food processing operations, surpassed established tolerance levels. The *Delaney Clause* set an important historical precedent, and also fuelled scientific debates about how best to regulate "potentially carcinogenic" chemicals that, with modern technologies, can be detected at exceptionally low levels. Since its passage, several other laws governing the use of chemicals in food and the environment have been passed. The U.S. government has also passed laws that have sought to protect vulnerable subpopulations by recognizing their physiological vulnerabilities to certain contaminants in the food supply. One such law was the 1996 *Food Quality Protection Act* (FQPA), which established stricter safety standards and lower

[248] United Nations Development Program (UNDP), "Chemical Management: The Why and How of Mainstreaming Gender in Chemicals Management."

[249] Calabrese, "Sex Differences in Susceptibility to Toxic Industrial Chemicals."

maximum residue limits for chemical contaminants in foods for infants and children.[250] The U.S. Environmental Protection Agency (EPA) is responsible for setting standards and tolerances for pesticides, herbicides, fungicides, and other chemical substances used in agricultural products, while the FDA is responsible for establishing premarket approval for food additives and colors. U.S. manufacturers must petition the FDA for approval of any food or color additive before selling or marketing it for use in the U.S. While the U.S. has passed many regulations on use of chemicals in food and the environment, the enforcement of those regulations has largely remained a domestic task. Globalization of the U.S. food supply and the associated increase in the number and complexity of food safety problems have prompted the U.S. government to rethink its food safety strategies. The increased food safety problems that emanate from globalization of the U.S. food supply recently culminated in the formulation of the *Food Safety Modernization Act* (FSMA), passed in December 2010 and signed into law in January 2011. The FSMA revolutionized the manner in which the FDA protects U.S. consumers from hazards in food imports; the new legislation authorizes the FDA to refuse admission of imported food if a foreign processing facility or country denies FDA inspectors access to the food facility to conduct inspection. The law also "[authorizes] the FDA to require certification, based on risk criteria that the imported food is in compliance with food safety requirements"[251] Additionally, the FSMA puts increased burden on food importers, requiring them to perform supplier verification to ensure that food imports are safe and conform to regulations.[252] The new legislation encourages production of safe food by providing "…an incentive for importers who take additional food safety measures by directing FDA to establish a voluntary program through which importers can receive expedited review of their shipments if the importer has taken certain measures to assure the safety of the food."[253]

The FSMA also recognizes the importance of public-private partnerships in securing U.S. food supplies; it recognizes that the U.S. cannot regulate itself to food safety and that securing the safety of food supplies requires the strengthening of collaboration among all stakeholders. The

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[250] U.S. Environmental Protection Agency, "Food Quality Protection Act (Fqpa) of 1996," EPA, http://www.epa.gov/opp00001/regulating/laws/fqpa/.

[251] F.D.A, "Food Safety Legislation," U.S. Department of Health and Human Services, http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm237934.htm.

[252] Ibid.

[253] Ibid.

FSMA recognizes the importance of building state, local, territorial, and tribal food safety program capacity.[254] The act directs the U.S. Undersecretary for Food Safety to "…improve training of state, local, territorial, and tribal food safety officials, as well as to authorize grants for training, inspection, lab construction, development of food safety programs, and other food safety activities."[255] Globalization has increased the complexity of problems that many countries face in securing their food supplies; the FSMA recognizes this complexity. There are no easy solutions to current food safety problems associated with imported food.[256] The U.S. government and importers of finished products and raw materials should, therefore, consider extending food safety programs and activities beyond U.S. borders to other countries where food imports originate;[257] cooperation and joint efforts between the U.S. government, farmers, producers, and food industries in exporting countries to take on food safety activities (e.g., education, training, extension services, food facilities inspections, et cetera) can help improve the safety of U.S. food imports.

Many of the current global food safety problems have no easy solutions. They require a policy-based approach, coupled with education, prevention, stringent regulatory action, constant inspection, surveillance, and monitoring to ensure conformance. There should also be continuous review of policies and regulations as more scientific data becomes available. In the meantime, the absence of scientific data should not be used as an excuse for failing to take measures to protect the public from potentially harmful substances in food supplies or in the environment. In the absence of scientific data, the Precautionary Principle can be used to help protect the public. The Precautionary Principle—first used in the 1992 Rio Declaration—is an aid to decision making on environmental and human health issues. Since its first use in 1992, the Principle has grown in popularity among

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[254] The FSMA recognizes that securing the globalised food safety goes beyond establishing laws regulations; it requires involvement all stakeholders (from the farm to the table) to ensure food safety.

[255] F.D.A, "Food Safety Legislation."

[256] In addition, the country cannot regulate itself to food safety, that is, regulations alone cannot secure the globalized U.S. food supplies. More needs to be done on the ground on collaborating with farmers and producers if import safety of U.S. food is to be improved.

[257] International partnership and sharing of knowledge can play a vital role in securing the safety of the nation's food supply. For increased success in dealing with food safety problem of imports, the U.S. government, importers, and other stakeholders may need to extend increased working relations with producers and food industries in exporting countries. Increased joint training and extension activities on safe food production methods may help improve the safety of U.S. food imports. However, this may require more resources.

national and international risk managers and decision makers. The current risk management approach used in the U.S. gives the public the burden of proving that a particular chemical substance causes harm; the approach requires no action in the presence of uncertainties or insufficient data. This can result in continuous exposure to hazards while proof of harm and sufficient scientific evidence is being obtained; lack of sufficient scientific data on a chemical does not imply safety of the chemical. The Precautionary Principle, which suggests that chemical contaminants should be considered "guilty until proven innocent," shifts the burden of "proof of innocence" to the creators of the hazard. While not without problems, the precautionary approach protects the public, and particularly the vulnerable subpopulations, from potentially dangerous substances that have yet to be proven harmless. Very few of the chemicals increasingly found in food imports have set tolerance levels or maximum residue limits for consumption. While some of these chemicals are known to be carcinogens, little is known about many of the other chemicals used in food. As mentioned earlier in this dissertation, the problem of chemical contamination in Chinese food products is complex. China, like other developing countries, has many food producers in a highly fragmented supply chain; furthermore, many Chinese transactions are done in cash, making it difficult to trace contaminated products or investigate food-safety-related problems.[258] Food and the environment are interrelated; it is difficult to produce safe, contaminant-free food in an unsafe or contaminated environment. Waste from agricultural farms, agricultural industries, and chemical industries that are in close proximity to food production facilities or farms are likely to affect the safety of food produced.[259] These factors complicate the process of solving food safety problems encountered in food imports.

Policy Dilemma

Scientists often attempt to be objective in interpreting data and arriving at conclusions; however, in most cases, scientific studies involve uncertainties and variability. Scientists often make efforts to minimize uncertainties and variability in their studies. Most scientific research on chemical contaminants in food and the environment tend to focus on what is not known or what is doubted

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[258] In the current globalised system of food supplies, traceability is important for timely identification of sources of food borne diseases or hazards. This enables authorities to safeguard the public health.

[259] Food safety problems in the U.S. are compounded by the difficulty in establishing product traceability for products originating in many developing countries.

rather than what is known; this is an attempt to establish certainty and proof for causation. Scientifically-based decisions are, in most cases, made with some level of uncertainty or insufficient knowledge, and some uncertainties encountered in scientific research are serious, resulting in incomplete understanding of the possible causal relationship between variables (e.g., the level of chemical contaminants in food or the environment) and outcomes (i.e., the effects of chemicals on human health). While scientists are often comfortable with the nature of uncertainties and variations in scientific studies, they are often uncomfortable with the likelihood that something known could shed light upon the unknown. The tendency of some scientists to focus on uncertainties and the need for further study makes it hard for decision makers and the public to adopt clear policy direction. Failure to make decisions to protect the public while data is being gathered leaves vulnerable subpopulations exposed to potentially hazardous substances in the food supply and the environment. Scientists should bear in mind the words of Sir Austin Bradford Hill, who aptly stated,

> *"All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have or postpone the action that it appears to demand at a given time."*[260]

Historically, decisions to protect public health, including the health of children, were made only in the presence of evidences of harm caused by chemicals in the environment or in the food supply. For example, early warnings of lead poisoning were largely ignored; this failure to heed warnings resulted in serious harm to both people and the environment. Many studies had to be conducted and evidence of harm had to be collected before lead could be removed from paint or gasoline. Similarly, in the case of asbestos, many studies had to be conducted and large amounts of data had to be obtained before the use of asbestos as a building material could be stopped. While decisions are easy to make in the presence of adequate scientific data, causation can be difficult to establish when a hazard has multiple causes or can be confounded by other factors such as genetics or exposure to multiple chemicals. Various factors make it difficult to estimate the hazard level that a chemical contaminant may present to consumer health; for example, more than 70,000 chemicals

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[260] Sir Austin Bradford Hill, "The Environment and Disease: Association or Causation?," *Proceedings of the Royal Society of Medicine,* (1965). Pg. 296. Policies need to be based on information or data that is available at the time of its formulation, and not data that is expected from studies that are underway.

are produced around the world, yet toxicological information is available for only about 10,000 of these chemicals. Difficulty also arises because in most cases, toxicological studies are often done in isolation, meaning that chemicals are studied individually, despite the fact that consumers are often exposed to many chemicals through various routes at the same time.[261]

Control of Chemical Contaminants in Aquaculture Farms

The first line of defense from chemical contaminants is the use of approved aquaculture chemicals and production drugs at levels that are permitted by the current legislation. The primary aquaculture farmers, aquaculture processing industries, and producers of aquaculture feed, drugs, and other inputs must comply with laws and regulations and must observe the principles of good agricultural practices and good manufacturing practices. The government must work in collaboration with educational institutions, extension officials, cooperative societies, et cetera, to provide training to farmers on proper farm management practices. The second line of defense is the intensive control and monitoring of chemical levels in food—a responsibility primarily bestowed upon various governments' regulatory and food control agencies. Agencies dedicated to food control and enforcement must be backed by up-to-date food legislation. Regulations on the use of agricultural chemicals, drugs, et cetera, should undergo periodic reviews and changes as more data become available. The third line of defense is the use of technologies to prevent or reduce the use of chemicals in food (for example, the use of biotechnology to develop disease-resistant fish species). This would reduce the need to use aquaculture drugs and chemicals to treat aquaculture diseases.[262] Consumers form the last—and most important—line of defense against chemical exposure via food intake. Consumers need to be aware of dietary guidelines and recommended daily intakes for aquaculture and seafood products in order to limit their exposure to chemical contaminants in aquaculture and other sea products. Government consumer protection agencies often provide recommended daily intake guidelines for certain foods based on the perceived levels of hazards in them; this ensures that consumers are not exposed to excessive levels of chemical contaminants in foods. The FDA and the Environmental Protection Agency (EPA), for example, provide special recommendations on fish consumption for specific subpopulations such as women who might

[261] K. A. Van der Heijden, *International Food Safety Handbook* (1999). Pg 665
[262] Ibid.

become pregnant, women who are pregnant, nursing mothers, and young children.[263] To limit their exposure to harmful chemical contaminants in fish, vulnerable U.S. subpopulations are advised to refrain from eating Sharks, Swordfish, King Mackerel, or Tilefish because they contain high levels of certain chemicals such as mercury.[264] For fish species that have lower levels of mercury, vulnerable subpopulations are advised to eat no more than 12 ounces (2 average meals) a week. The FDA and EPA categorize shrimp, canned light tuna, salmon, pollock, and catfish as low-mercury fish products. The FDA and EPA recommend consumption of no more than 6 ounces (one average meal) per week of high-mercury fish species such as albacore (white tuna).[265] Seafood consumers should follow dietary recommendations by the FDA, EPA, and other public health officials to ensure that they are safe from contaminants in the food supply.

The objective of this study was to shed light on the complexities of environmental health and food safety issues in China and how they relate to the safety of internationally-traded Chinese aquaculture products. This study focused mainly on the safety of U.S. imports of Chinese aquaculture products. We hope that the results of this study will be helpful to regulatory authorities in formulating food safety and public health policies for protecting the physiologically vulnerable U.S. subpopulation. In summary, this study found that U.S. seafood consumers were, in our contrived hypothetical scenario using actual consumption and contamination data, exposed to unsafe levels of chemical contaminants from imported Chinese aquaculture products. The following is a summary of the research findings addressed in chapters 1, 3, 4, and 5 of this dissertation; the findings in those chapters addressed the following research questions:

1. What is the origin of food safety and environmental health problems in the aquaculture industry in China?
2. How effective are the U.S. and Chinese governments' regulations in protecting consumers from hazards in Chinese aquaculture products?
3. Considering the prevailing U.S. seafood consumption patterns (amongst the entire population as well as within specific sensitive sub-populations), was the dietary intake of

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[263] F.D.A, "2004 Epa and FDA Advice For: Women Who Might Become Pregnant, Women Who Are Pregnant, Nursing Mothers, and Young Children " http://www.fda.gov/food/foodsafety/product-specificinformation/seafood/foodbornepathogenscontaminants/methylmercury/ucm115662.htm.

[264] Ibid.

[265] Ibid.

specific chemicals from Chinese aquaculture imports within safe levels (in a contrived scenario using actual consumption and contamination data)?

The summary of the findings for the above research question are provided below:

Research question 1

What is the origin of food safety and environmental health problems in the aquaculture industry in China?

This study found several sources of food safety and environmental health problems in China; the following is a non-exhaustive list of the findings:

a. Complex regulatory system,
b. Poor environmental waste management,
c. Excessive use of agricultural chemicals such as fertilizers, pesticides, veterinary drugs, etc.,
d. Counterfeits resulting from replacement with low-priced unsafe food and drug ingredients,
e. Laxity of Chinese government in developing and enforcing SPS and GMP measures in food industries, and
f. Large number of Chinese agricultural producers, making it difficult for regulatory authorities to manage important aspects of production.

Research question 2

How effective are the U.S. and Chinese governments' regulations in protecting consumers from hazards in Chinese aquaculture products?

The U.S. government has made consistent efforts to ensure the safety of imported food products; the most recent efforts include implementing the 2007 recommendations of the Interagency Working Group on Import Safety, and the passage of the *Food Safety Modernization Act* which was signed into law in January 2011. The following is a summary of other steps covered by both the 2007 recommendations by the Interagency Working Group on Import Safety, and the *Food Safety Modernization Act*:

a. Authorize the FDA to require producers of high-risk foods from certain countries to certify that their products conform to regulations;
b. Introduce a system of voluntary certification for foreign manufacturers so that U.S. inspectors can quickly clear products from certified importers;

c. Provide incentives to importers who uphold higher safety practices for high-risk products;
d. Establish information sharing agreements with foreign governments to facilitate the timely exchange of import- and recall-related data;
e. Publicize names of certified producers and importers in order to increase transparency and thus allow consumers and distributors to make informed decisions on the safety of products;
f. Require the FDA to recall adulterated or contaminated products from the market;
g. Establish agreements with foreign countries in which the FDA can certify equivalency of food safety standards, thus shifting some of the FDA's inspection burdens to foreign governments wishing to export food to the U.S.;
h. Explore the possibility of certifying third-party inspectors who would conduct inspections on behalf of the FDA in foreign and domestic food processing facilities;
i. Consider accrediting private laboratories to conduct testing on seafood; and
j. Consider entering into an agreement with the National Oceanic and Atmospheric Administration (NOAA) in which the NOAA uses its resources to conduct seafood inspections on behalf of the FDA.

The Chinese government has also made numerous efforts in ensuring the safety of its food exports; these efforts include, but are not limited to, adopting new policies such as:

a. Establishing mechanisms to enable the traceability of products, including the use of farm records and third-party certifiers;
b. Banning the use of toxic and unapproved chemicals in food;
c. Blacklisting of several seafood processors and revocation of licenses of companies found to be exporting food tainted with illegal drugs or banned substances;
d. Establishing end-product testing for residues of unapproved chemicals and drugs; and
e. Drafting of new food laws such as: *The Food Hygiene Law* and the *Food Safety Law*, drafted by the Ministry of Health; and the *Law of Quality and Safety for Agricultural Products*, drafted by the Ministry of Agriculture

Research question 3

Considering the prevailing U.S. seafood consumption patterns (amongst the entire population as well as within specific sensitive sub-populations), was the dietary intake of specific *chemicals from Chinese aquaculture imports within safe levels (in our contrived scenario rooted in actual consumption and contamination data)?*

Exposure among the 2003-2004 NHANES adult seafood consumers

Adult NHANES seafood consumers would have been exposed to high levels of fluoroquinolone contaminants. Adult NHANES 2003-2004 seafood consumers would have been exposed to higher levels of gentian violet contaminants from imported Chinese aquaculture products than they would in a hypothetical MRL-compliant scenario. Adult NHANES seafood consumers in the upper 50th percentile would have been exposed to 67 times more malachite green from imports than in a hypothetical MRL-compliant scenario. In addition, they would have been exposed to 16 times more gentian violet and 4.9 times more fluoroquinolone than from imported aquaculture products than in a hypothetical MRL-compliant scenario. Therefore, the seafood consumers would have been exposed to high levels of fluoroquinolone, malachite green, and gentian violet from imported Chinese aquaculture products. However, adult NHANES 2003-2004 seafood consumers would have been at low risk from nitrofuran contaminants in imported Chinese aquaculture products. This is because imported Chinese aquaculture products had nitrofuran contaminants at levels that were within the maximum residue limit.

Exposure in children versus adult consumers

The fluoroquinolone exposure among children and adult NHANES 2003-2004 seafood consumers would have been within the established acceptable daily intake level of 0.03mg/kg/day. Children in the upper 50^{th}, 95^{th}, and 99.5^{th} percentile would have been exposed to lower levels of fluoroquinolone contaminants than their corresponding adult counterparts. Therefore, fluoroquinolone contaminants in imported Chinese aquaculture products posed less risk to NHANES 2003-2004 children. Adult NHANES consumers would have been exposed to higher levels of fluoroquinolone contaminants than NHANES 2003-2004 children. When considering contaminant intake per unit of body weight in the exposure analysis, NHANES 2003-2004 children in the upper 50^{th}, 95^{th}, and 99.5^{th} percentile would have been exposed to lower levels of fluoroquinolone contaminants per kilogram of body weight than the NHANES 2003-2004 adult seafood consumers. The upper 95^{th} percentile of both NHANES 2003-2004 children and their adult counterparts would have been exposed to high levels of gentian violet contaminants in imported Chinese aquaculture products. Overall, NHANES 2003-2004 children would have been exposed to higher levels of gentian violet than would NHANES 2003-2004 adults. Both the NHANES 2003-2004 children and adults would have been exposed to extremely high levels of malachite green contaminants in imported Chinese aquaculture products. Malachite green exposure in milligrams per kilogram of body weight would have been higher among NHANES 2003-2004 children than among their adult counterparts. The level of nitrofuran contaminant exposure among the upper 99.5th percentile of NHANES 2003-2004 children would have been higher than the exposure among NHANES 2003-2004 adult seafood consumers. The frequency of exposure to low levels of nitrofuran contaminants from imported Chinese aquaculture products would have been higher among children than among adult NHANES seafood consumers.

Exposure among vulnerable adult sub-populations: females and the elderly

Exposure among NHANES women

Adult NHANES 2003-2004 female consumers would have been exposed to high levels of fluoroquinolone contaminants. The range of fluoroquinolone exposure was highest among the upper 99.9th percentile of 2003-2004 NHANES adult female consumers. The 2003-2004 NHANES adult female consumers forming the upper 95th percentile of all NHANES adult female seafood consumers would have been exposed to high levels of gentian violet; the highest gentian violet exposure level would have occurred among the upper 99.9th percentile of NHANES 2003-2004 female consumers. NHANES 2003-2004 female consumers would have also encountered much higher malachite green exposure from imported Chinese aquaculture products than they would if the imported Chinese aquaculture products contained malachite green at MRL-compliant levels. The level of nitrofuran contaminant exposure among NHANES 2003-2004 women would have been slightly higher than it would have been if the Chinese aquaculture imports contained nitrofuran contaminants at the maximum residue limit.

Exposure among adults aged 60 years and older

The likely fluoroquinolone contaminant exposure among NHANES 2003-2004 seafood consumers aged 60 years and older would have been within safe levels. However, the likely gentian violet exposure among NHANES 2003-2004 seafood consumers aged 60 years and older would have been considerably high and unsafe. The likely levels of malachite green exposure among the elderly would have been high and would have posed health risk to consumers. Therefore, NHANES

2003-2004 seafood consumers aged 60 years and older would have been exposed to unsafe levels of malachite green from imported Chinese aquaculture products; the elderly NHANES 2003-2004 seafood consumers would have been exposed to high levels of nitrofuran contaminants from imported Chinese aquaculture products.

This study was intended provided an insight into the complexity of food safety and environmental health issues regarding internationally-traded Chinese aquaculture products. Hopefully, the findings of this study will be useful to public health officials, food safety regulators, consumer advisory groups, et cetera, in formulating policies, and providing the necessary guidance and recommendations to consumers in order protect the vulnerable subpopulations from chemical contaminants in the food supply.

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Appendix A - Summary Tables for Chemical Contaminant Exposure

Table A.1 Chemical Exposure in Children

		Percentile of NHANES Consumers					
Chemical		**50th Percentile**		**95th Percentile**		**99.9th Percentile**	
		mg/kg/day	mg/day	mg/kg/day	mg/day	mg/kg/day	mg/day
Fluoroquinolone	Mean	0.0004	0.0144	0.0019	0.0631	0.0322	0.8901
	Std Deviation	0.0000	0.00081	0.0004	0.0124	0.0044	0.0934
	Maximum	0.0005	0.0165	0.0030	0.1079	0.0502	1.186
	Minimum	0.0004	0.0122	0.0008	0.0243	0.0227	0.6284
Gentian violet	Mean	0.0015	0.0481	0.0049	0.1666	0.1130	3.2478
	Std Deviation	0.0001	0.003	0.0011	0.0388	0.0171	0.3477
	Maximum	0.0017	0.0584	0.0087	0.2867	0.1904	4.4559
	Minimum	0.0011	0.0365	0.0000	0.0000	0.0754	2.3863
Malachite green	Mean	0.0061	0.2005	0.0148	0.5047	0.5026	14.4189
	Std Deviation	0.0004	0.0138	0.0046	0.1530	0.0805	1.6883
	Maximum	0.0075	0.2382	0.0309	0.9440	0.8029	20.1770
	Minimum	0.0049	0.1595	0.0031	0.0957	0.3099	9.1321
Nitrofuran	Mean	0.00005	0.0016	0.0001	0.0039	0.0040	0.1174
	Std Deviation	0.000003	0.0001	0.0000	0.0014	0.0006	0.0133
	Maximum	0.00006	0.0019	0.0003	0.0083	0.0066	0.1705
	Minimum	0.00003	0.0013	0.0000	0.0169	0.0026	0.0816

Table A.1 above shows the levels of contaminant exposure that would have resulted among the upper 50th, 95th, and 99.9th percentiles of NHANES 2003-2004 children consumers of imported Chinese aquaculture products (scenario 1). The table shows the mean, the maximum, and the minimum contaminant exposure that would have occurred among children consumers; the table also shows the standard deviation for the likely exposures that would have occurred among children consumers.

Table A.2 Chemical Exposure in Female Consumers of Ages 18 Years and Older

	Percentile of NHANES Consumers						
Chemical		**50th Percentile**		**95th Percentile**		**99.9th Percentile**	
		mg/kg/day	mg/day	mg/kg/day	mg/day	mg/kg/day	mg/day
Fluoroquinolone	Mean	0.00049	0.02776	0.00342	0.2086	0.02549	1.13007
	Std Deviation	0.00002	0.00118	0.00020	0.00246	0.00367	0.12059
	Maximum	0.00060	0.03302	0.00412	0.25970	0.03731	1.57028
	Minimum	0.00042	0.02414	0.00277	0.17099	0.01786	0.81892
Gentian violet	Mean	0.00162	0.08992	0.01056	0.63947	0.09121	4.12312
	Std Deviation	0.00009	0.00453	0.00077	0.04511	0.01370	0.43888
	Maximum	0.00194	0.10696	0.01422	0.05999	0.14645	6.16382
	Minimum	0.00138	0.07684	0.00779	0.49712	0.06395	3.17189
Malachite green	Mean	0.00672	0.37343	0.04227	2.56138	0.39212	18.06824
	Std Deviation	0.00040	0.01999	0.00357	0.21458	0.05572	1.99718
	Maximum	0.00806	0.44134	0.05267	3.13403	0.59344	28.12491
	Minimum	0.00564	0.32779	0.03360	1.99101	0.25740	13.46006
Nitrofuran	Mean	0.00007	0.00414	0.00046	0.02651	0.00329	0.15349
	Std Deviation	0.00000	0.00012	0.00001	0.00102	0.00051	0.01662
	Maximum	0.00008	0.00456	0.00052	0.03022	0.00546	0.23876
	Minimum	0.00006	0.00381	0.00039	0.02276	0.00222	0.10814

Table A.2 above shows the levels of contaminant exposure that would have resulted among the upper 50th, 95th, and 99.9th percentiles of NHANES 2003-2004 consumers of ages 18 years and older; the exposure would have occurred among consumers of imported Chinese aquaculture products (scenario 1). The table shows the mean, the maximum, and the minimum contaminant exposure that would have occurred among consumers, and the standard deviation for the likely exposures that would have occurred among children consumers.

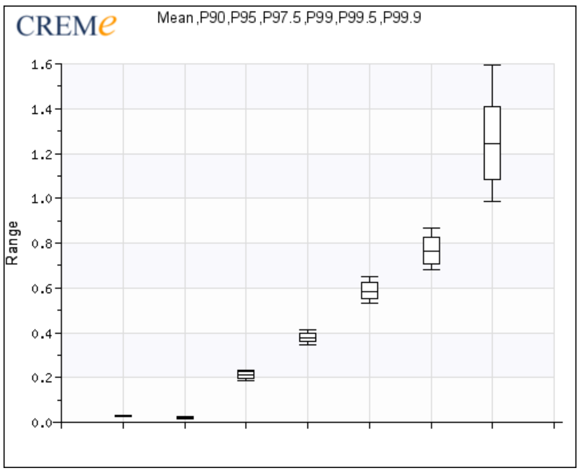
Table A.3 Chemical Exposure in Elderly Consumers of Ages 60 Years and Older

	Percentile of NHANES Consumers						
Chemical		**50th Percentile**		**95th Percentile**		**99.9th Percentile**	
		mg/kg/day	mg/day	mg/kg/day	mg/day	mg/kg/day	mg/day
Fluoroquinolone	Mean	0.00071	0.05268	0.00499	0.37345	0.02023	1.4646
	Std Deviation	0.00004	0.00295	0.00027	0.01883	0.00321	0.24540
	Maximum	0.00086	0.06426	0.00587	0.43240	0.03132	2.30067
	Minimum	0.00058	0.04367	0.00418	0.31650	0.01402	0.99870
Gentian violet	Mean	0.00236	0.17535	0.01673	1.26349	0.07344	5.27431
	Std Deviation	0.00015	0.01145	0.00115	0.08289	0.01254	0.91577
	Maximum	0.00279	0.20582	0.02035	1.48323	0.11690	8.84198
	Minimum	0.00181	0.13829	0.01262	1.04350	0.04491	3.45336
Malachite green	Mean	0.00991	0.75507	0.07058	5.33687	0.32403	23.10074
	Std Deviation	0.00063	0.04658	0.00500	0.36231	0.05465	4.29433
	Maximum	0.01217	0.89342	0.08721	6.65894	0.50224	37.42859
	Minimum	0.00825	0.60929	0.05935	4.45906	0.20942	14.97812
Nitrofuran	Mean	0.00008	0.00596	0.00057	0.04360	0.00262	0.18870
	Std Deviation	0.00000	0.00041	0.00004	0.00319	0.00045	0.03534
	Maximum	0.00009	0.00705	0.00069	0.05188	0.00449	0.34028
	Minimum	0.00006	0.00466	0.00045	0.03495	0.00162	0.12339

Table A.3 above shows the levels of contaminant exposure that would have occurred among the upper 50th, 95th, and 99.9th percentiles of NHANES 2003-2004 consumers aged 60 years and older. The exposure would have occurred among consumers of imported Chinese aquaculture products (scenario 1). The table shows the mean, the maximum, and the minimum contaminant exposure, it also shows the standard deviation for the likely exposures that would have occurred among children consumers.

Appendix B - Box-plots and Exposure Distributions for NHANES 2003-2004 Seafood Consumers

Fluoroquinolone Exposure (in mg/day) among All NHANES Adult Consumers



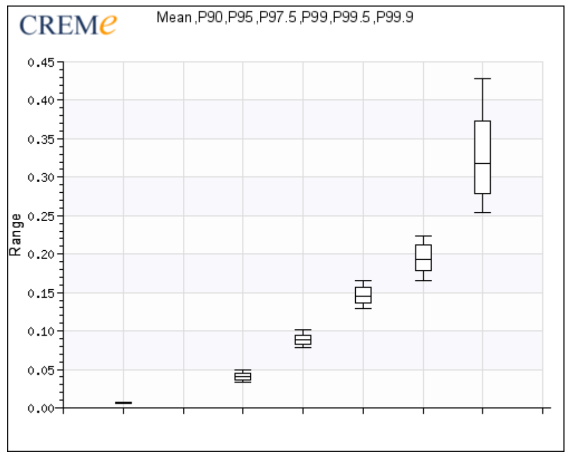


Figure B.1a Fluoroquinolone in scenario 1 Figure B.1b Fluoroquinolone in scenario 2

Figure B.1a shows box-plots for the likely fluoroquinolone contaminant exposure that would have resulted in scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.1b shows box-plots for the likely fluoroquinolone contaminant exposure that would have resulted in scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The figures show box-plots for the upper 50th, 90th, 95th, 97.5th, 99.5th, and 99.9th percentile of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.

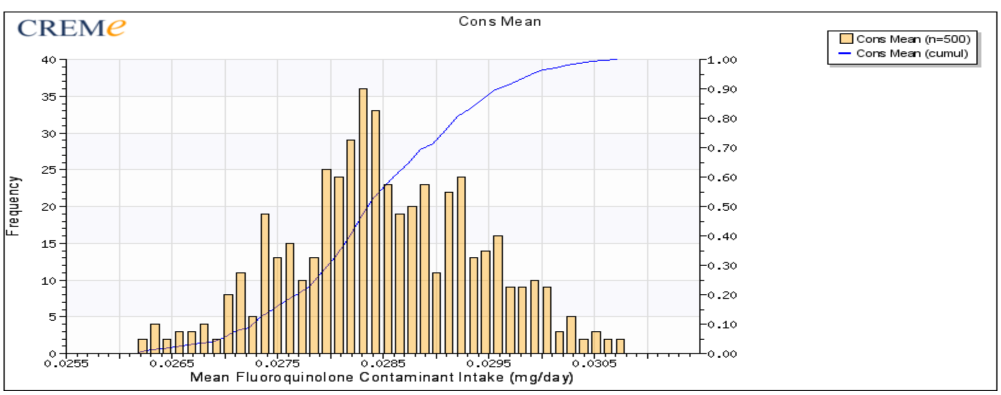


Figure B.2a Mean fluoroquinolone contaminant intakes in scenario 1 (mg/day)

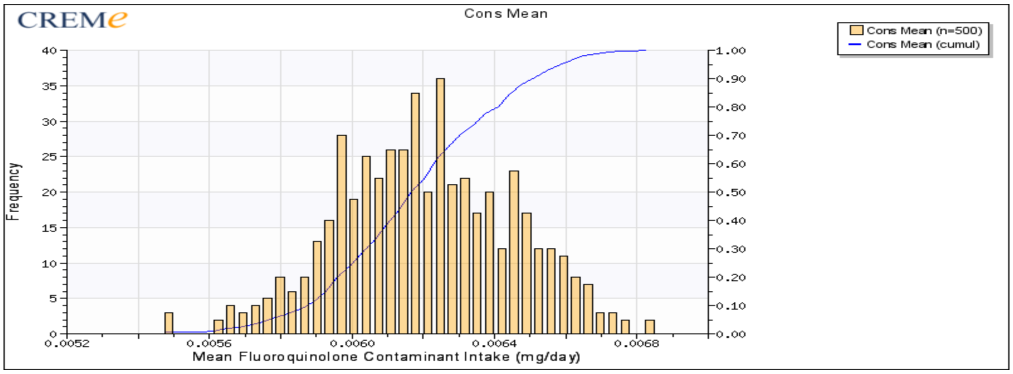


Figure B.2b Mean fluoroquinolone contaminant intakes at MRL (mg/day)

Figure B.2a shows the likely fluoroquinolone contaminant exposure that would have resulted in scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.2b shows the likely fluoroquinolone contaminant exposure that would have resulted in scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). Note: The X-axes for the two graphs are on different scales

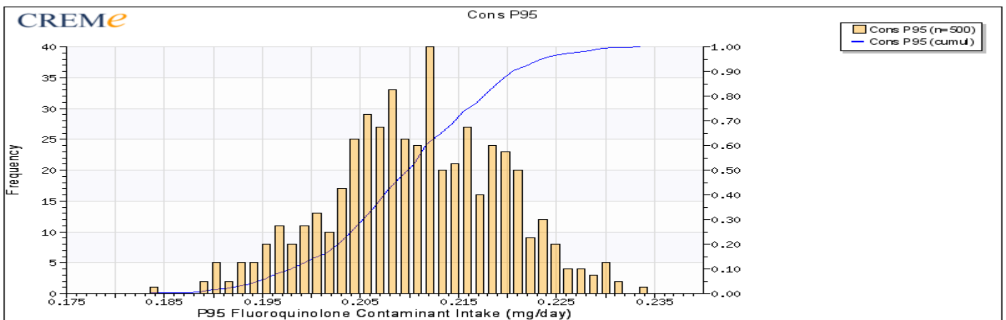


Figure B.3a Fluoroquinolone contaminant intakes in scenario 1 for the 95th P (mg/day)

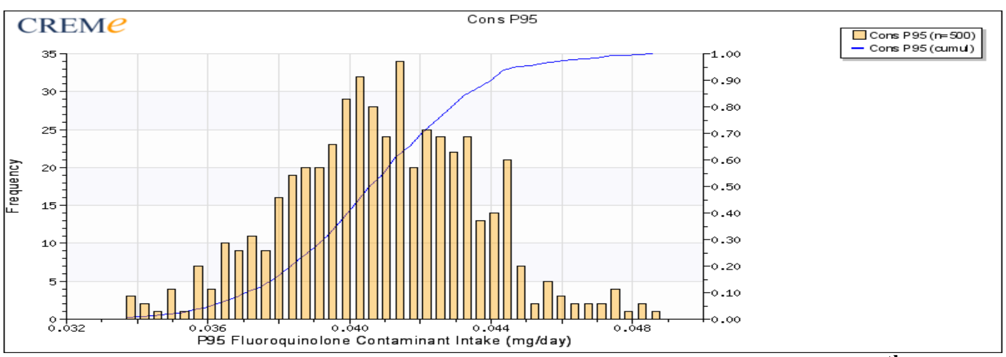
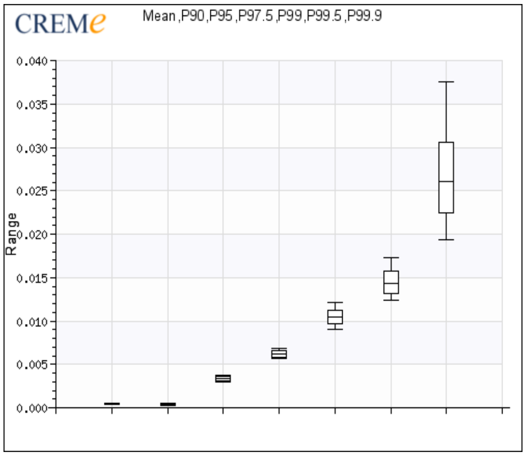


Figure B.3b Fluoroquinolone contaminant intakes at MRL for the 95th P (mg/day)

Figure B.3a shows the likely fluoroquinolone contaminant exposure that would have resulted in scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.3b shows the likely fluoroquinolone contaminant exposure that would have resulted in scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). Note: The X-axes for the two graphs are on different scales

Fluoroquinolone Exposure (in mg/kg/day) among All NHANES Adult Consumers



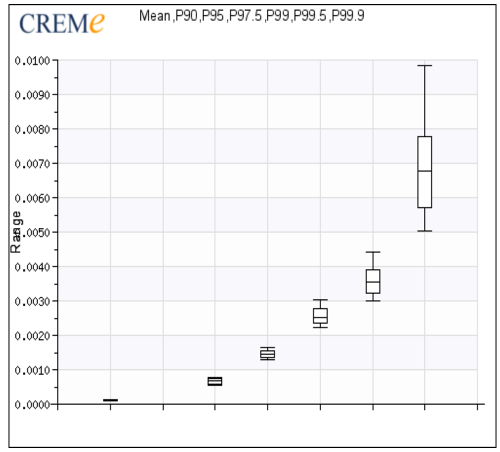


Figure B.4a Fluoroquinolone in scenario 1 Figure B.4b Fluoroquinolone in scenario 2

Figure B.4a shows box-plots for the likely fluoroquinolone contaminant exposure in mg/kg/day that would have resulted in scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.4b shows box-plots for the likely fluoroquinolone contaminant exposure in mg/kg/day that would have resulted in scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The figures show box-plots for the upper 50th, 90th, 95th, 97.5th, 99.5th, and 99.9th percentile of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.

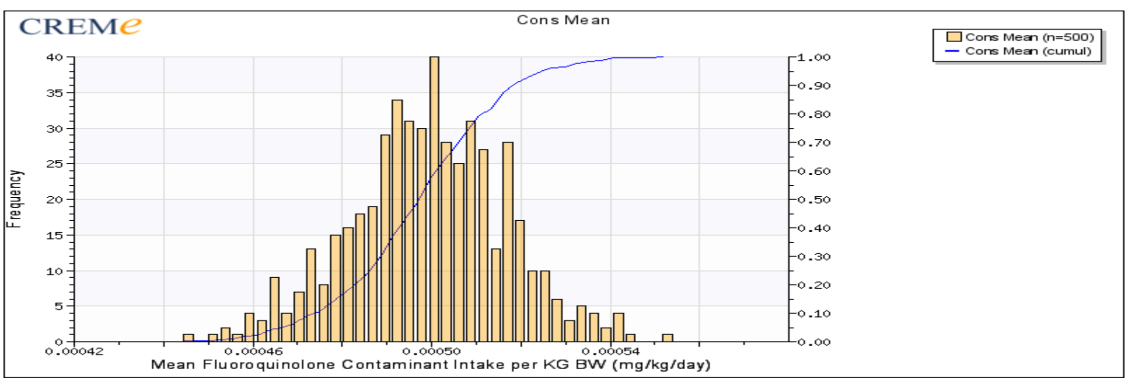


Figure B.5a Mean fluoroquinolone contaminant intakes in scenario 1 (mg/kg/day)

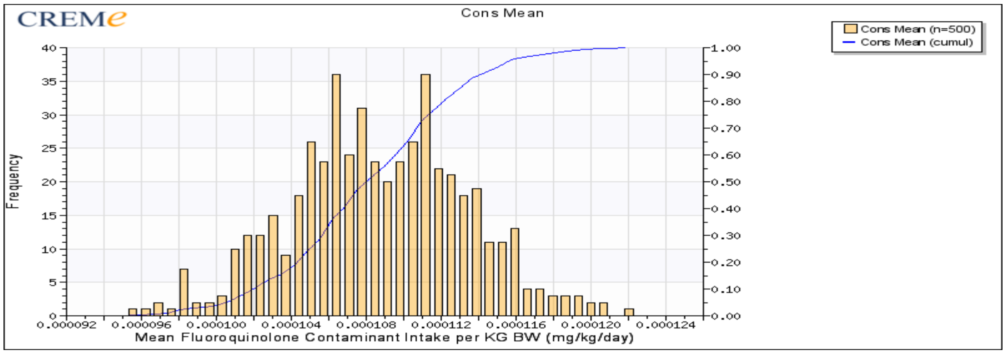


Figure B.5b Mean fluoroquinolone contaminant intakes at MRL (mg/kg/day)

Figure B.5a shows the distribution for the likely fluoroquinolone contaminant exposure (in mg/kg/day) that would have resulted in scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.5b shows the distribution of the likely fluoroquinolone contaminant exposure (in mg/kg/day) that would have resulted in scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). Note: The X-axes for the two graphs are on different scales.

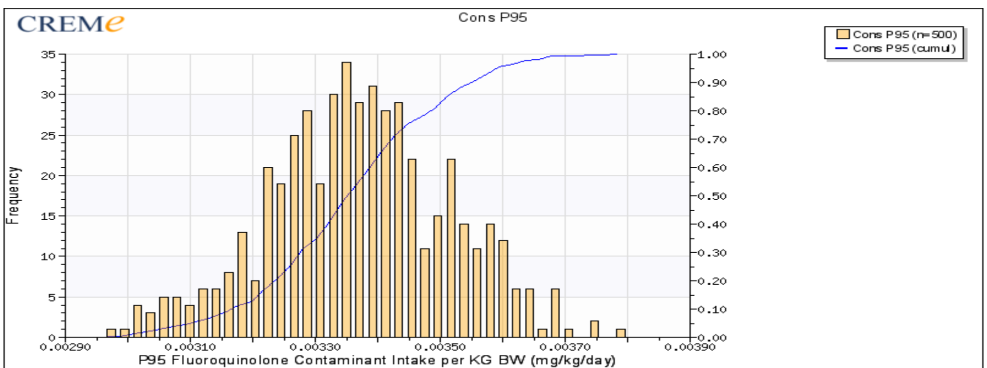


Figure B.6a Fluoroquinolone contaminant intakes for the 95th P (mg/kg/day)

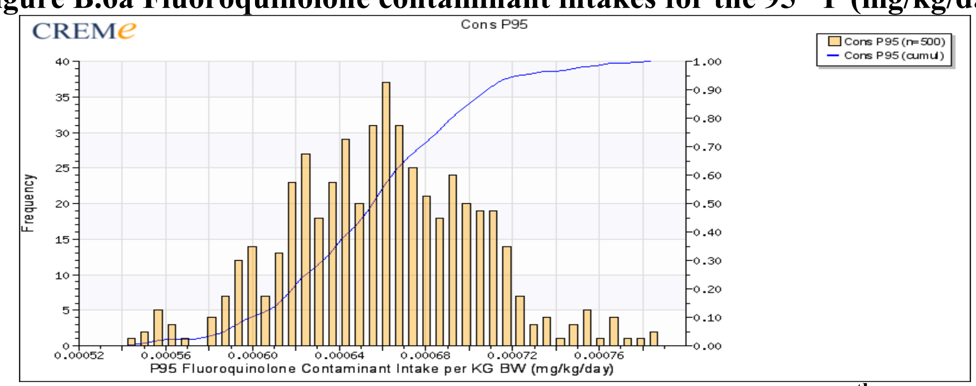
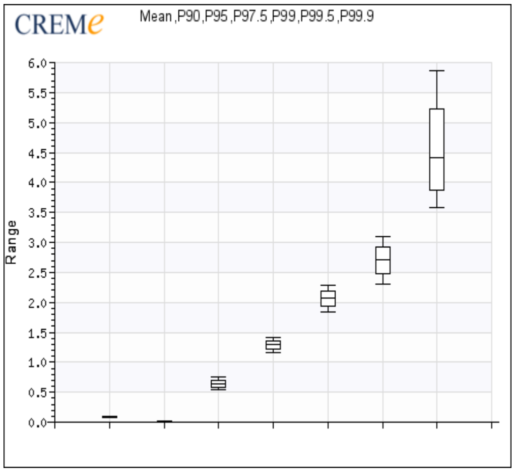


Figure B.6b Fluoroquinolone contaminant intakes at MRL for the 95th P (mg/kg/day)

Figure B.6a shows the distribution for the likely fluoroquinolone contaminant exposure (in mg/kg/day) that would have resulted in scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.6b shows the distribution for the likely fluoroquinolone contaminant exposure (in mg/kg/day) that would have resulted in scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). Note: The X-axes for the two graphs are on different scales.

Gentian Violet Exposure (in mg/day) among All NHANES Adult Consumers



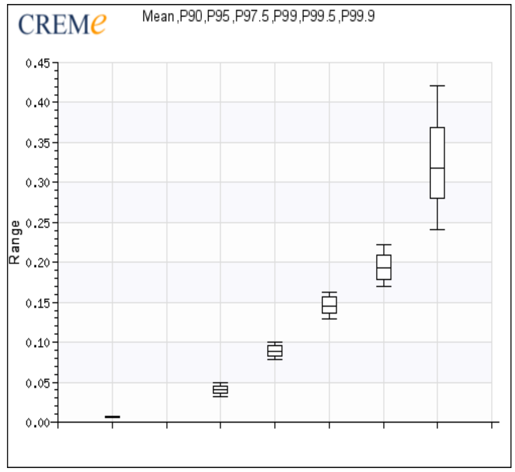


Figure B.7a Gentian violet intake in scenario 1 Figure B.7b Gentian violet intake in scenario 2.

Figure B.7a shows box-plots for the likely gentian violet contaminant exposure (in mg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.7b shows box-plots for the likely gentian violet contaminant exposure in (mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The figures show box-plots for the upper 50^{th}, 90^{th}, 95^{th}, 97.5^{th}, 99.5^{th}, and 99.9^{th} percentile of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.

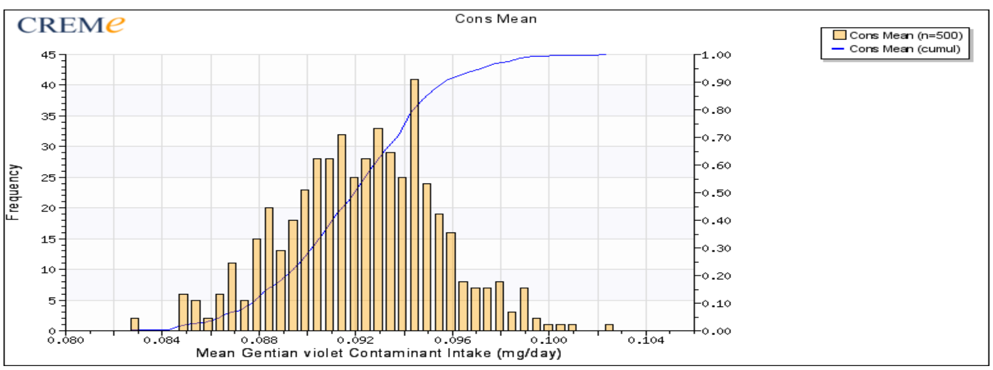


Figure B.8a Mean gentian violet contaminant intakes in scenario 1 (mg/day)

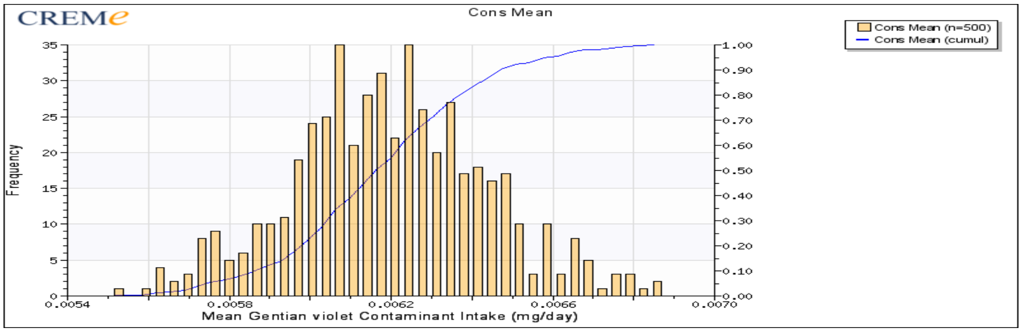


Figure B.8b Mean gentian violet contaminants intakes at MRL (mg/day)

Figure B.8a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.8b shows the distribution for the likely gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show exposures in the upper 50th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

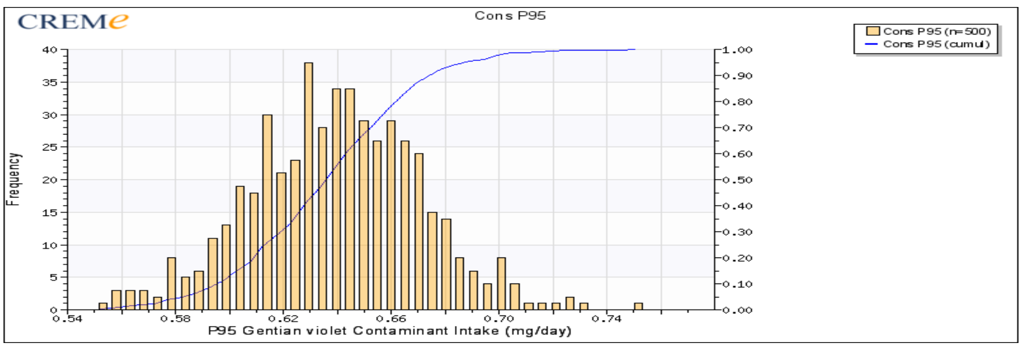


Figure B.9a Gentian violet contaminants intake for the 95th P (mg/day)

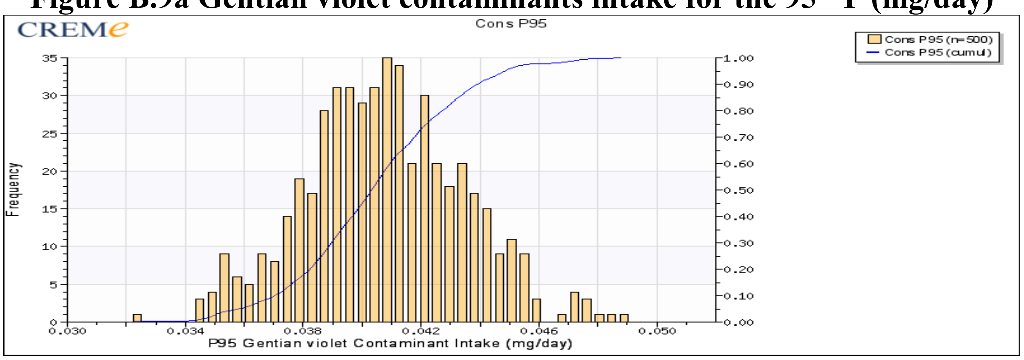
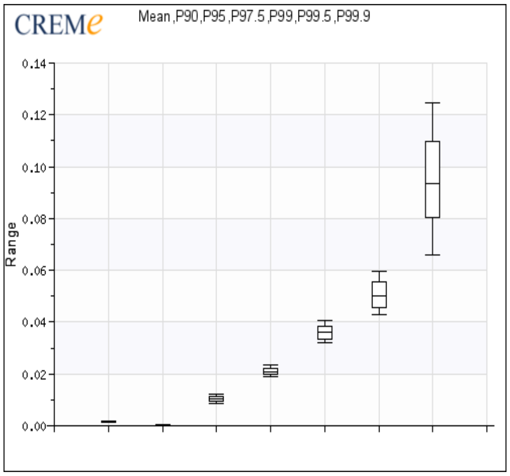
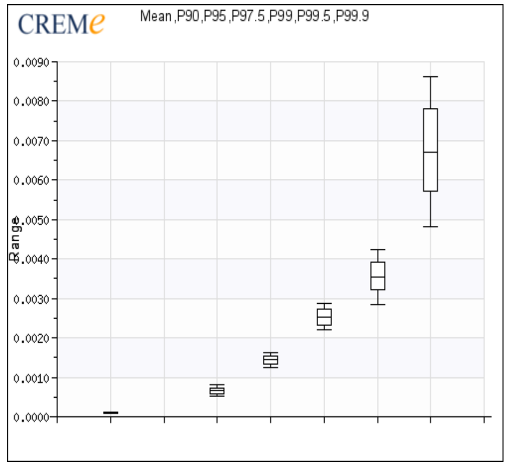


Figure B.9b Gentian violet contaminants intakes at MRL for the 95th P (mg/day)

Figure B.9a shows the distribution for the likely gentian violet contaminant exposure (in mg/day) that would have resulted in scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.9b shows the distribution for the likely gentian violet contaminant exposure (in mg/day) that would have resulted in scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 95th percentile of NHANES seafood consumers. Note: The X-axes for the two graphs are on different scales.

Gentian Violet Exposure (in mg/kg/day) among All NHANES Adult Consumers





FigureB.10a Gentian violet in imports Figure B.10b Gentian violet at MRL

Figure B.10a shows box-plots for the likely gentian violet contaminant exposure in (mg/kg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.10b shows box-plots for the likely gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The figures show box-plots for the upper 50th, 90th, 95th, 97.5th, 99.5th, and 99.9th percentile of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.

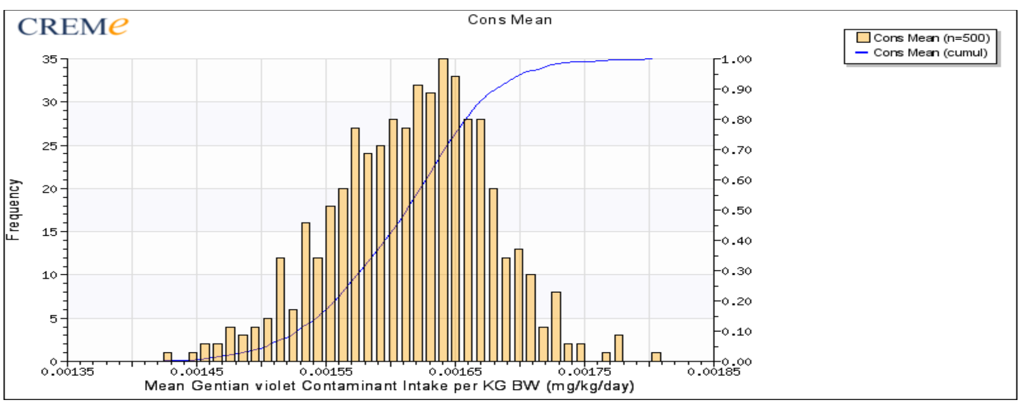


Figure B.11a Gentian violet contaminant intakes in scenario 1 (mg/kg/day)

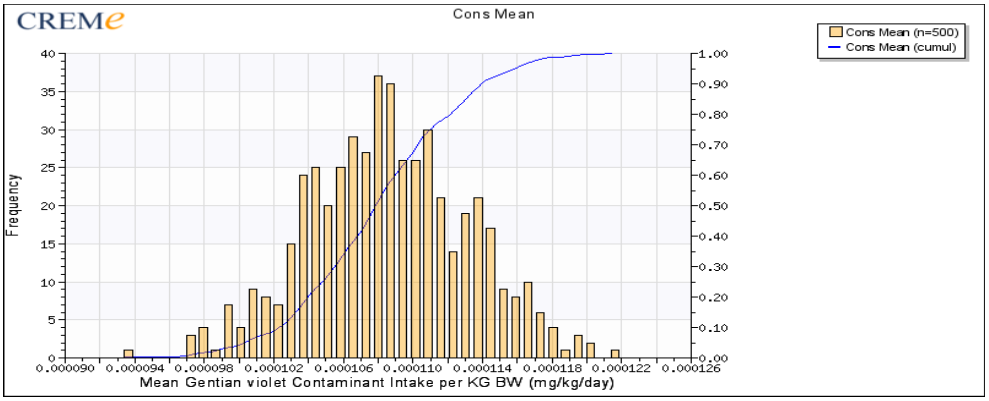


Figure B.11b Gentian violet contaminant intakes at MRL (mg/kg/day)

Figure B.11a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.11b shows the distribution for the likely gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 50th percentile of NHANES seafood consumers. Note: The X-axes for the two graphs are on different scales.

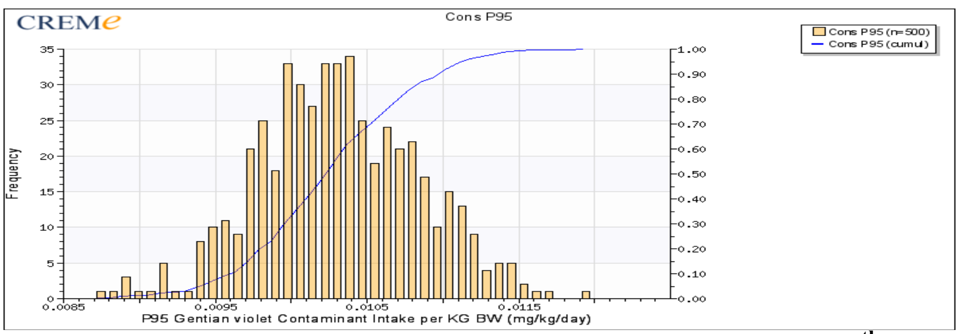


Figure B.12a Gentian violet contaminant intakes in scenario 1 for the 95th P (mg/kg/day)

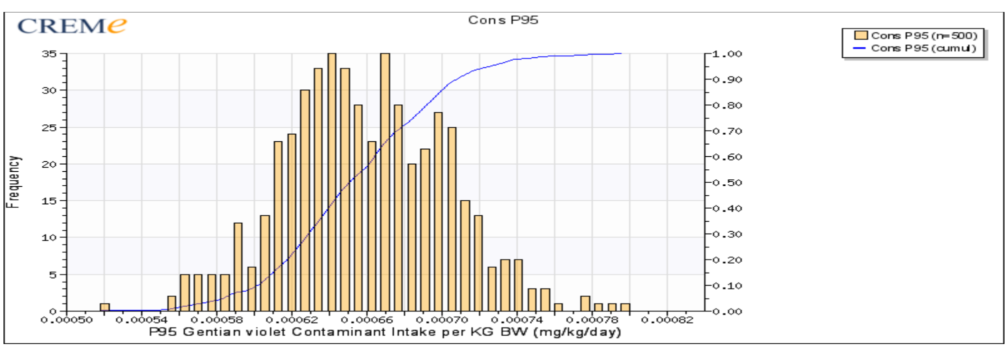
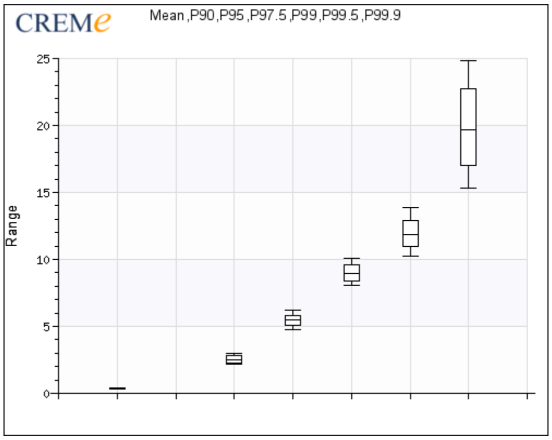


Figure B.12b Gentian violet contaminant intakes at MRL (mg/kg/day)

Figure B.12a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.12b shows the distribution for the likely gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 95th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

Malachite Green Exposure (in mg/day) among All NHANES Adult Consumers



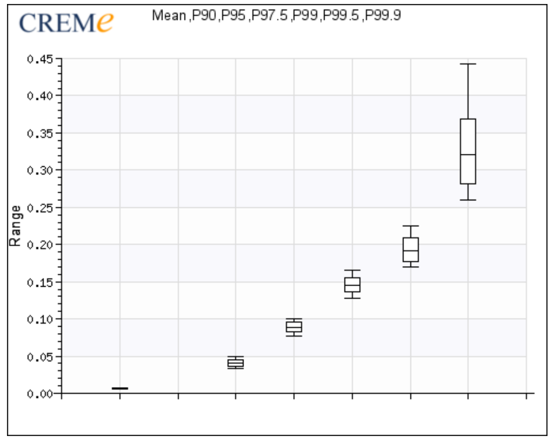


Figure B.13a Malachite green in imports **Figure B.13b Malachite green at MRL**

Figure B.13a shows the likely malachite green contaminant exposure in (mg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.13b shows the likely malachite green contaminant exposure (in mg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The figures show box-plots for the upper 50th, 90th, 95th, 97.5th, 99.5th, and 99.9th percentile of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.

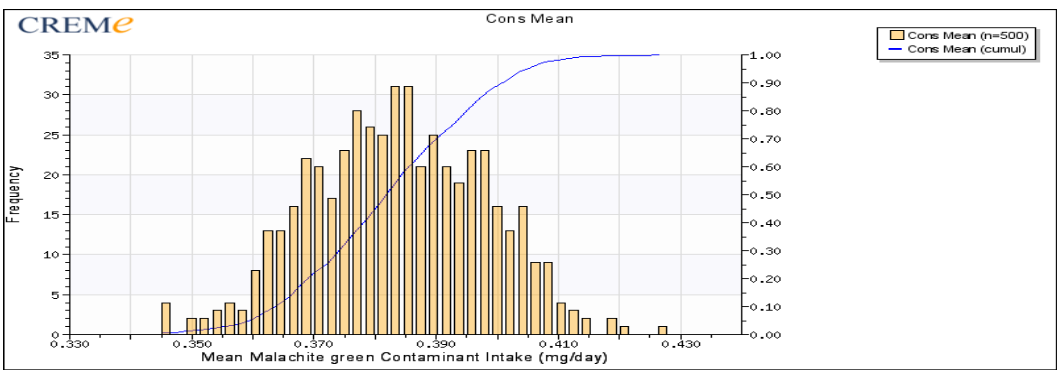


Figure B.14a Malachite green contaminant intakes in scenario 1 (mg/day)

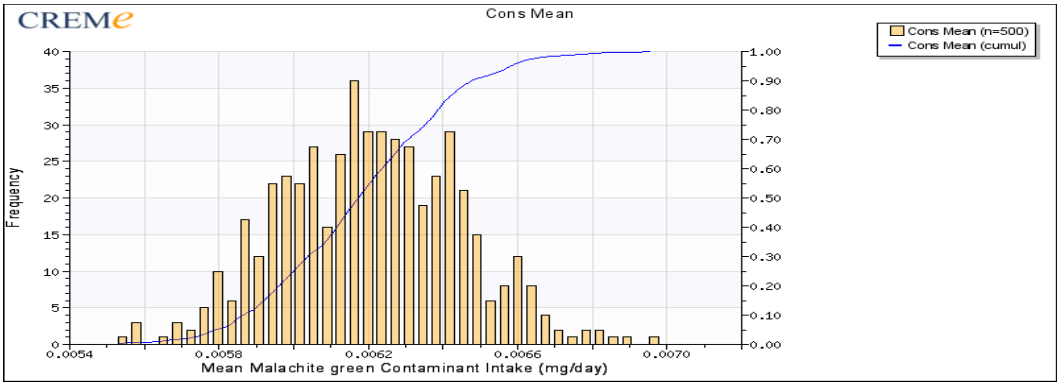


Figure B.14b Malachite green contaminant intakes at MRL (mg/day)

Figure B.14a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.14b shows the distribution for the likely gentian violet contaminant exposure (in mg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 50th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

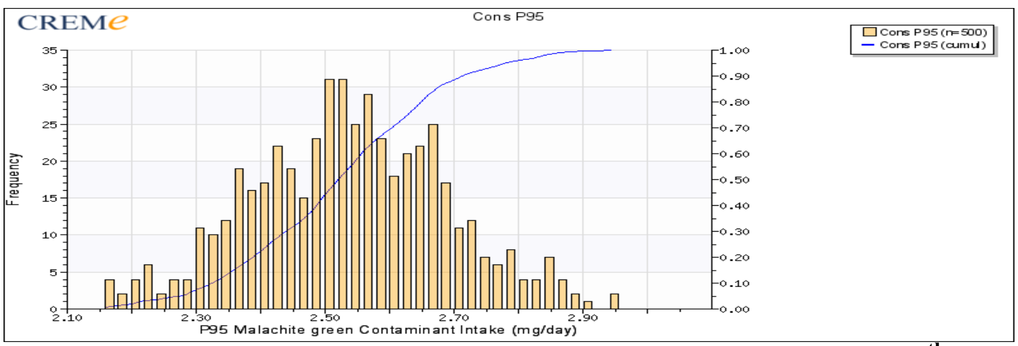


Figure B.15a Malachite green contaminant intakes in scenario 1 for the 95th P (mg/day)

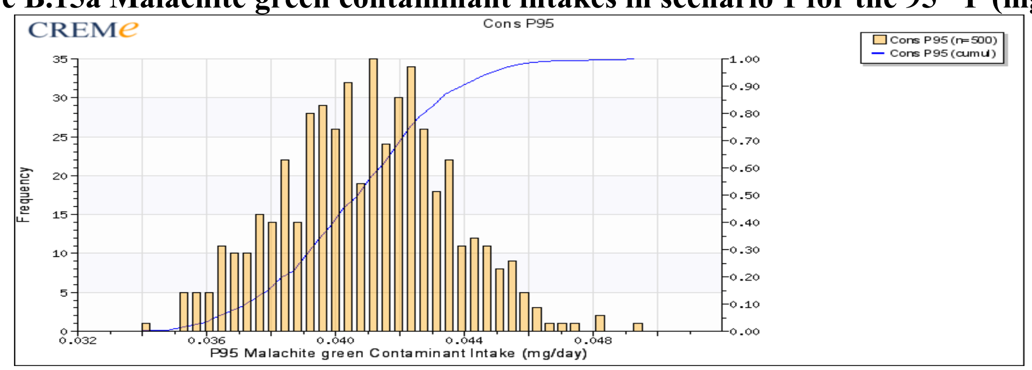
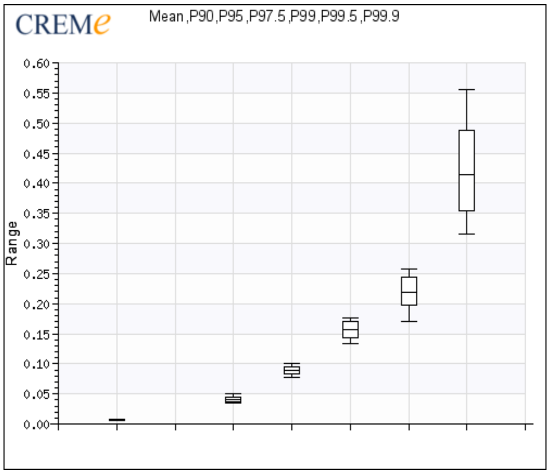


Figure B.15b Malachite green contaminant intakes at MRL (mg/day)

Figure B.15a shows the distribution for the likely malachite green contaminant exposure (in mg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.15b shows the distribution for the likely gentian violet contaminant exposure (in mg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 95th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

Malachite Green Exposure (in mg/kg/day)

among All NHANES Adult Consumers



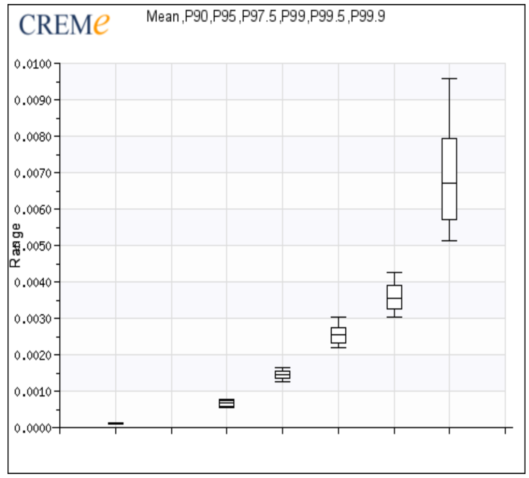


Figure B.16a Malachite green in imports **Figure B.16b Malachite green at MRL**

Figure B.16a shows box-plots for the likely malachite green contaminant exposure in (mg/kg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.16b shows box-plots for the likely malachite green contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The figures show box-plots for the upper 50th, 90th, 95th, 97.5th, 99.5th, and 99.9th percentile of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.

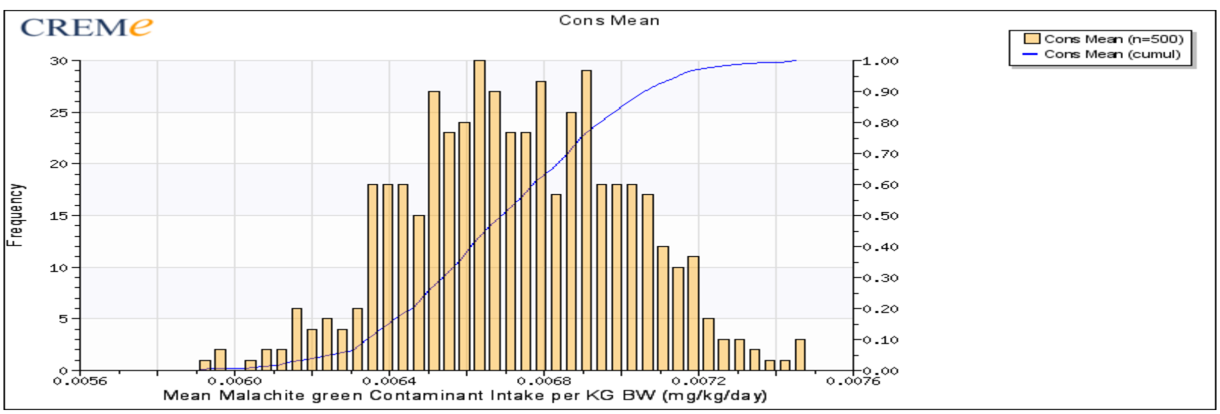


Figure B.17a Mean malachite green contaminant intakes in scenario 1 (mg/kg/day)

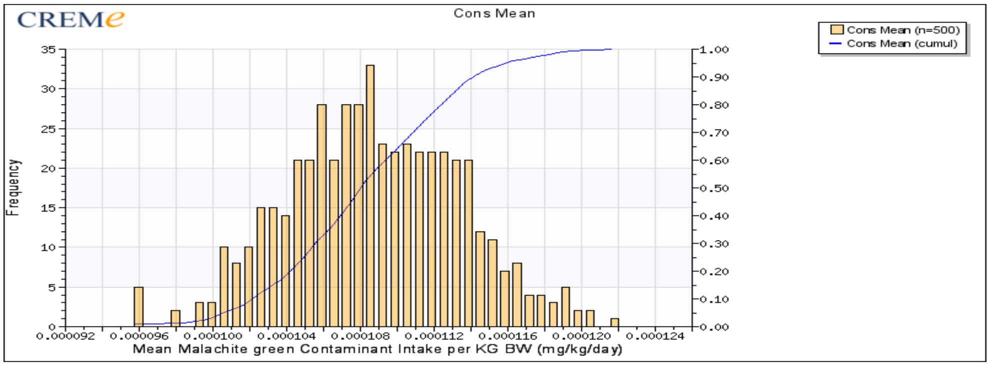


Figure B.17b Mean malachite green contaminant intakes at MRL (mg/kg/day)

Figure B.17a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.17b shows the distribution for the likely gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 50th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

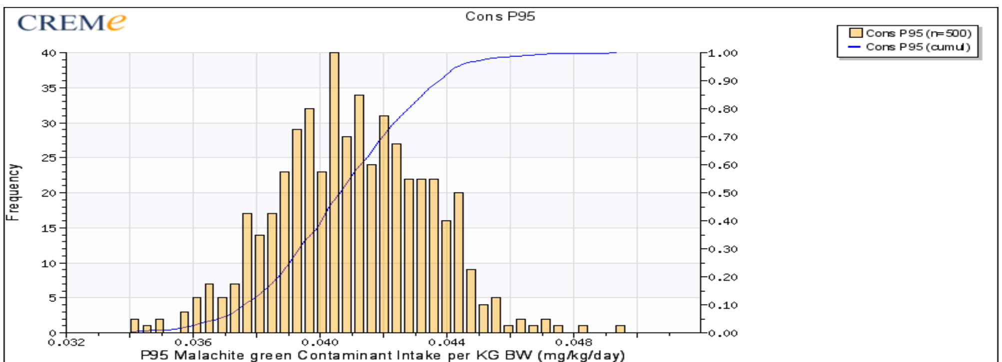


Figure B.18a Malachite green contaminant intakes in scenario 1 for the 95th P (mg/kg/day)

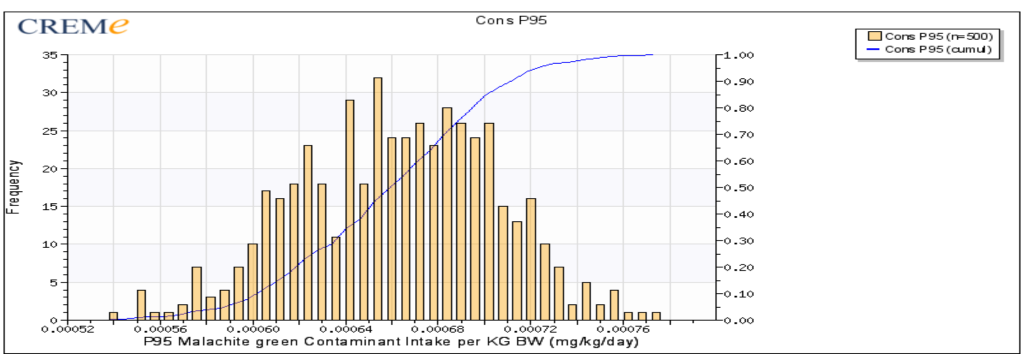


Figure B.18b Malachite green contaminant intakes at MRL (mg/kg/day)

Figure B.18a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.18b shows the distribution for the likely gentian violet contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 95th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

Nitrofuran Exposure (in mg/day) among All NHANES Adult Consumers

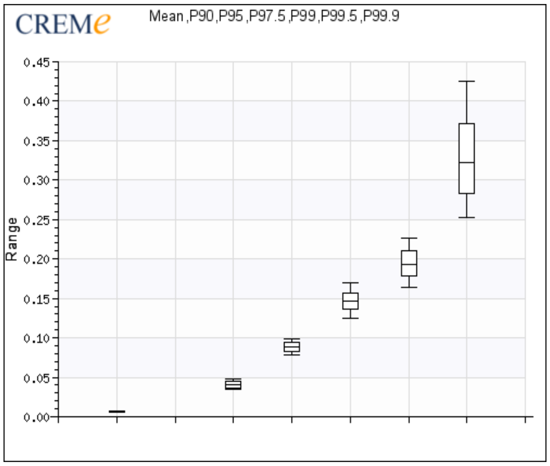


Figure B.19a Nitrofuran at MRL

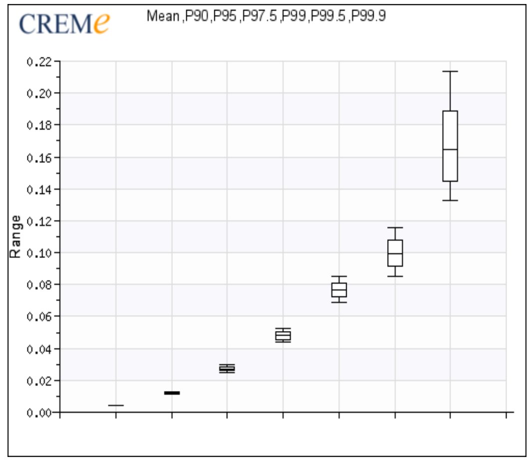


Figure B.19b Nitrofuran from imports

Figure B.19a shows box-plots for the likely nitrofuran contaminant exposure in (mg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.19b shows box-plots for the likely nitrofuran contaminant exposure (in mg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The figures show box-plots for the upper 50th, 90th, 95th, 97.5th, 99.5th, and 99.9th percentile of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.

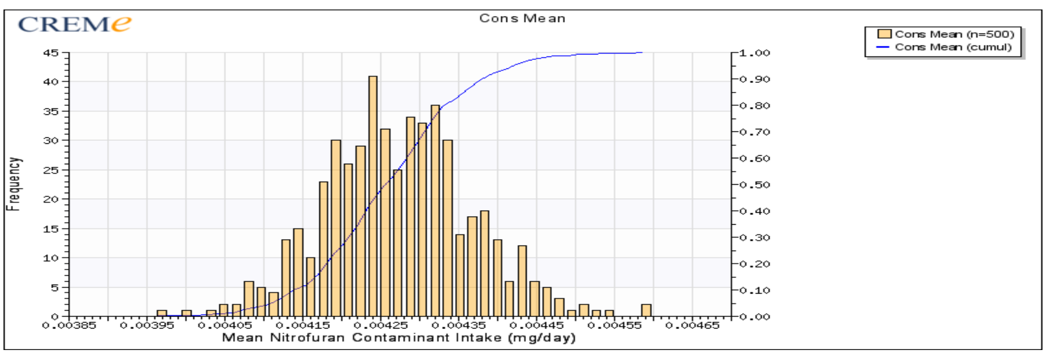


Figure B.20a Mean nitrofuran contaminant intakes in scenario 1 (mg/day)

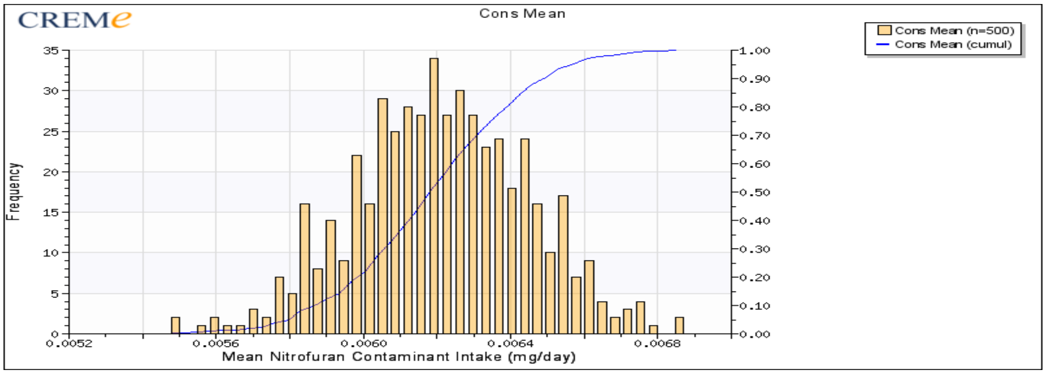


Figure B.20b Mean nitrofuran contaminant intakes at MRL (mg/day)

Figure B.20a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.20b shows the distribution for the likely nitrofuran contaminant exposure (in mg/ day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 50th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

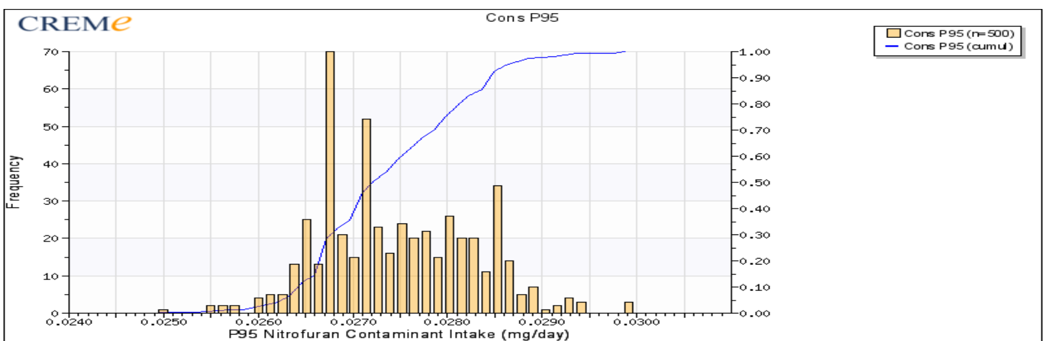


Figure B.21a Nitrofuran contaminant intakes in scenario 1 for the 95th P (mg/day)

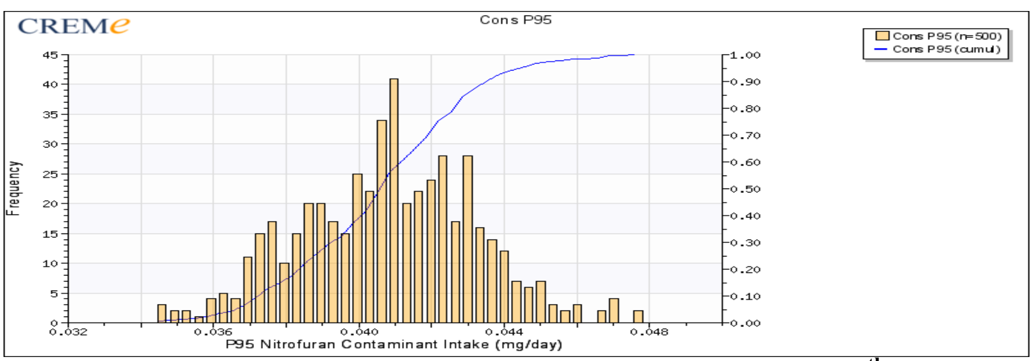
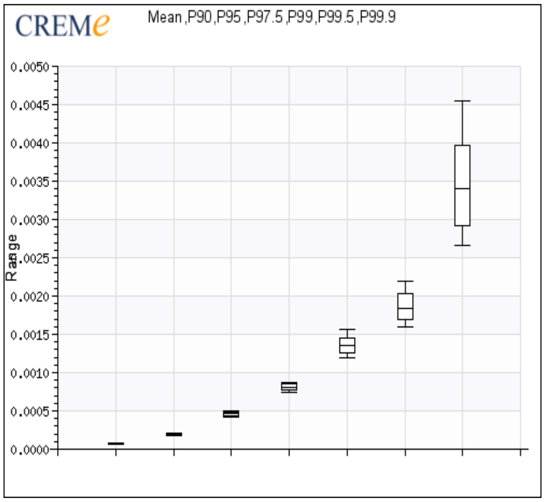


Figure B.21b Nitrofuran contaminant intakes at MRL for the 95th P (mg/day)

Figure B.21a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.21b shows the distribution for the likely nitrofuran contaminant exposure (in mg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 95th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

Nitrofuran Exposure (in mg/kg/day) among All NHANES Adult Consumers



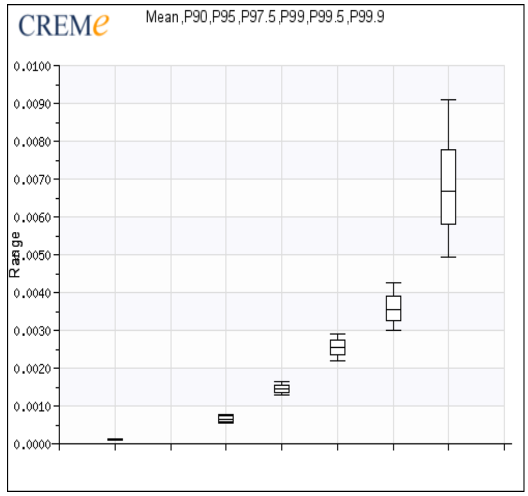


Figure B.22a Nitrofuran in imports **Figure B.22b Nitrofuran at MRL**

Figure B.22a shows box-plots for the likely nitrofuran contaminant exposure in (mg/kg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.22b shows box-plots for the likely nitrofuran contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The figures show box-plots for the upper 50th, 90th, 95th, 97.5th, 99.5th, and 99.9th percentile of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.

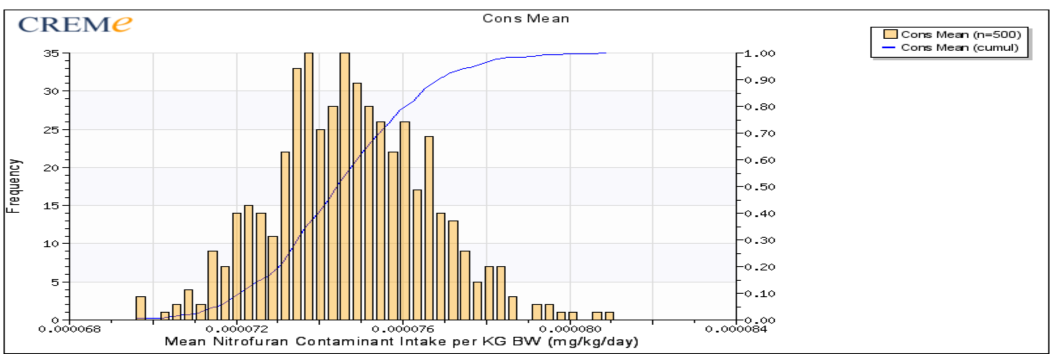


Figure B.23a Nitrofuran contaminant intakesin scenario 1 (mg/kg/day)

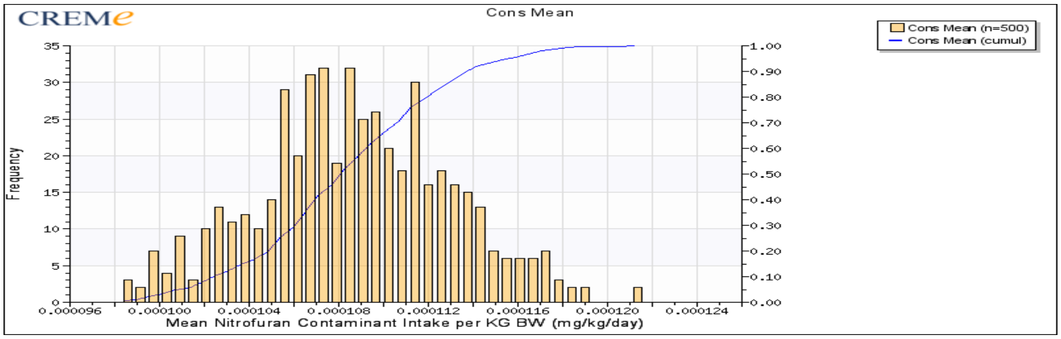


Figure B.23b Nitrofuran contaminant intakes at MRL (mg/kg/day)

Figure B.23a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/kg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.23b shows the distribution for the likely nitrofuran contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 50th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

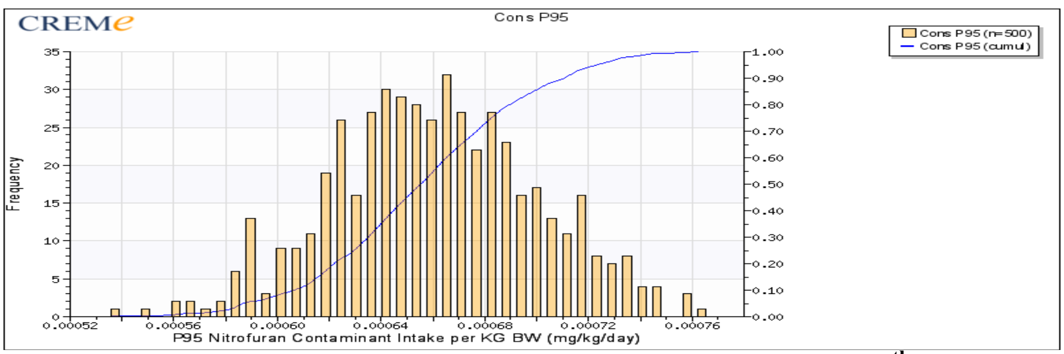


Figure B.24a Nitrofuran contaminant intakes in scenario 1 for the 95th P (mg/kg/day)

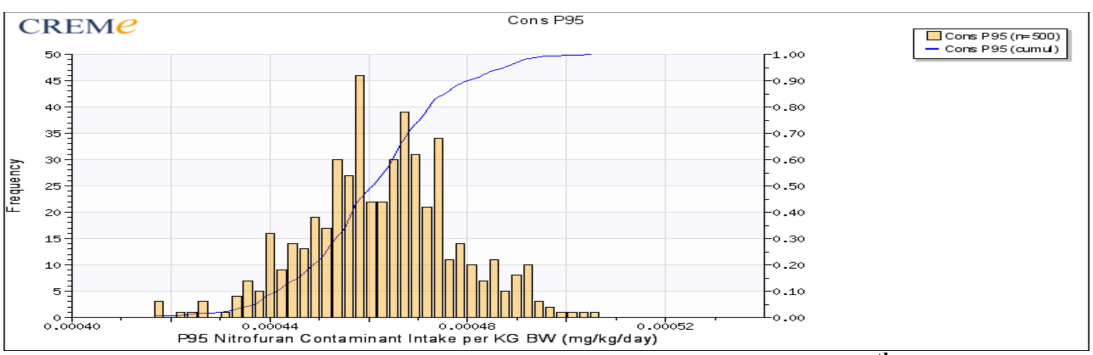
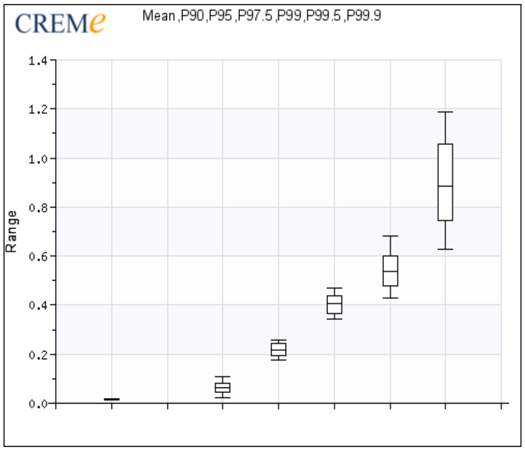


Figure B.24b Nitrofuran contaminant intakes at MRL for the 95th P (mg/kg/day)

Figure B.24a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/kg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.24b shows the distribution for the likely nitrofuran contaminant exposure (in mg/kg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The two distributions show the likely exposures in the upper 95th percentile of NHANES consumers. Note: The X-axes for the two graphs are on different scales.

Fluoroquinolone Exposure (in mg/day) among Children vs. Adult Consumers



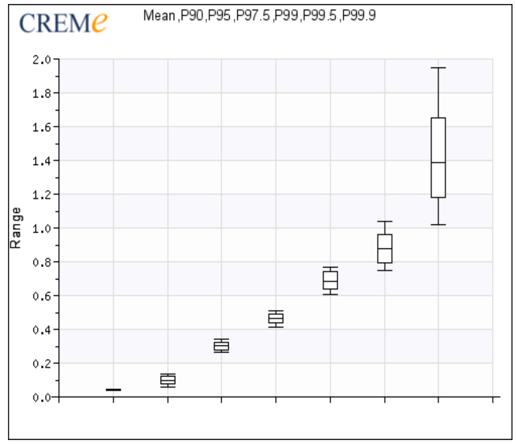
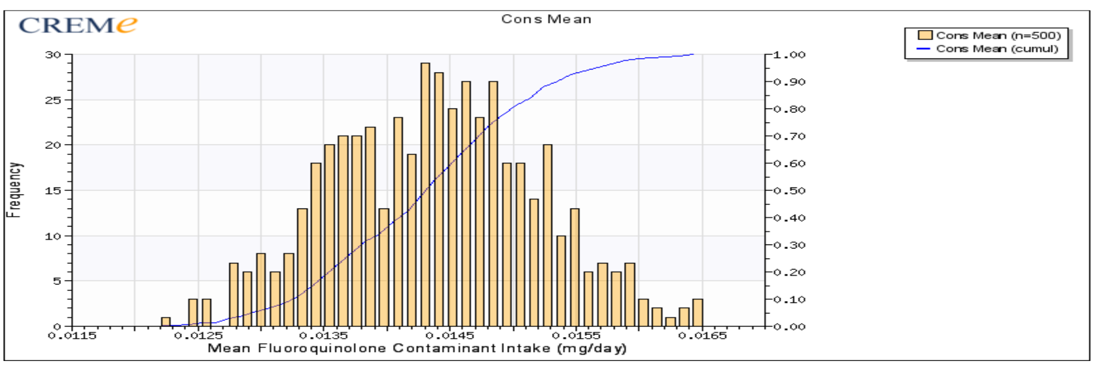


Figure B.25a Fluoroquinolone intakes in children Figure B.25B Fluoroquinolone intakes in adults

Figure B.25a shows box-plots for the likely fluoroquinolone contaminant exposure in (mg/day) that would have resulted from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.25b shows box-plots for the likely fluoroquinolone contaminant exposure (in mg/day) that would have resulted from scenario 2 (a contrived scenario in which aquaculture imports have contaminants at MRLs). The figures show box-plots for the upper 50th, 90th, 95th, 97.5th, 99.5th, and 99.9th percentile of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.



FigureB.26a Fluoroquinolone contaminant intakes in children (mg/day)

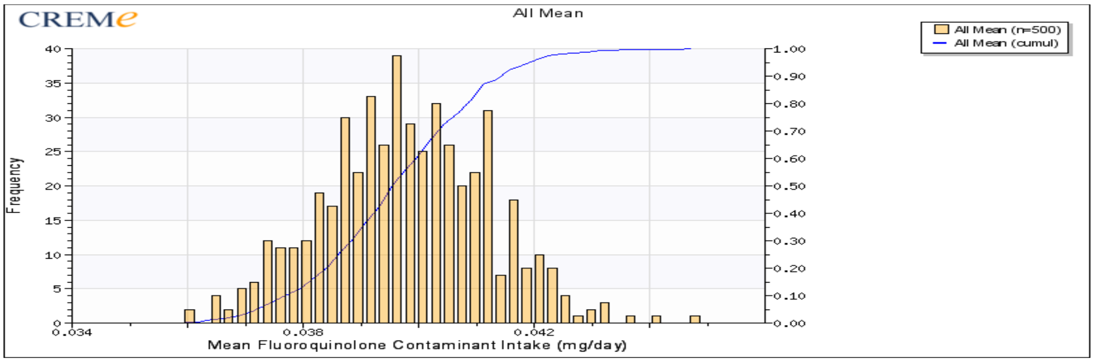


Figure B.26b Fluoroquinolone contaminant intakes in adults (mg/day)

Figure B.26a shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 children consumers, while Figure B.26b shows the distribution for the likely fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

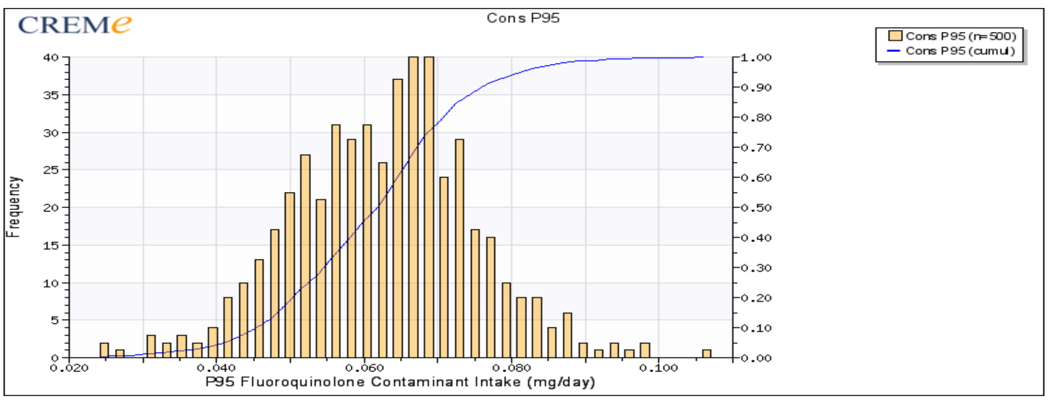


Figure B.27a Fluoroquinolone contaminant intakes in children (mg/day)

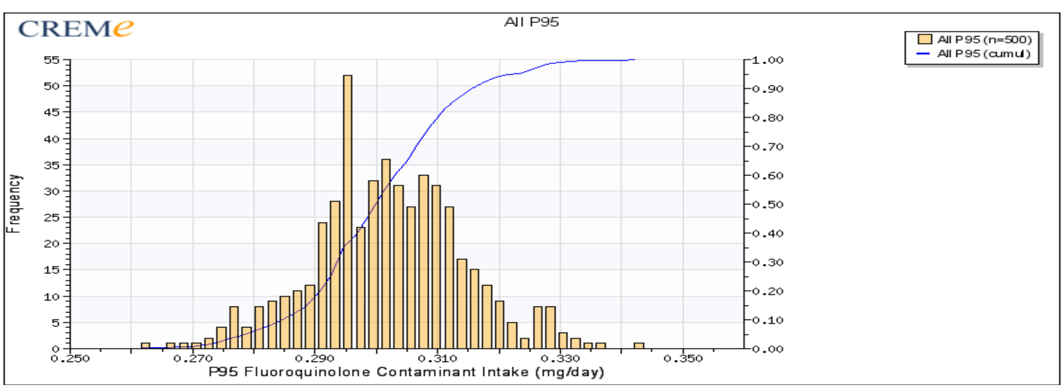


Figure B.27b Fluoroquinolone contaminant intakes in adults (mg/day)

Figure B.27a shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 children consumers, while Figure B.27b shows the distribution for the likely fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

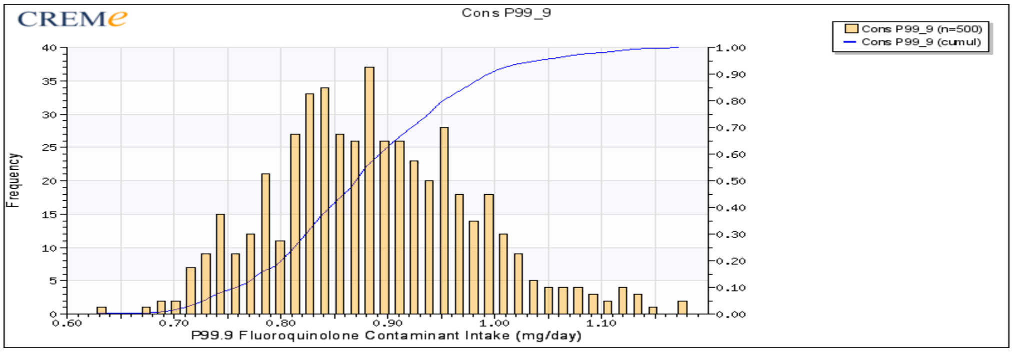


Figure B.28a Fluoroquinolone contaminant intakes in children (mg/day)

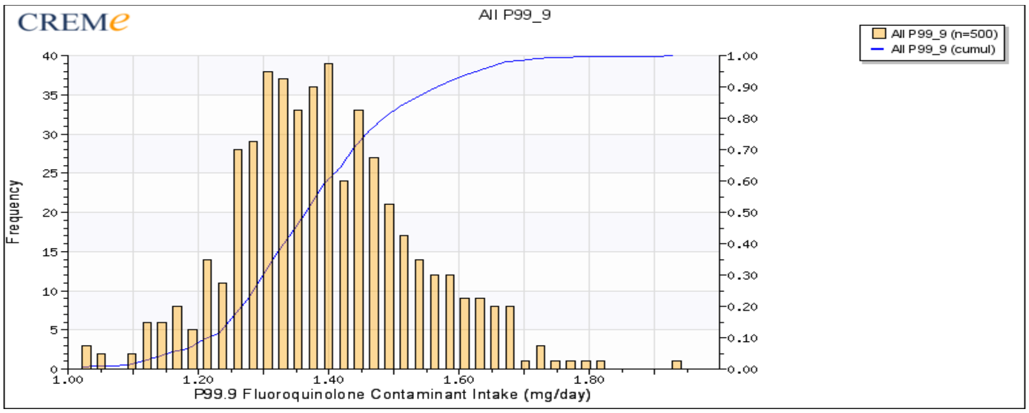


Figure B.28b Fluoroquinolone contaminant intakes in adults (mg/day)

Figure B.28a shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 99.9th percentile of NHANES 2003-2004 children consumers, while Figure B.28b shows the distribution for the likely fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 99.9th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

Fluoroquinolone Exposure (in mg/kg/day) among Children vs. Adult Consumers

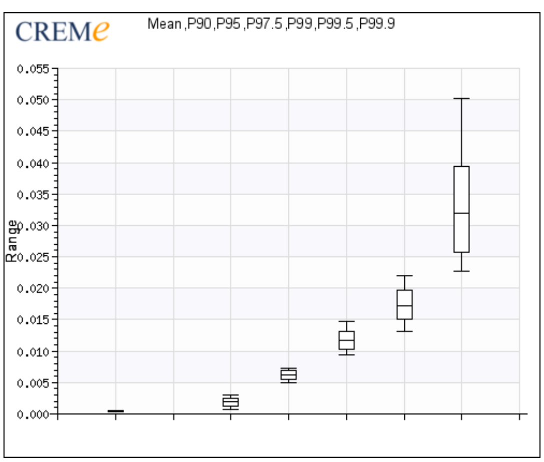


Figure B.29a Fluoroquinolone intakes in children

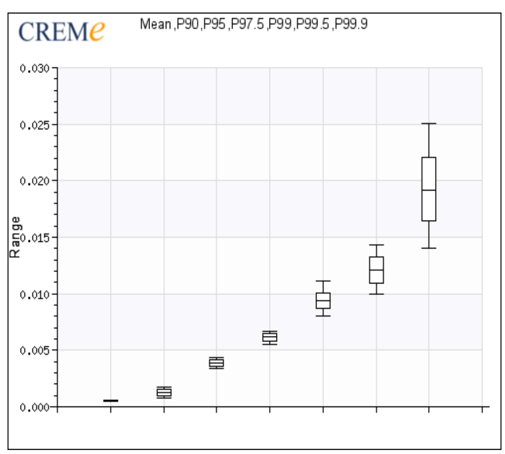


Figure B.29b Fluoroquinolone intakes in adults

Figure B.29a shows box-plots for the likely fluoroquinolone contaminant exposure in (mg/kg/day) that would result among children consumers from scenario 1 (a contrived scenario based on actual 2006-2007 FDA contaminant sampling data), while Figure B.29b shows box-plots for the likely fluoroquinolone contaminant exposure (in mg/kg/day) that would result in scenario 1 among adults. The figures show box-plots for the upper 50th, 90th, 95th, 97.5th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 consumers. Note: The Y-axes for the two graphs are on different scales.

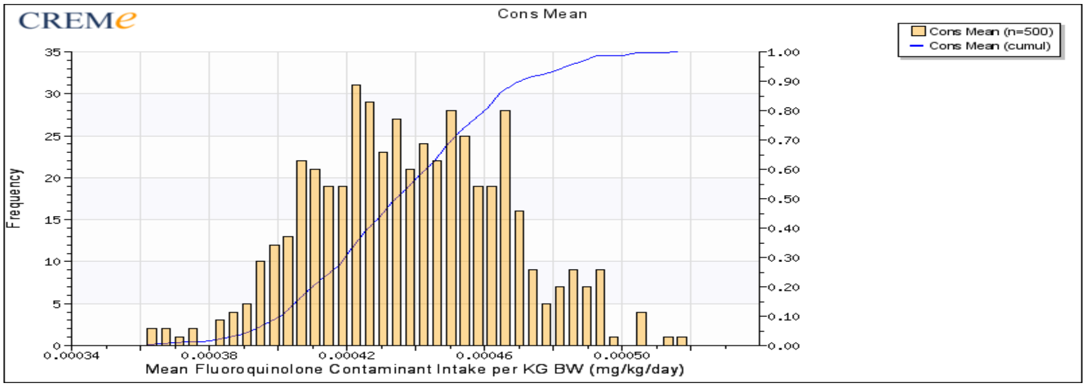


Figure B.30a Fluoroquinolone contaminant intakes in children (mg/kg/day)

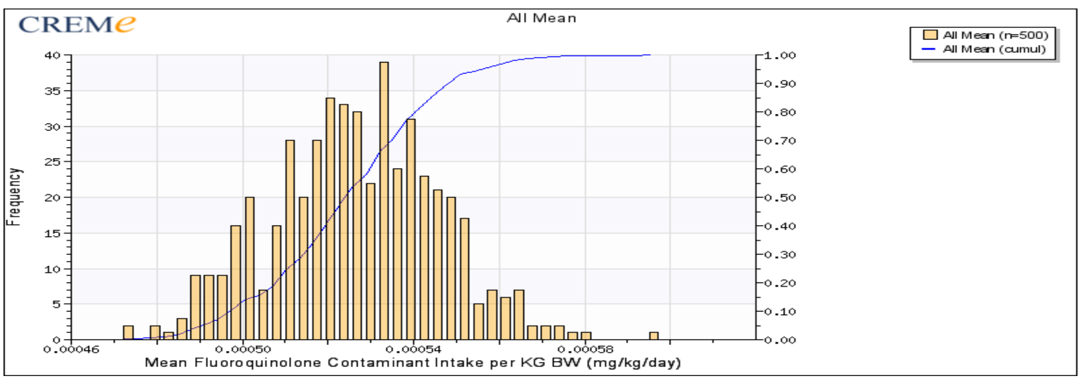


Figure B.30b Fluoroquinolone contaminant intakes in adults (mg/kg/day)

Figure B.30a shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 children consumers, while Figure B.30b shows the distribution for the likely fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

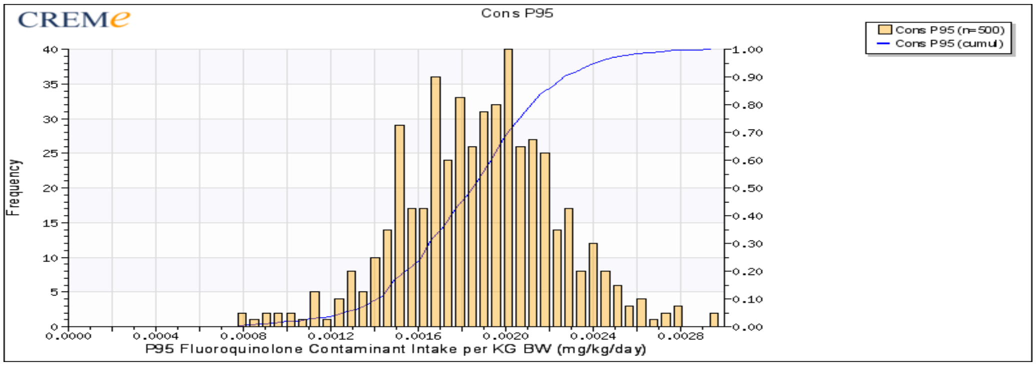


Figure B.31a Fluoroquinolone contaminant intakes in children (mg/kg/day)

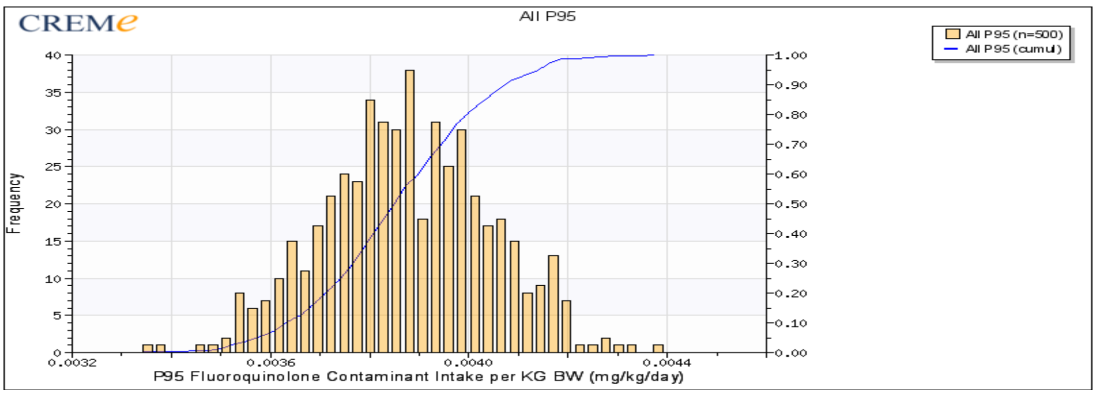


Figure B.31a Fluoroquinolone contaminant intakes in adults (mg/kg/day)

Figure B.31a shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 children consumers, while Figure B.31b shows the distribution for the likely fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

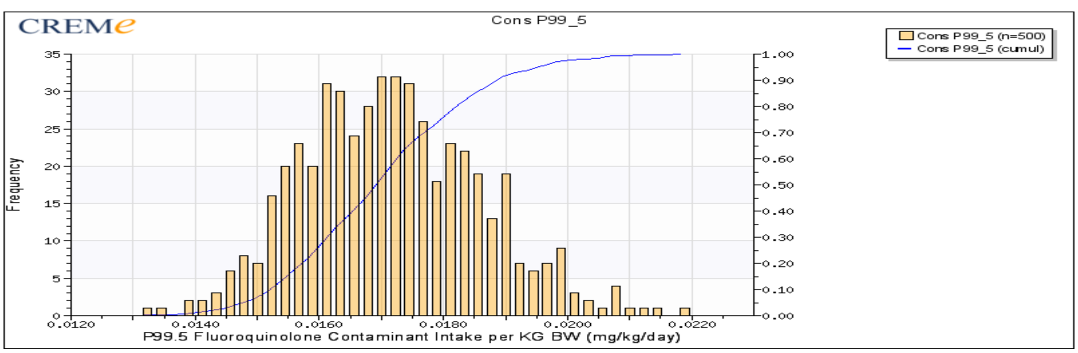


Figure B.32a Fluoroquinolone contaminant intakes in children (mg/kg/day)

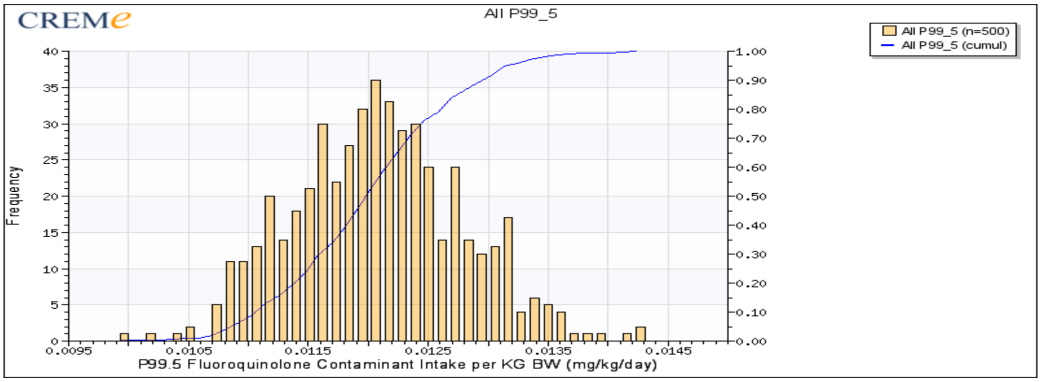


Figure B.32b Fluoroquinolone contaminant intakes in adults (mg/kg/day)

Figure B.32a shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 children consumers, while Figure B.32b shows the distribution for the likely fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

Gentian Violet Exposure (in mg/day) among Children vs. Adult Consumers

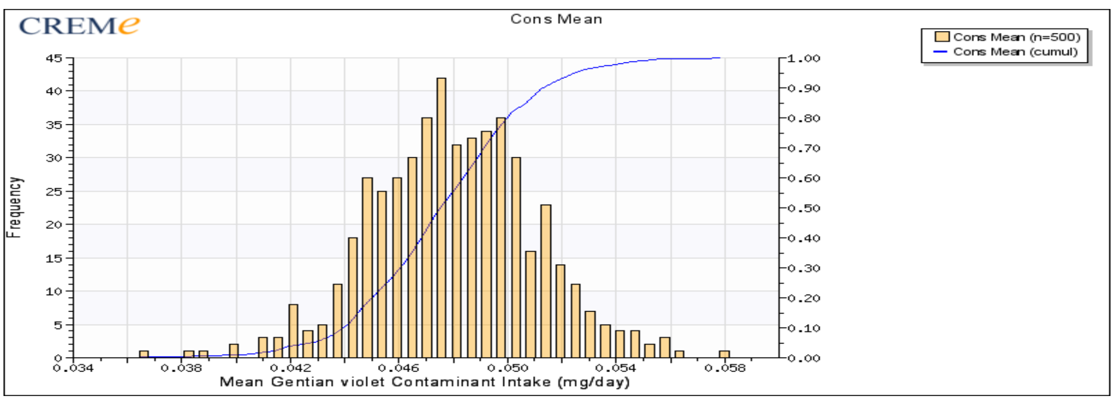


Figure B.33a Gentian violet contaminant intakes in children (mg/day)

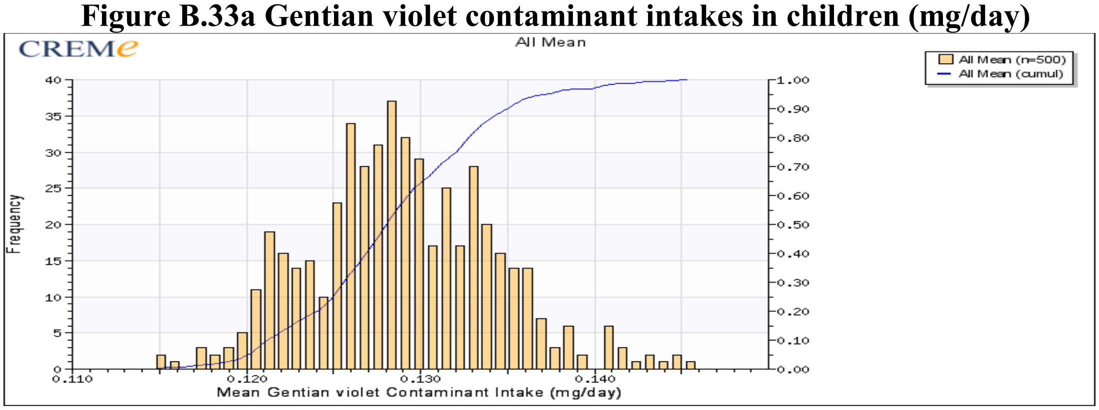


Figure B.33b Gentian violet contaminant intakes in adults (mg/day)

Figure B.33a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 children consumers, while Figure B.33b shows the distribution for the likely gentian violet contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

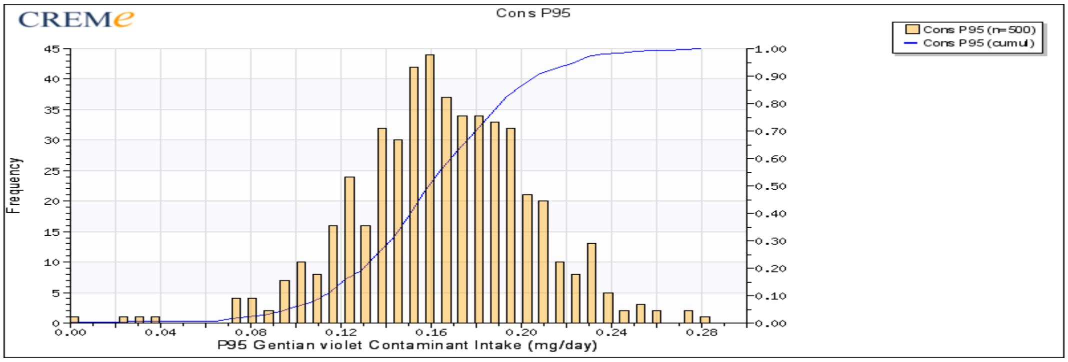


Figure B.34a Gentian violet contaminant intakes in children (mg/day)

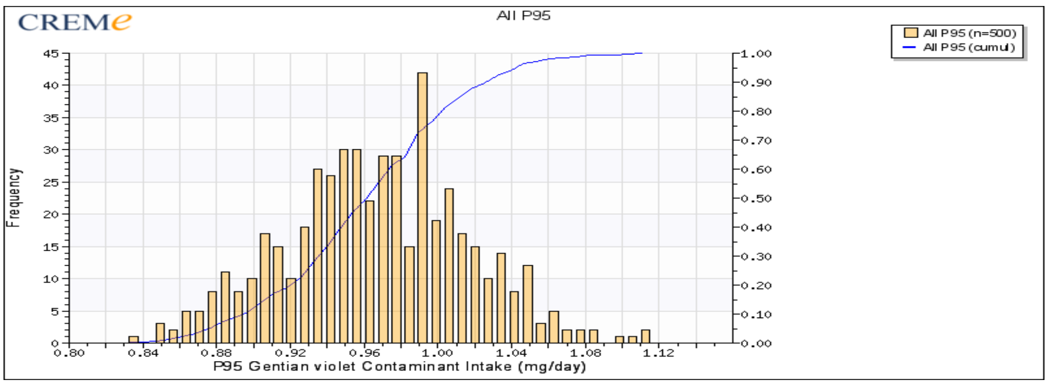


Figure B.34b Gentian violet contaminant intakes in adults (mg/day)

Figure B.34a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 children consumers, while Figure B.34b shows the distribution for the likely gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

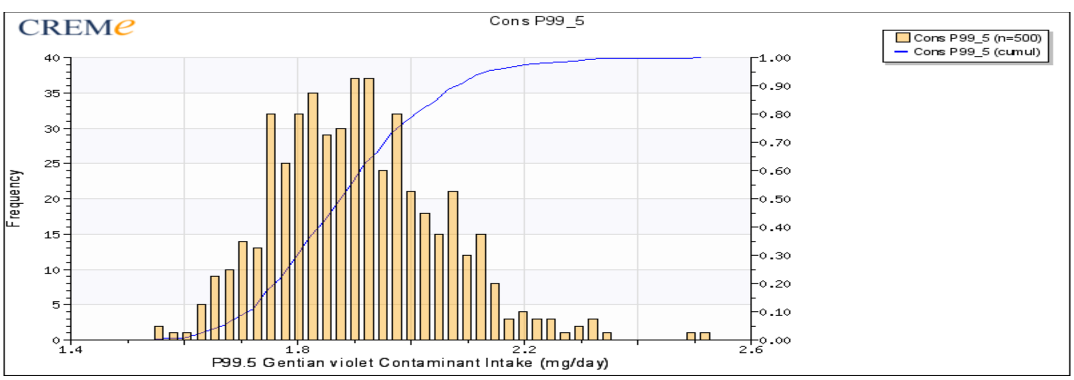


Figure B.35a Gentian violet contaminant intakes in children (mg/day)

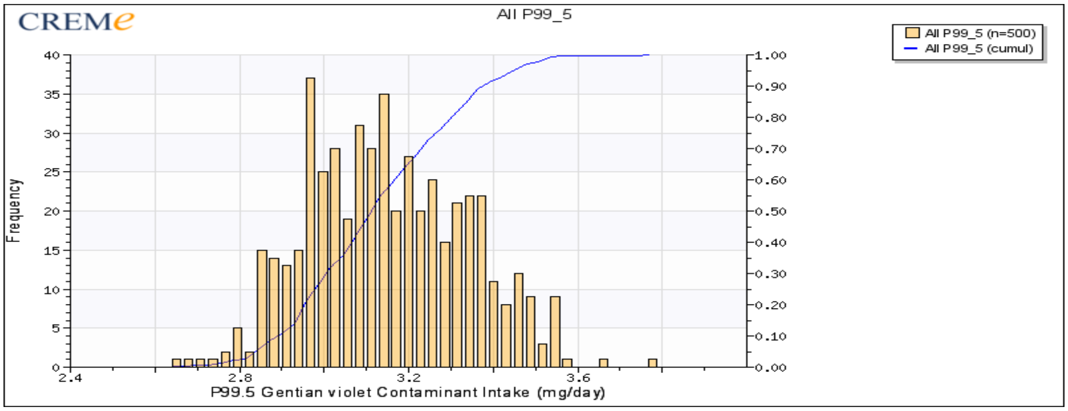


Figure B.35b Gentian violet contaminant intakes in adults (mg/day)

Figure B.35a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 children consumers, while Figure B.35b shows the distribution for the likely gentian violet contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

Gentian Violet Exposure (in mg/kg/day) among Children vs. Adult Consumers

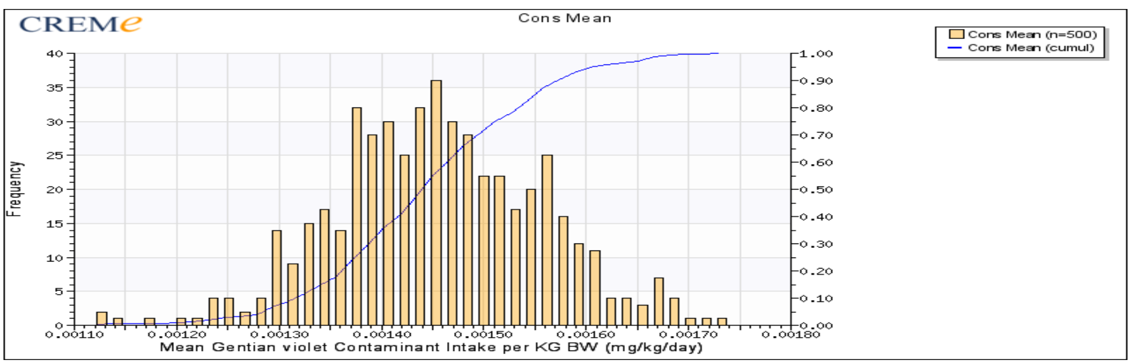


Figure B.36a Gentian violet contaminant intakes in children (mg/kg/day)

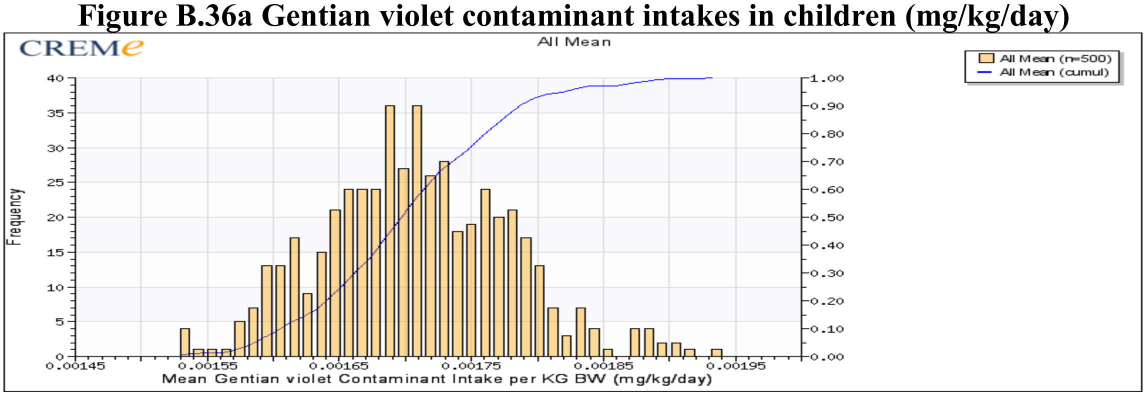


Figure B.36b Gentian violet contaminant intakes in adults (mg/kg/day)

Figure B.36a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 children consumers, while Figure B.36b shows the distribution for the likely gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

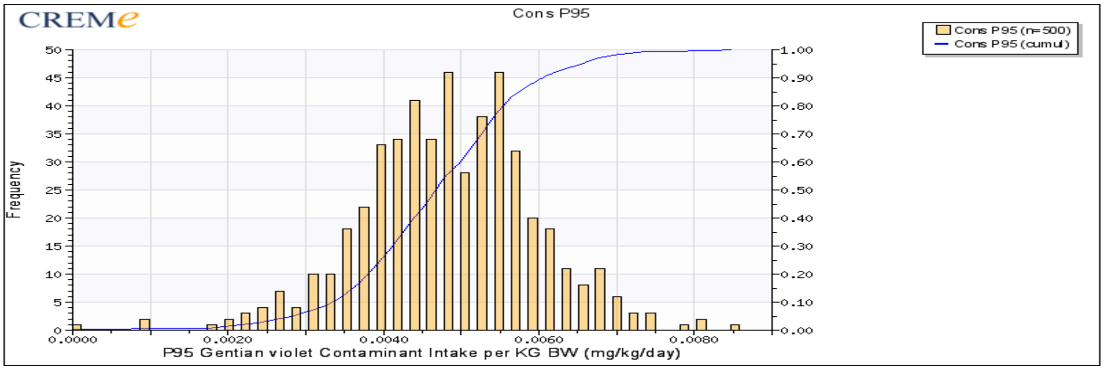


Figure B.37a Gentian violet contaminant intakes in children (mg/kg/day)

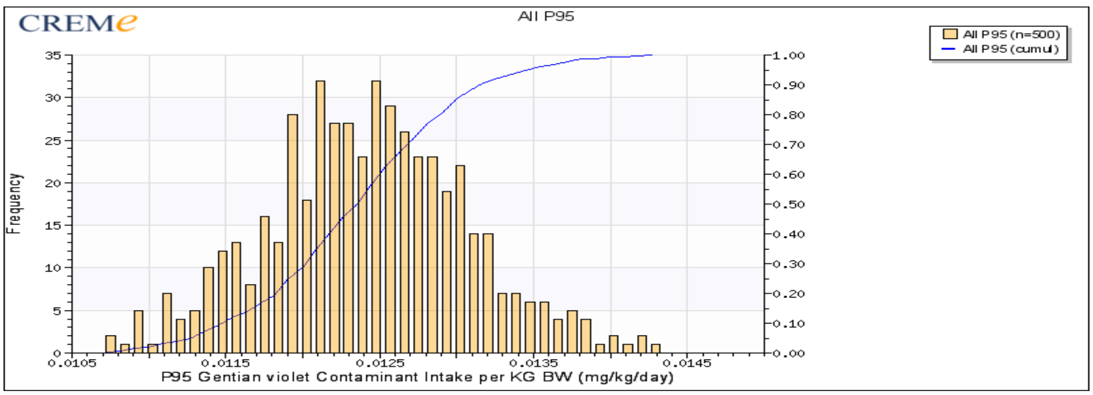


Figure B.37b Gentian violet contaminant intakes (mg/kg/day)

Figure B.37a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 children consumers, while Figure B.37b shows the distribution for the likely gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

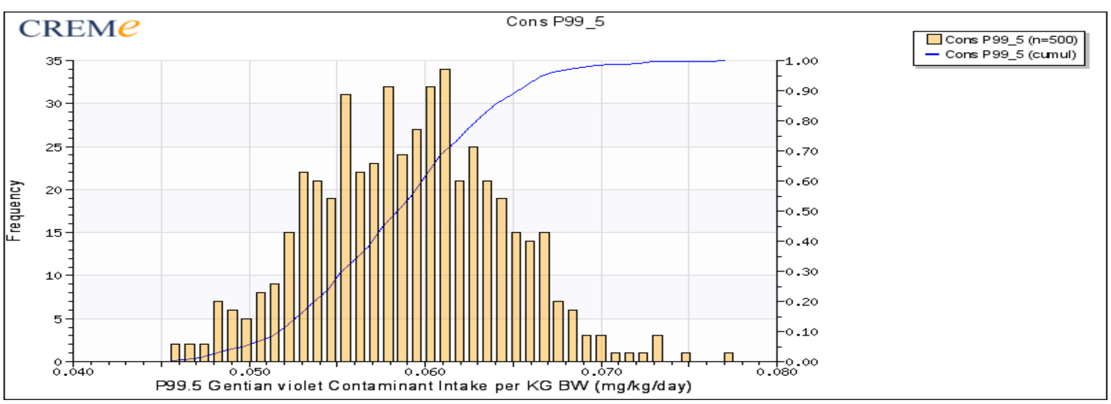


Figure B.38a Gentian violet contaminant intakes in children (mg/kg/day)

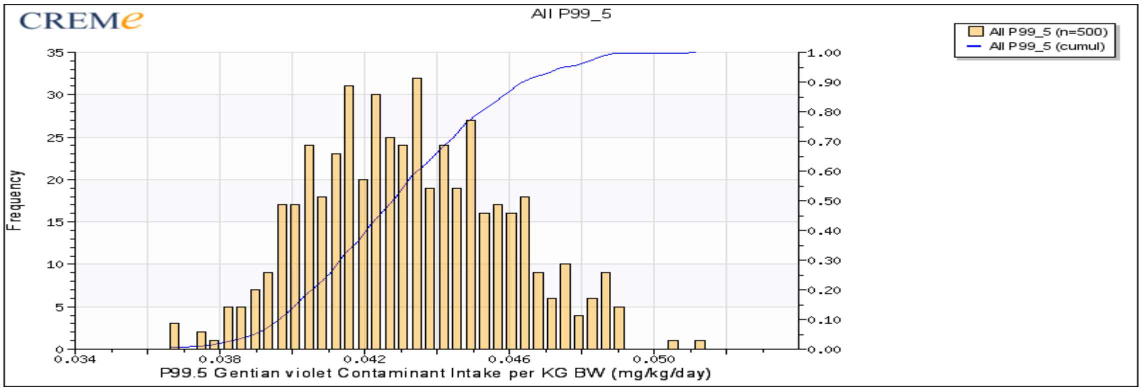


Figure B.38b Gentian violet contaminant intakes in adults (mg/kg/day)

Figure B.38a shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 children consumers, while Figure B.38b shows the distribution for the likely gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

Malachite Green Exposure (in mg/day) among Children vs. Adult Consumers

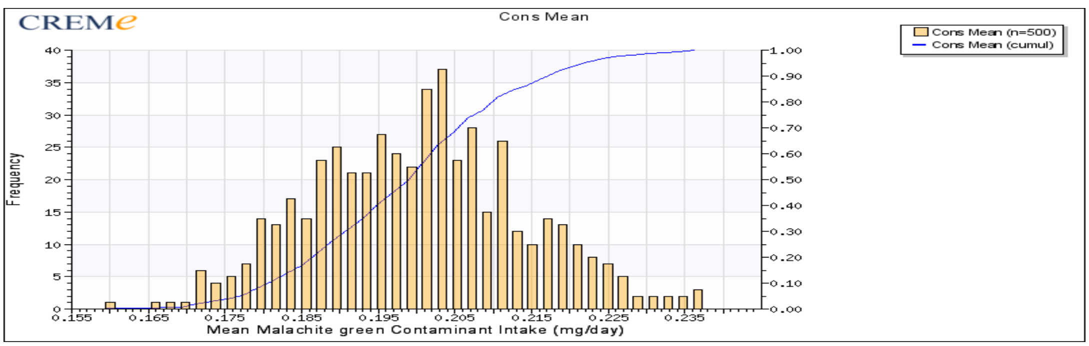


Figure B.39a Malachite green contaminant intakes in children (mg/day)

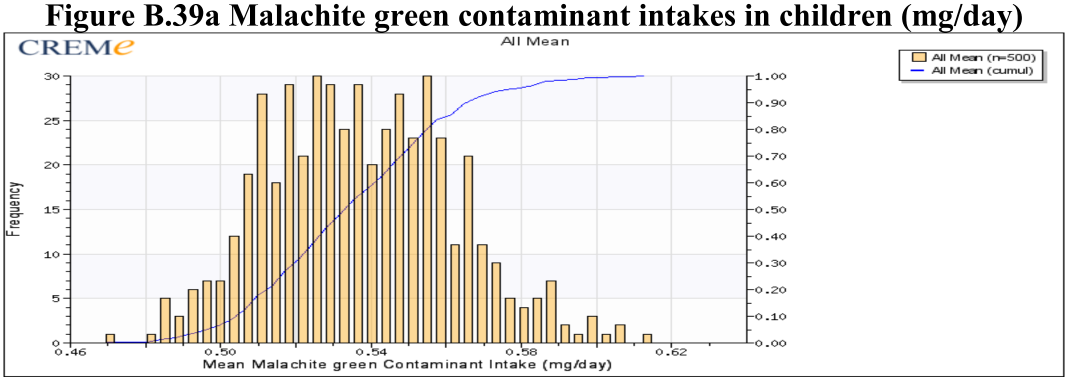


Figure B.39b Malachite green contaminant intakes in adults (mg/day)

Figure B.39a shows the distribution for the likely mean malachite green contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 children consumers, while Figure B.39b shows the distribution for the likely malachite green contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

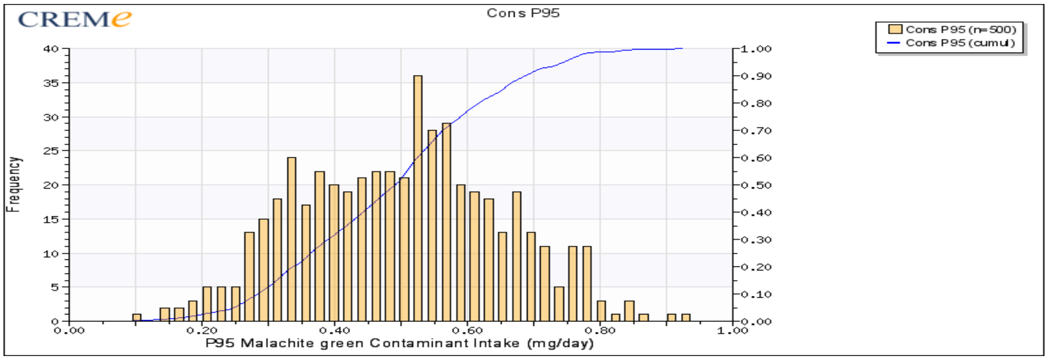


Figure B.40a Malachite green contaminant intakes in children (mg/day)

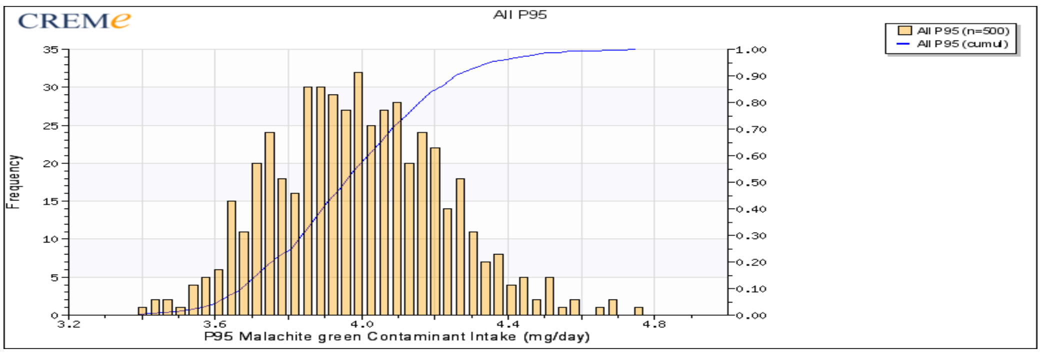


Figure B.40b Malachite green contaminant intakes in adults (mg/day)

Figure B.40a shows the distribution for the likely mean malachite green contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 children consumers, while Figure B.40b shows the distribution for the likely malachite green contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

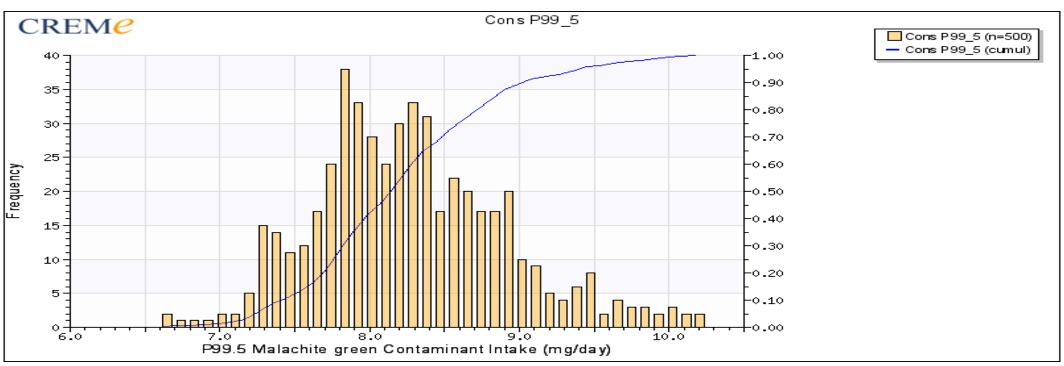


Figure B.41a Malachite green contaminant intakes in children (mg/day)

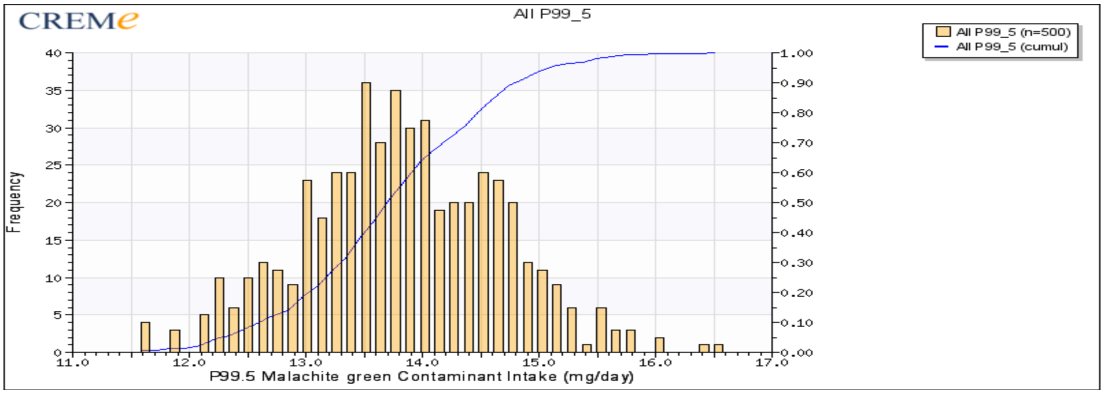


Figure B.41b Malachite green contaminant intakes in adults (mg/day)

Figure B.41a shows the distribution for the likely mean malachite green contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 children consumers, while Figure B.41b shows the distribution for the likely malachite green contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

Malachite Green Exposure (in mg/kg/day) among Children vs. Adult Consumers

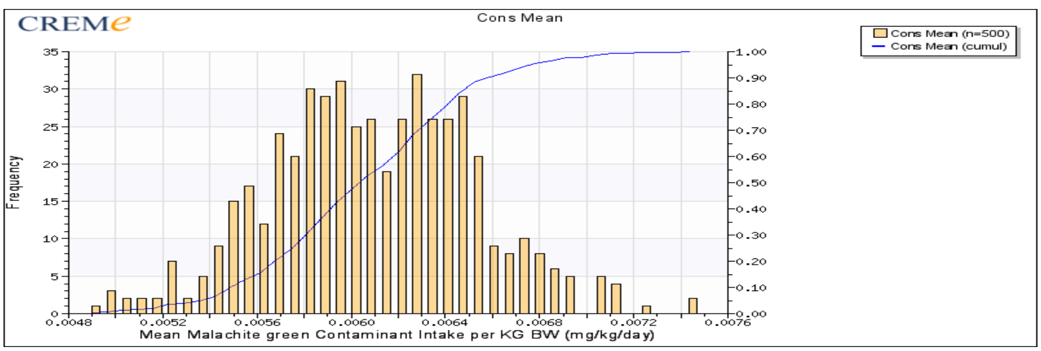


Figure B.42a Malachite green contaminant intake in children (mg/kg/day)

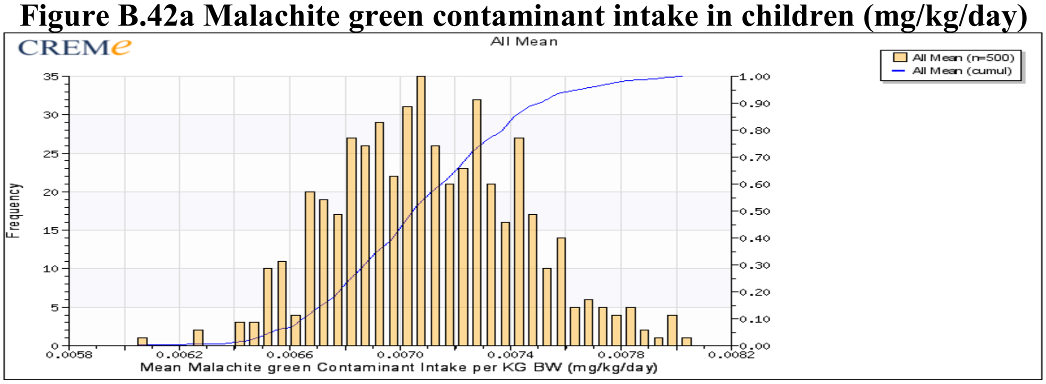


Figure B.43b Malachite green contaminant intake in adults (mg/kg/day)

Figure B.43a shows the distribution for the likely mean malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 children consumers, while Figure B.43b shows the distribution for the likely malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

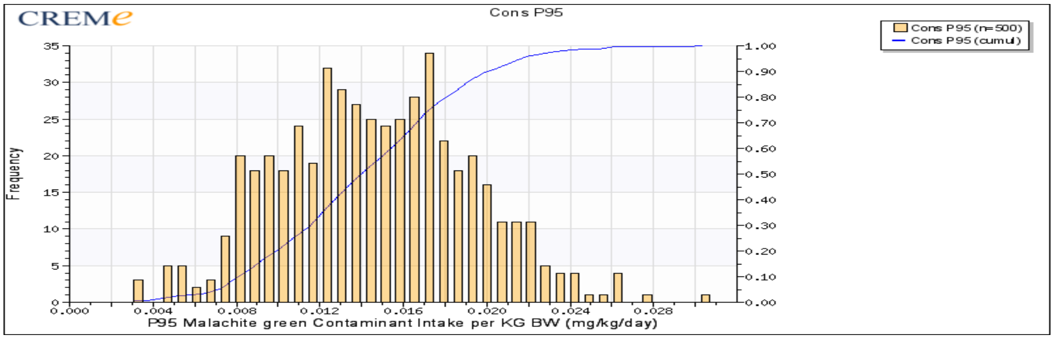


Figure B.44a Malachite green contaminant intakes in children (mg/kg/day)

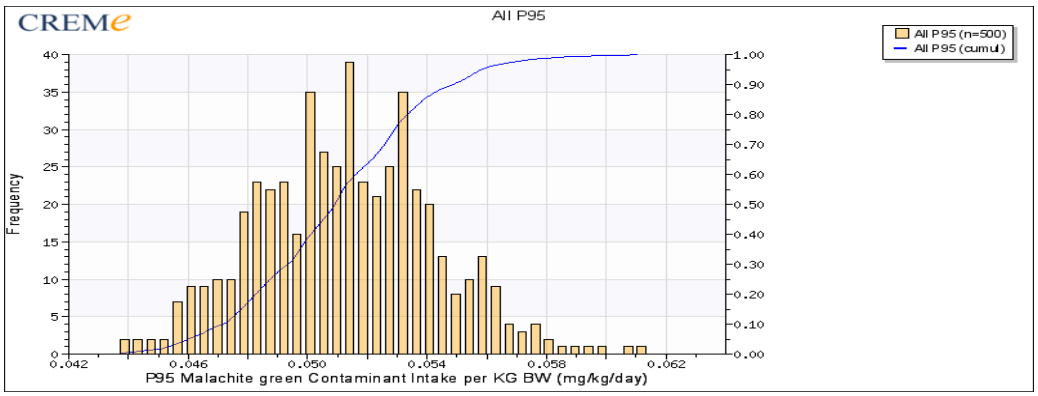


Figure B.44b Malachite green contaminant intakes in adults (mg/kg/day)

Figure B.44a shows the distribution for the likely mean malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 children consumers, while Figure B.44b shows the distribution for the likely malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

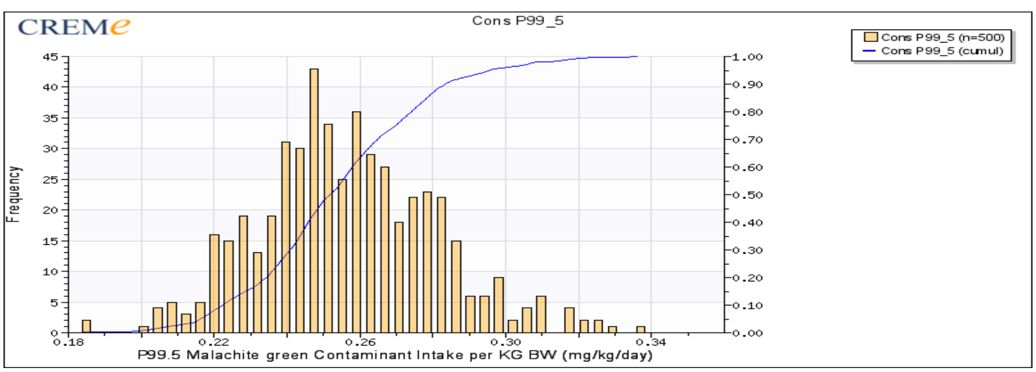


Figure B.45a Malachite green contaminant intake in children (mg/kg/day)

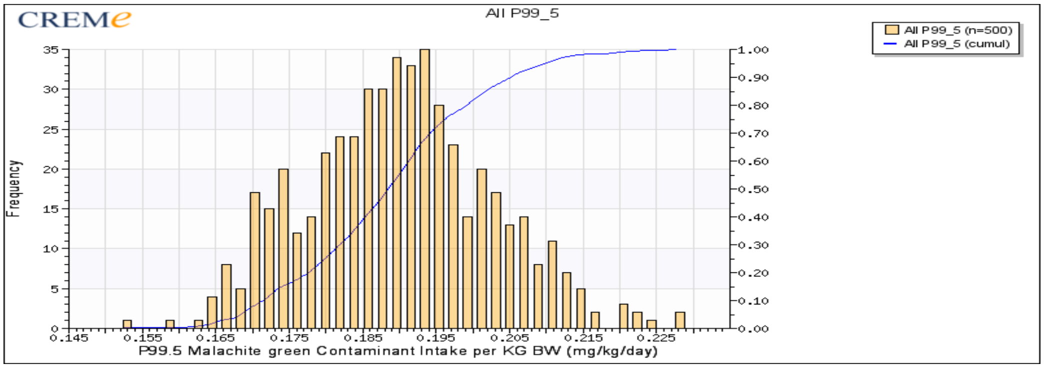


Figure B.45b Malachite green contaminant intakes in adults (mg/kg/day)

Figure B.45a shows the distribution for the likely mean malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 children consumers, while Figure B.45b shows the distribution for the likely malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

Nitrofuran Exposure (in mg/day) among Children vs. Adult Consumers

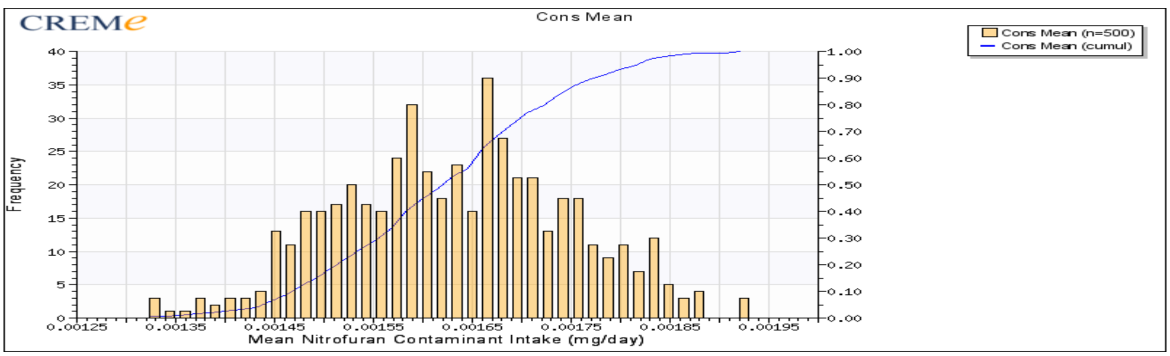


Figure B.46a Nitrofuran contaminant intakes in children (mg/day)

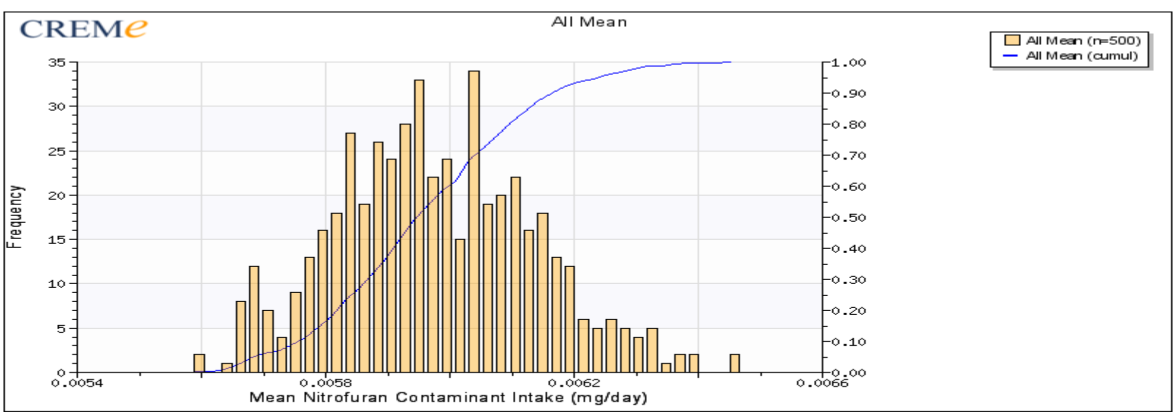


Figure B.46b Nitrofuran contaminant intakes in adults (mg/day)

Figure B.46a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 children consumers, while Figure B.46b shows the distribution for the likely nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

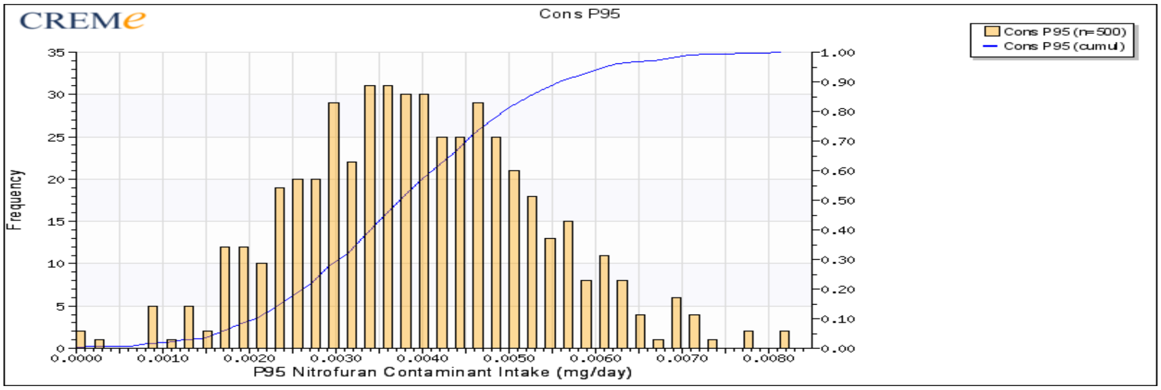


Figure B.47a Nitrofuran contaminant intakes in children (mg/day)

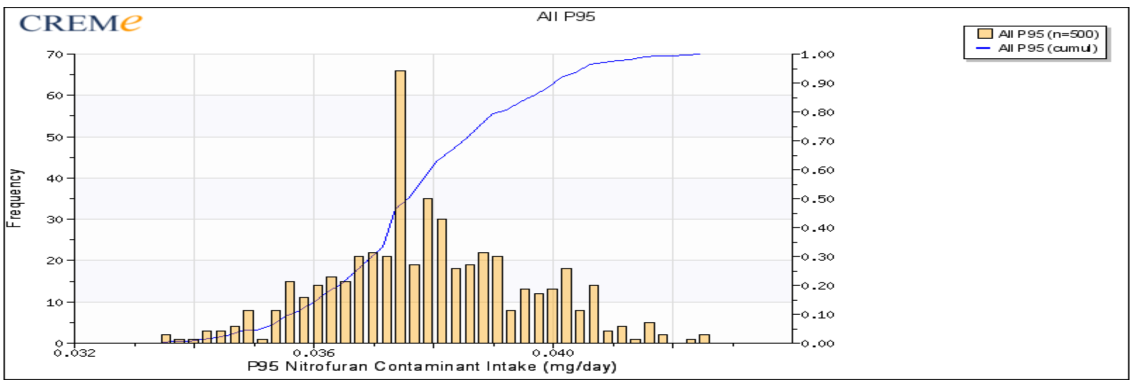


Figure B.47b Nitrofuran contaminant intakes in adults (mg/day)

Figure B.47a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 children consumers, while Figure B.47b shows the distribution for the likely nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

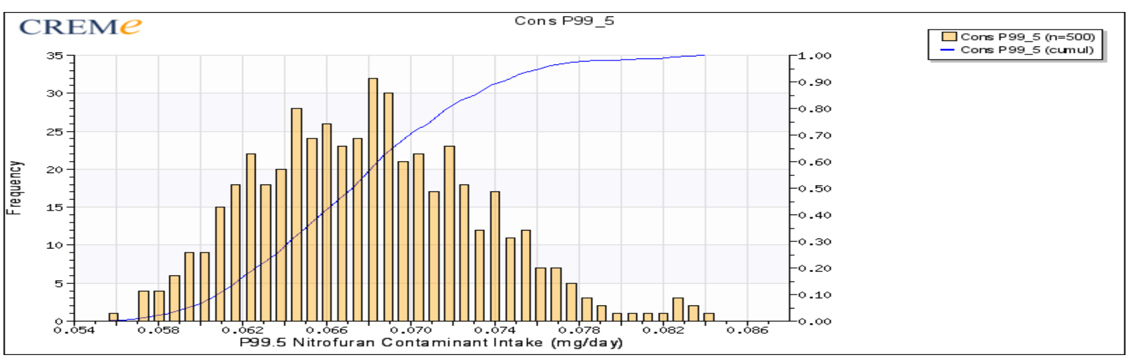


Figure B.48a Nitrofuran contaminant intakes in children (mg/day)

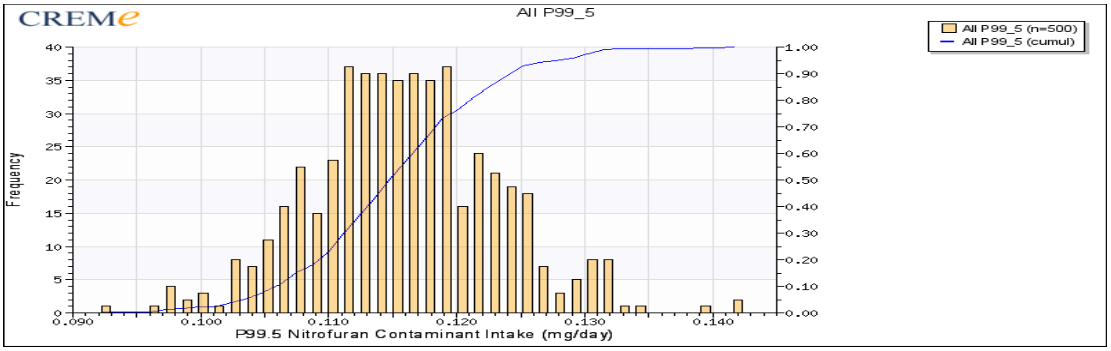


Figure B.48b Nitrofuran contaminant intakes in adults (mg/day)

Figure B.48a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 children consumers, while Figure B.48b shows the distribution for the likely nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

Nitrofuran Exposure (in mg/kg/day) among Children vs. Adult Consumers

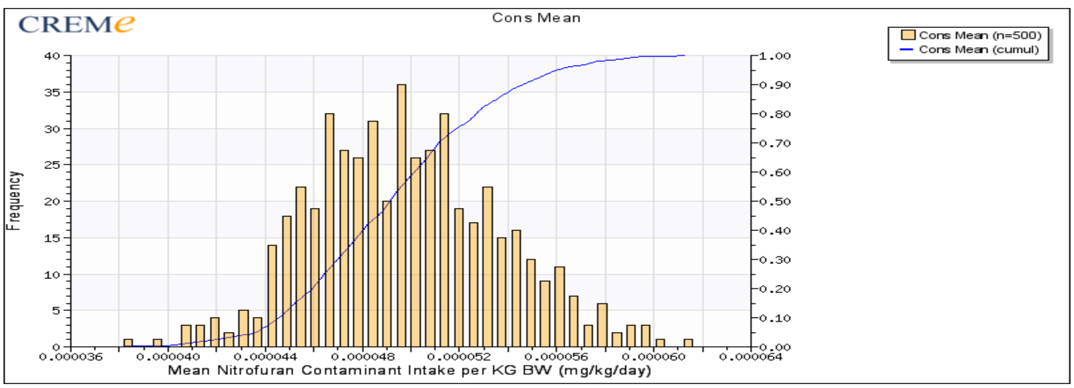


Figure B.49a Nitrofuran contaminant intakes in children (mg/kg/day)

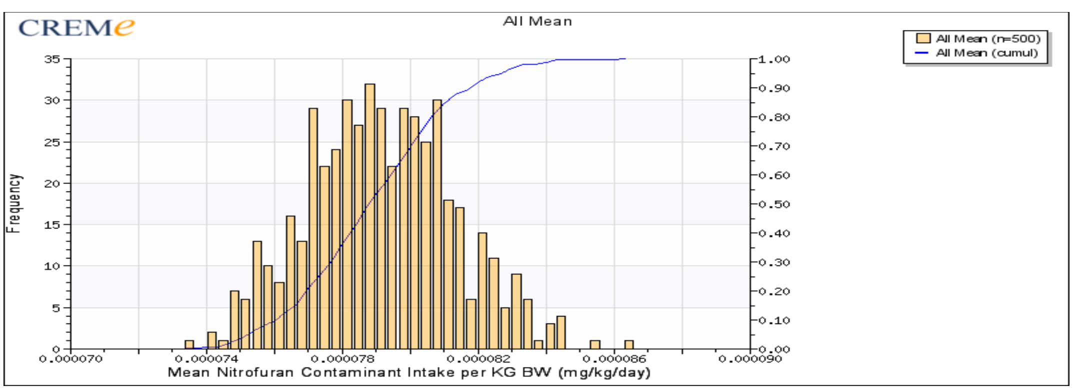


Figure B.49b Nitrofuran contaminant intakes in adults (mg/kg/day)

Figure B.49a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 children consumers, while Figure B.49b shows the distribution for the likely nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

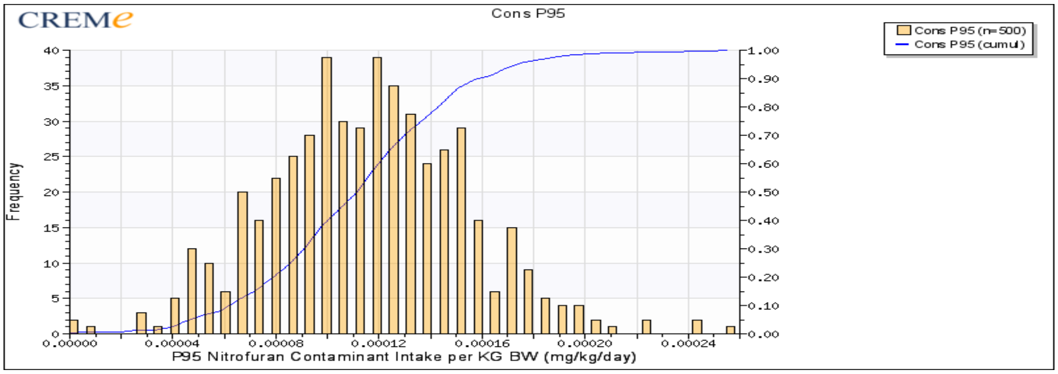


Figure B.50a Nitrofuran contaminant intakes in children (mg/kg/day)

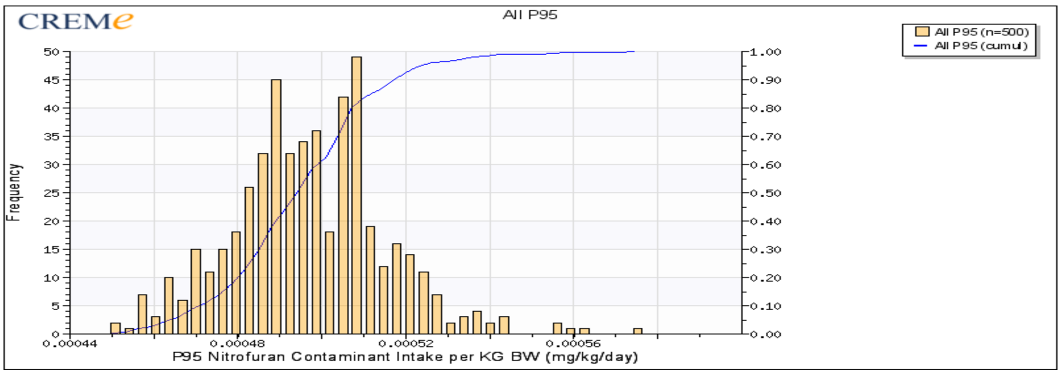


Figure B.50b Nitrofuran contaminant intakes in adults (mg/kg/day)

Figure B.50a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 children consumers, while Figure B.50b shows the distribution for the likely nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

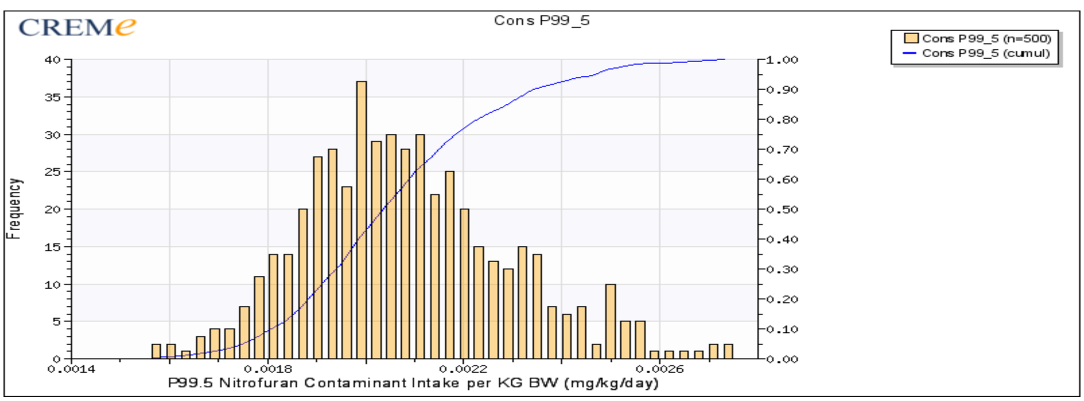


Figure B.51a Nitrofuran contaminant intakes in children (mg/kg/day)

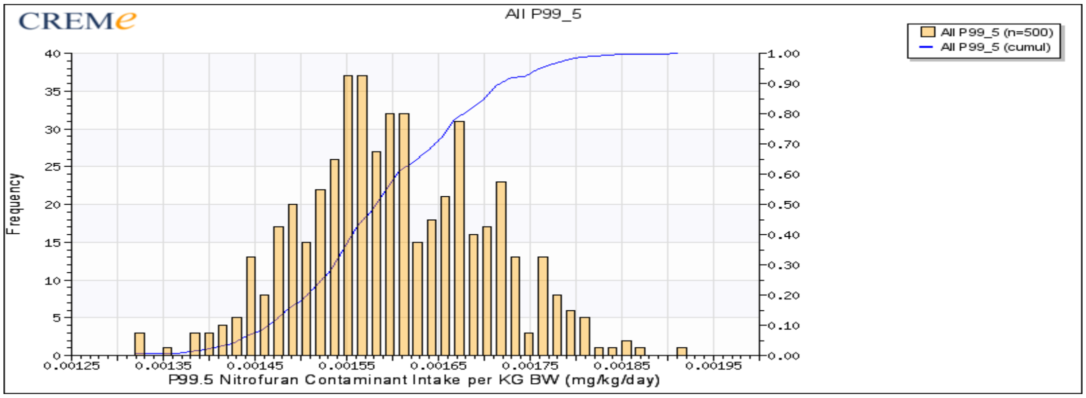


Figure B.51b Nitrofuran contaminant intakes in adults (mg/kg/day)

Figure B.51a shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 children consumers, while Figure B.51b shows the distribution for the likely nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult seafood consumers. Note: The X-axes for the two graphs are on different scales.

Fluoroquinolone Exposure (in mg/day) among NHANES 2003-2004 Adult Female Consumers

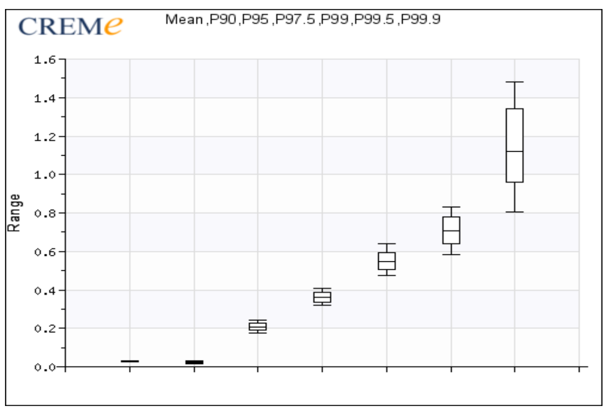


Figure B.52 Fluoroquinolone contaminant intakes (mg/day)

Figure B.52 shows box-plots for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 50th , 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 adult female consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

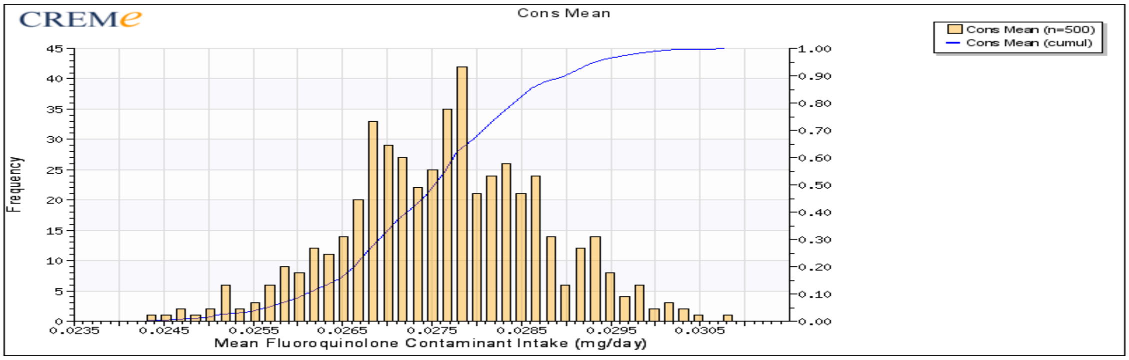


Figure B.53 Fluoroquinolone intakes in NHANES adult females (mg/day)

Figure B.53 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult female consumers.

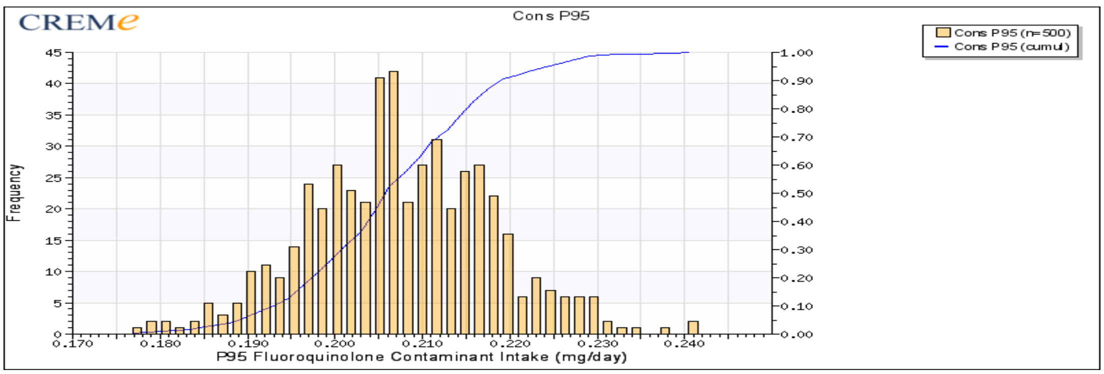


Figure B.54 Fluoroquinolone intakes in NHANES adult females (mg/day)

Figure B.54 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult female consumers.

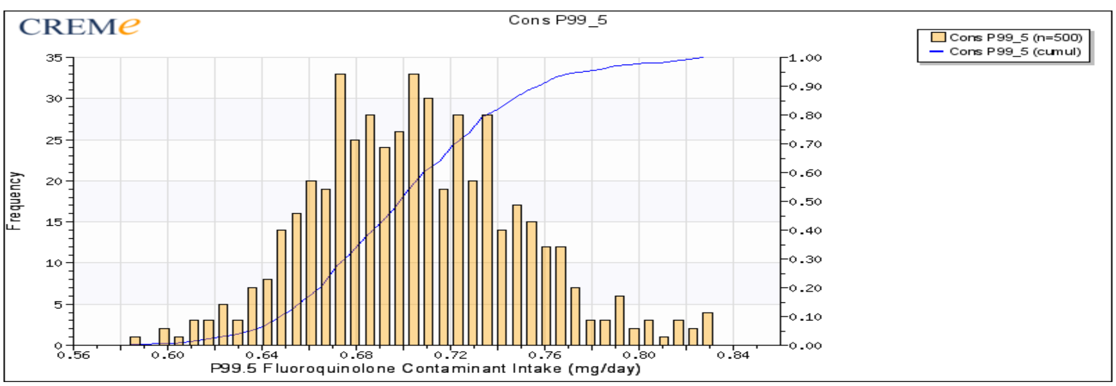


Figure B.55 Fluoroquinolone intakes in NHANES adult females (mg/day)

Figure B.55 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult female consumers.

Fluoroquinolone Exposure (in mg/kg/day) among NHANES 2003-2004 Adult Female Consumers

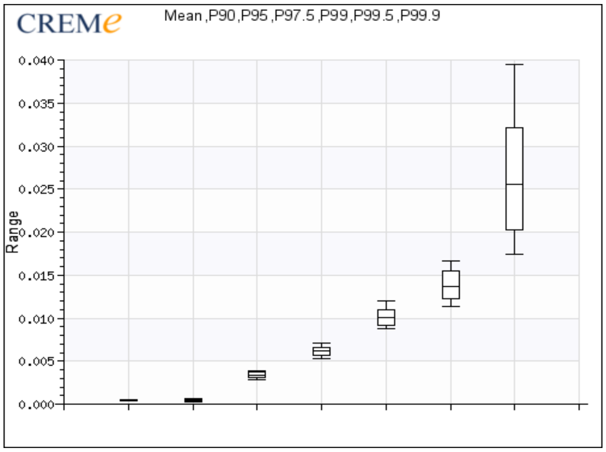


Figure B.56 Fluoroquinolone contaminant intakes (mg/kg/day)

Figure B.56 shows box-plots for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th , 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 adult female consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

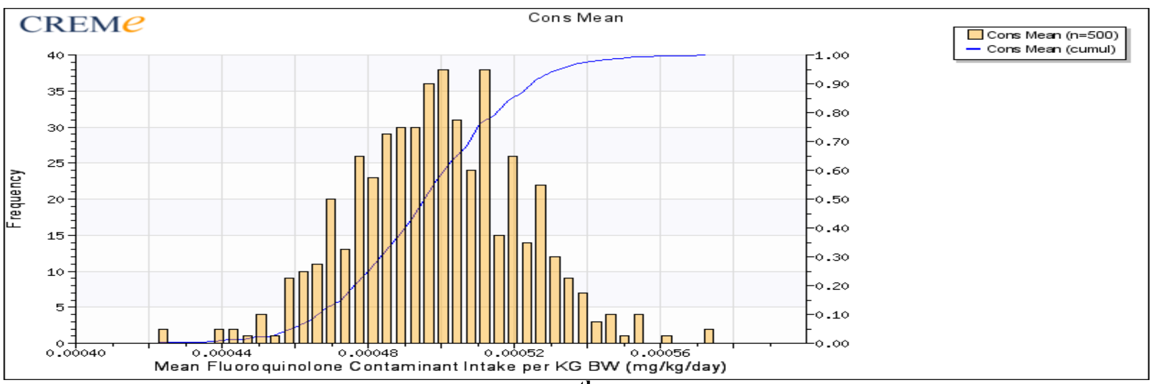


Figure B.57 Fluoroquinolone intakes in 50th P of NHANES adult female (mg/kg/day)

Figure B.57 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult female consumers.

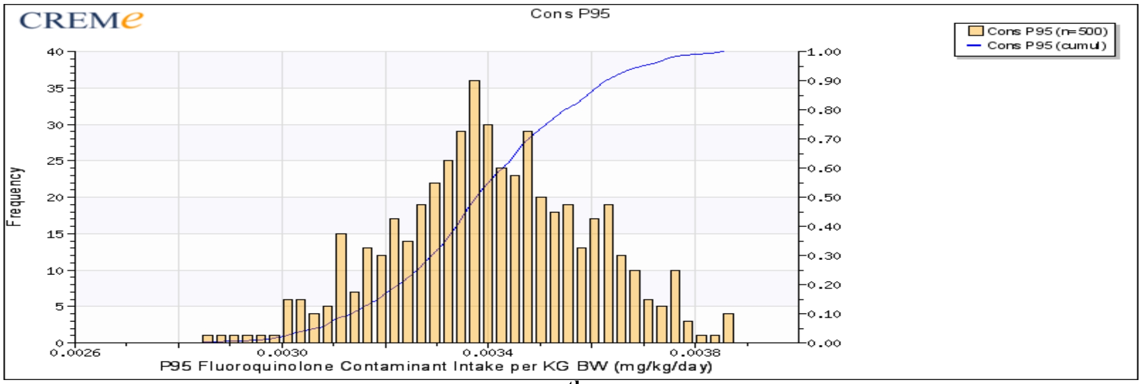


Figure B.58 Fluoroquinolone intakes in 95th P of NHANES adult females (mg/kg/day)

Figure B.58 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult female consumers.

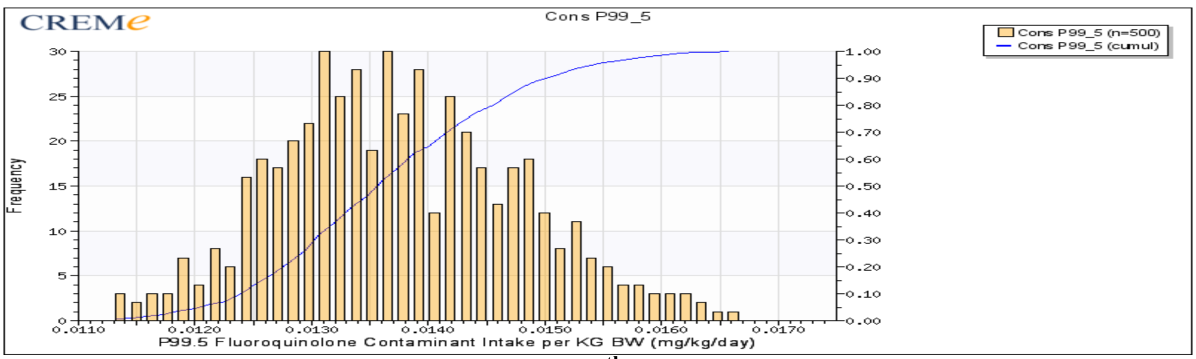


Figure B.59 Fluoroquinolone intakes in 99.5th P of NHANES adult females (mg/kg/day)

Figure B.59 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult female consumers.

Gentian Violet Exposure (in mg/day) among NHANES 2003-2004 Adult Female

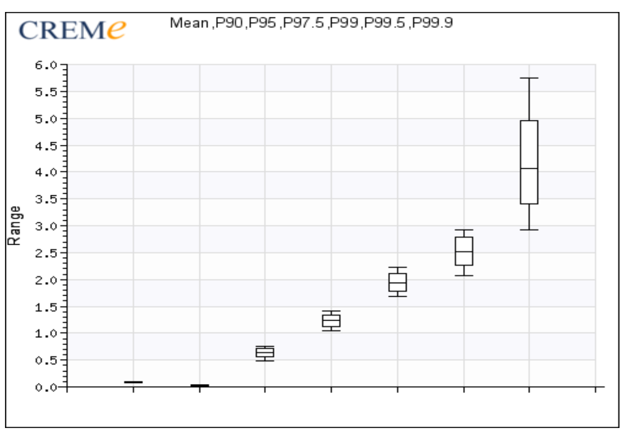


Figure B.60 Gentian violet contaminant intakes (mg/day)

Figure B.60 shows box-plots for the likely mean gentian violet contaminant exposure (in mg/day) that would have occurred among the upper 50th , 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 adult female consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

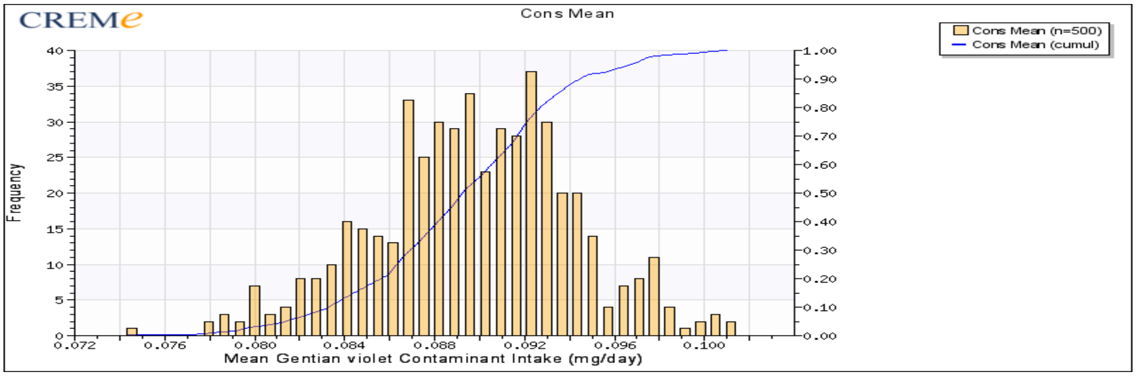


Figure B.61 Mean gentian violet intakes in NHANES adult females (mg/day)

Figure B.61 shows the distribution for the likely mean gentian violet contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult female consumers.

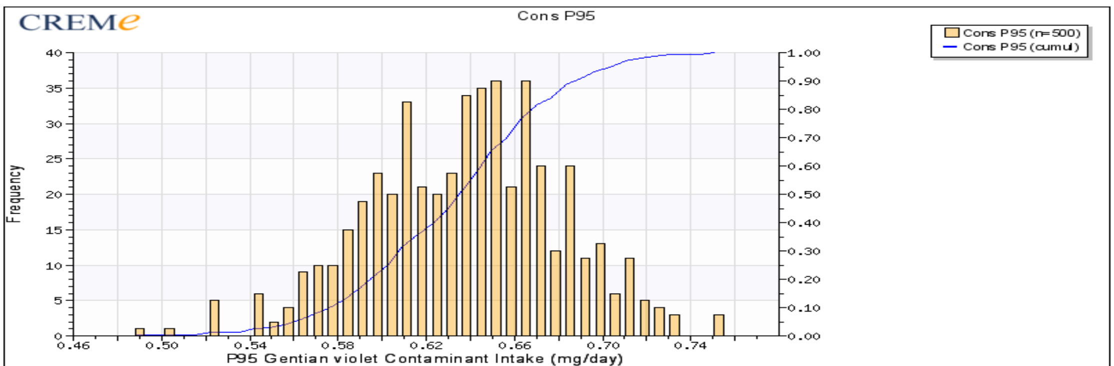


Figure B.62 Gentian violet intakes in 95th P of NHANES adult females (mg/day)

Figure B.62 shows the distribution for the likely mean gentian violet contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult female consumers.

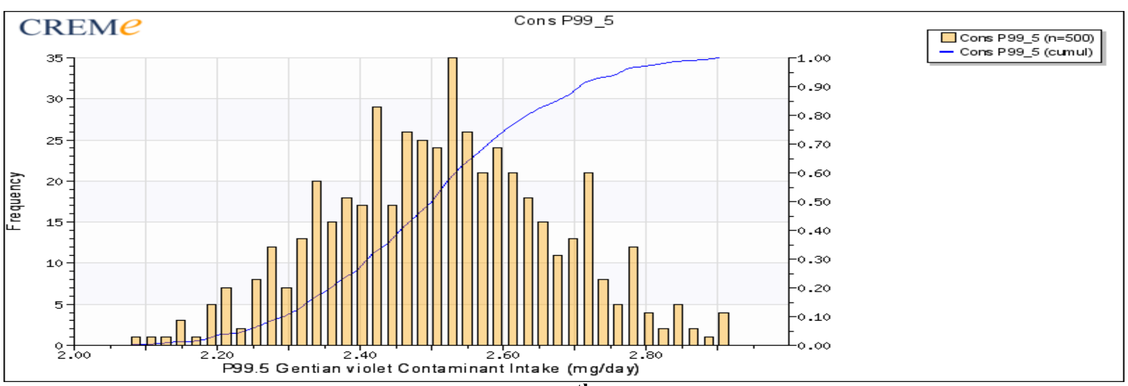


Figure B.63 Gentian violet intakes in 99.5th P of NHANES adult females (mg/day)

Figure B.63 shows the distribution for the likely mean gentian violet contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult female consumers.

Gentian Violet Exposure (in mg/kg/day) among NHANES 2003-2004 Adult Female Consumers

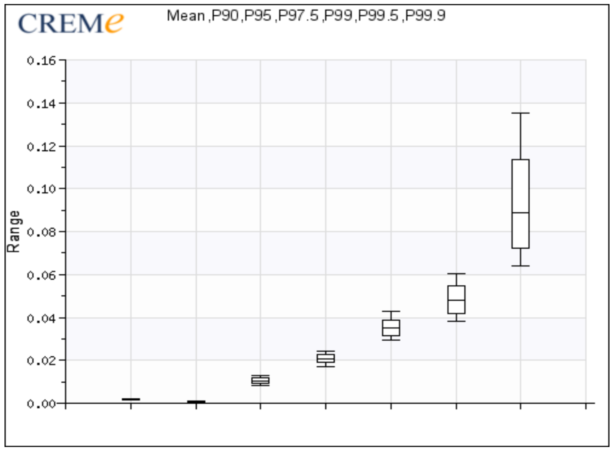


Figure B.64 Gentian violet intakes in NHANES adult females (mg/kg/day)

Figure B.64 shows box-plots for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th , 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 adult female consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

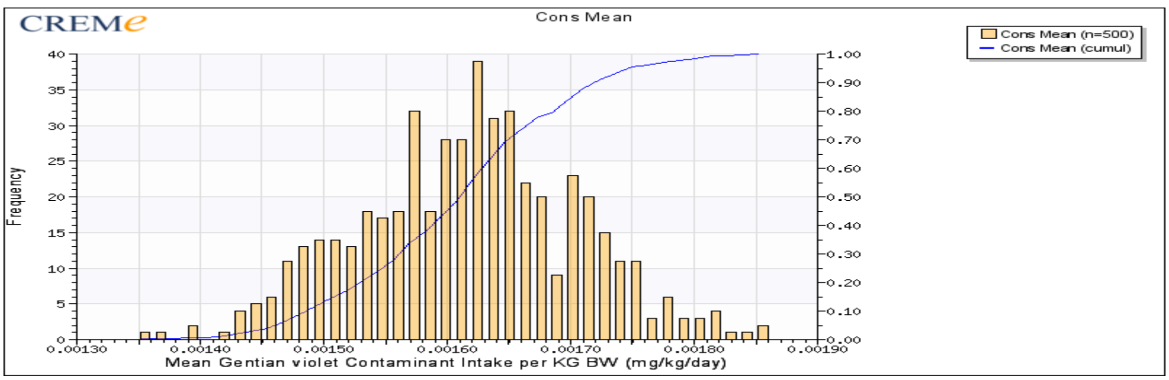


Figure B.65 Mean gentian violet intakes in NHANES adult females (mg/kg/day)

Figure B.65 shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult female consumers.

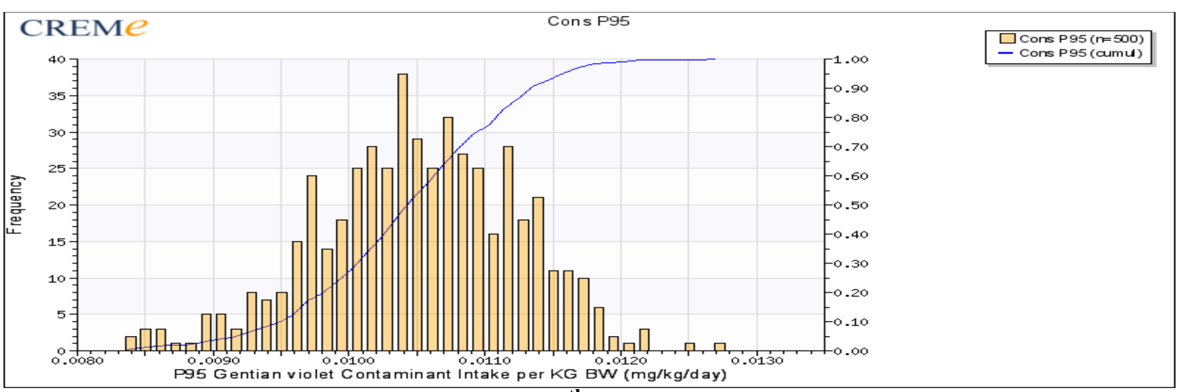


Figure B.66 Gentian violet intakes in 95th P of NHANES adult females (mg/kg/day)

Figure B.66 shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult female consumers.

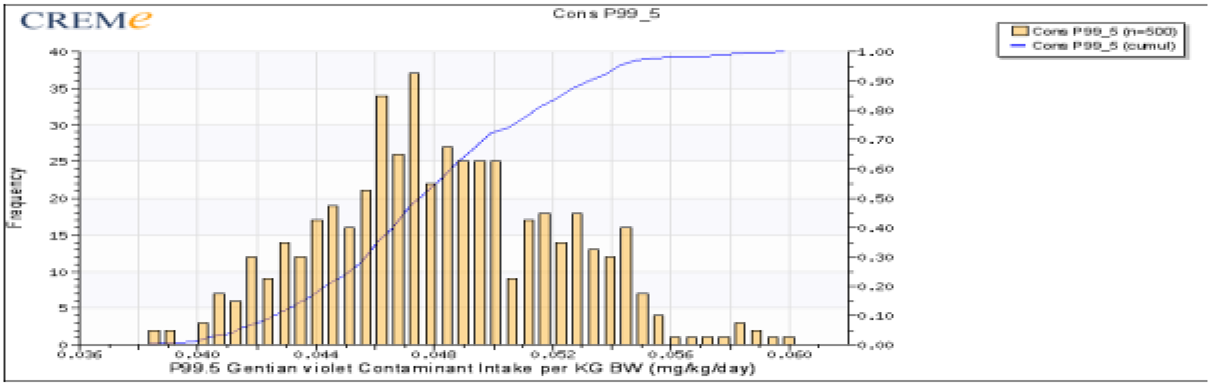


Figure B.67 Gentian violet intakes in 99.5th P of NHANES adult females (mg/kg/day)

Figure B.67 shows the distribution for the likely mean gentian violet contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult female consumers.

Malachite Green Exposure (in mg/day) among NHANES 2003-2004 Adult Females

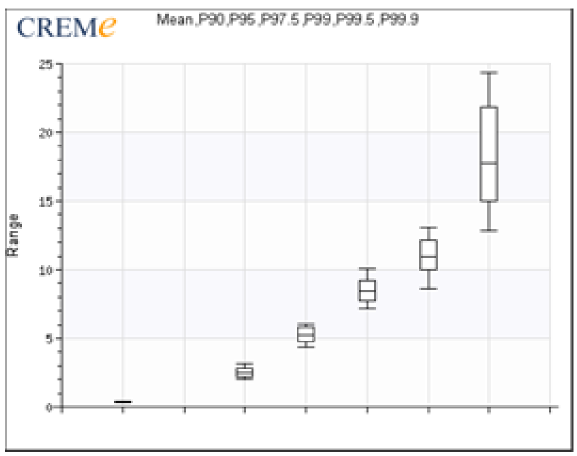


Figure B.68 Malachite green intakes in adult females (mg/day)

Figure B.68 shows box-plots for the likely mean malachite green contaminant exposure (in mg/day) that would have occurred among the upper 50th , 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 adult female consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

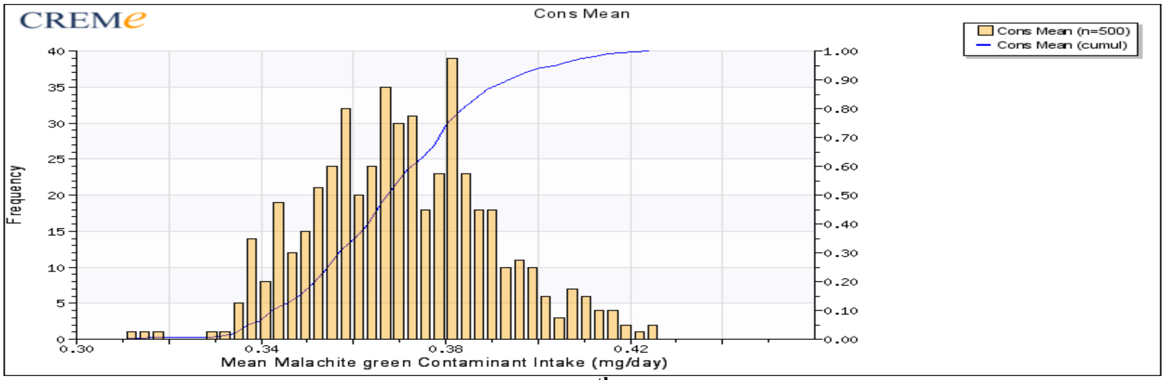


Figure B.69 Malachite green intakes in 50th P of NHANES adult females (mg/day)

Figure B.69 shows the distribution for the likely mean malachite green contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult female consumers.

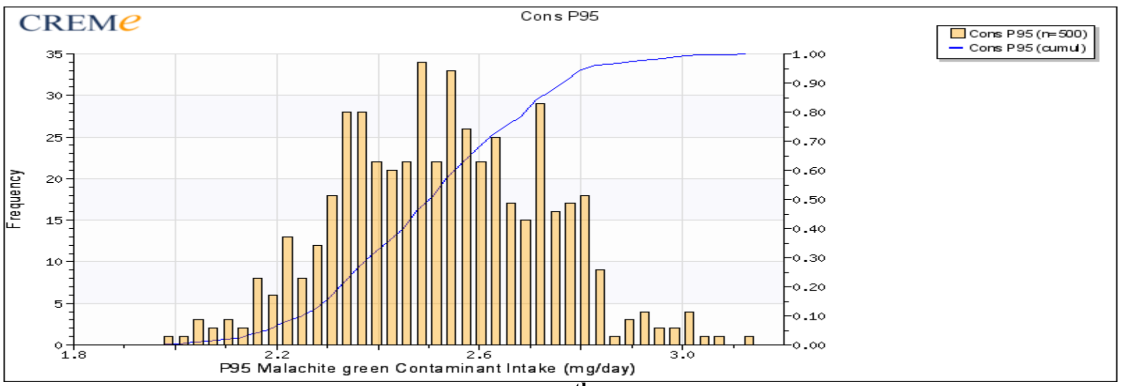


Figure B.70 Malachite green intakes in 95th P of NHANES adult females (mg/day)

Figure B.70 shows the distribution for the likely mean malachite green contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult female consumers.

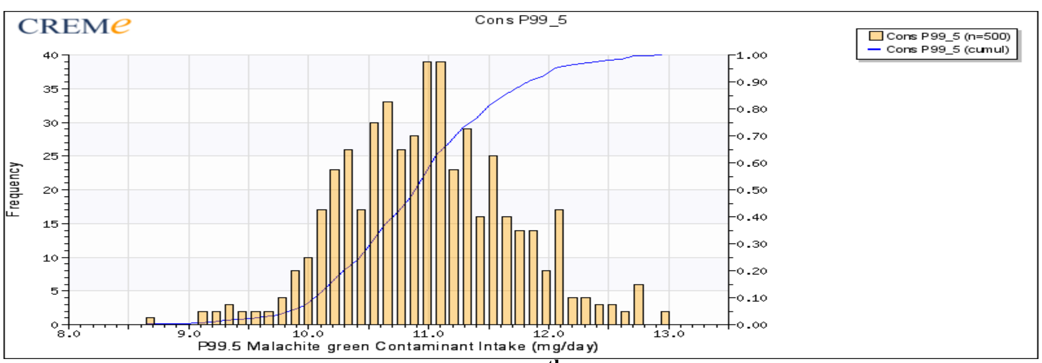


Figure B.71 Malachite green intakes in 99.5th P of NHANES adult females (mg/day)

Figure B.71 shows the distribution for the likely mean malachite green contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult female consumers.

Malachite Green Exposure (in mg/kg/day) among NHANES 2003-2004 Adult Females

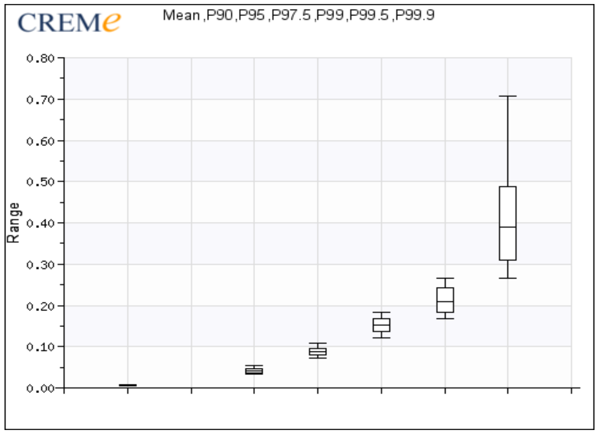


Figure B.72 Malachite green intakes in NHANES adult females (mg/kg/day)

Figure B.72 shows box-plots for the likely mean malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th , 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 adult female consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

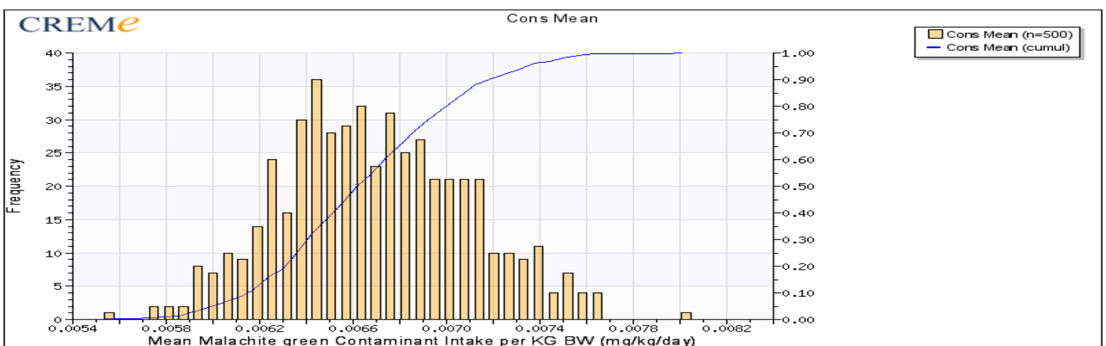


Figure B.73 Malachite green intakes in 50th P of NHANES adult females (mg/kg/day)

Figure B.73 shows the distribution for the likely mean malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult female consumers.

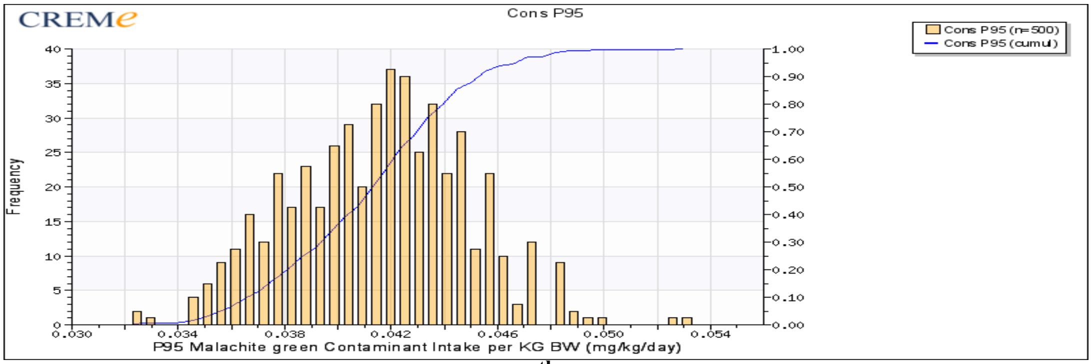


Figure B.74 Malachite green intakes in 95th P of NHANES adult females (mg/kg/day)

Figure B.74 shows the distribution for the likely mean malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult female consumers.

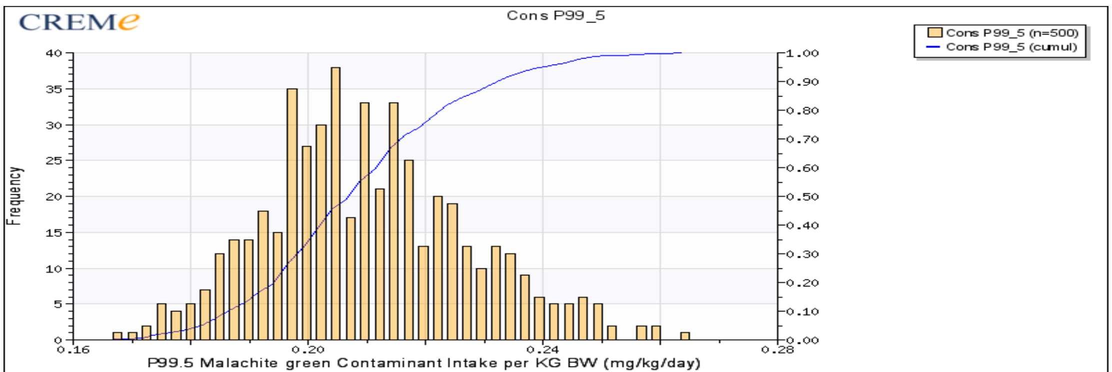


Figure B.75 Malachite green intakes in 99.5th P of NHANES adult females (mg/kg/day)

Figure B.75 shows the distribution for the likely mean malachite green contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult female consumers.

Nitrofuran Exposure (in mg/day) among NHANES 2003-2004 Adult Female

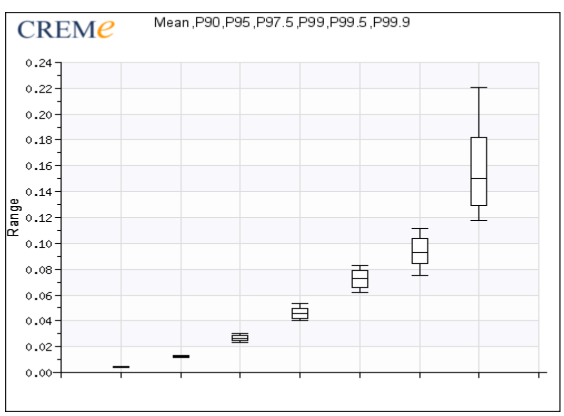


Figure B.76 Nitrofuran intakes in NHANES adult females (mg/day)

Figure B.76 shows box-plots for the likely mean nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 50th , 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 adult female consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

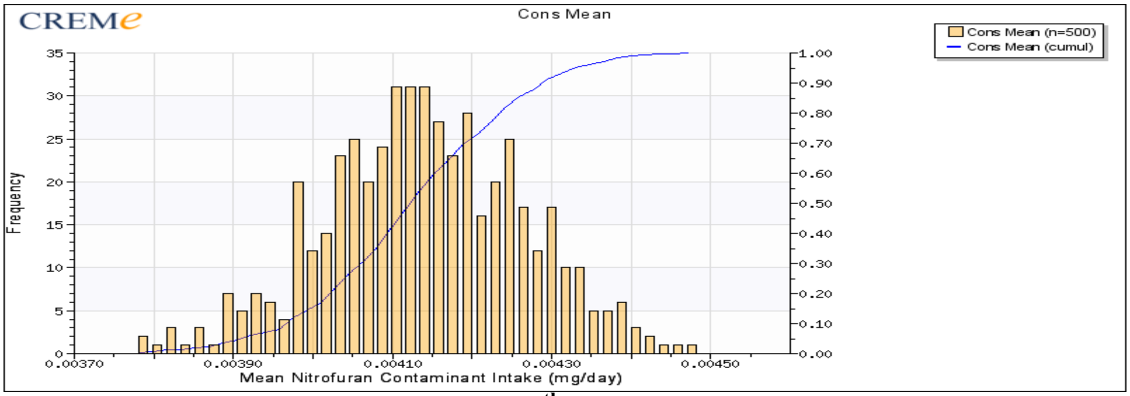


Figure B.77 Nitrofuran intakes in 50th P of NHANES adult females (mg/day)

Figure B.77 shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult female consumers.

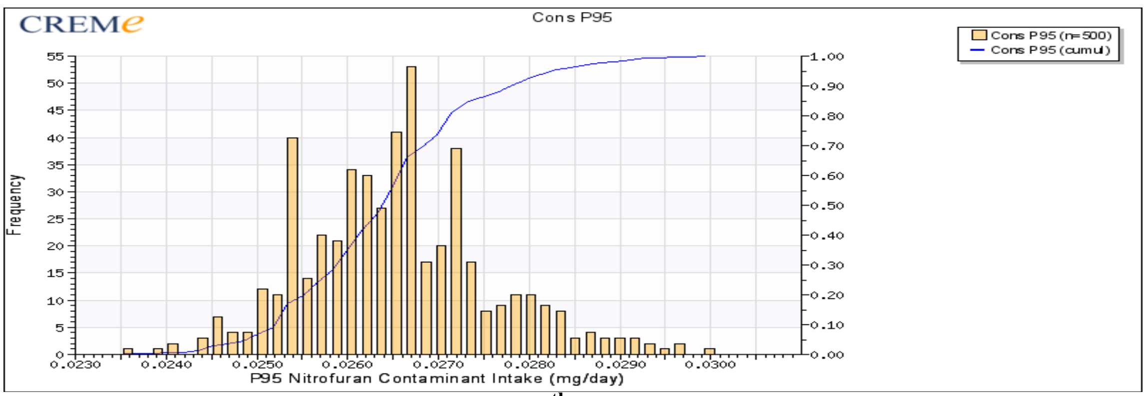


Figure B.78 Nitrofuran intakes in 95th P of NHANES adult females (mg/day)

Figure B.78 shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult female consumers.

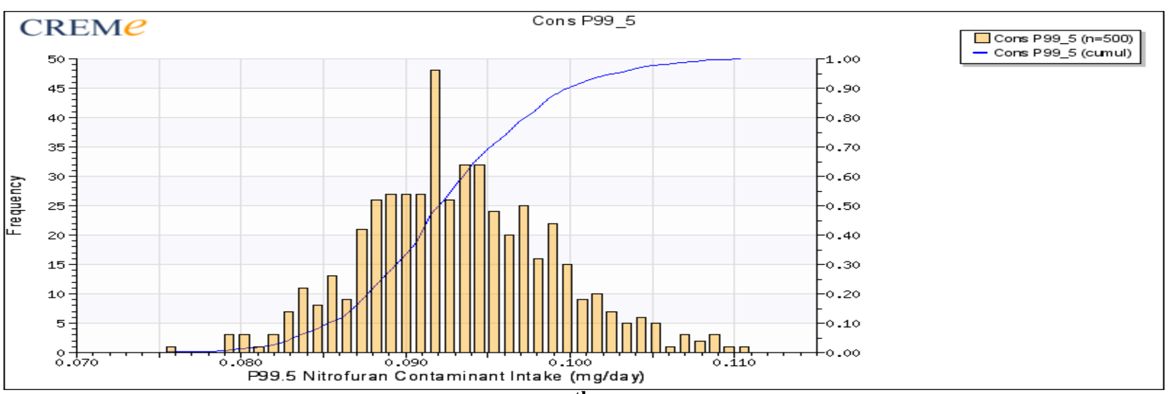


Figure B.79 Nitrofuran intakes in 99.5th P of NHANES adult females (mg/day)

Figure B.79 shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult female consumers.

Nitrofuran Exposure (in mg/day) among NHANES 2003-2004 Adult Females

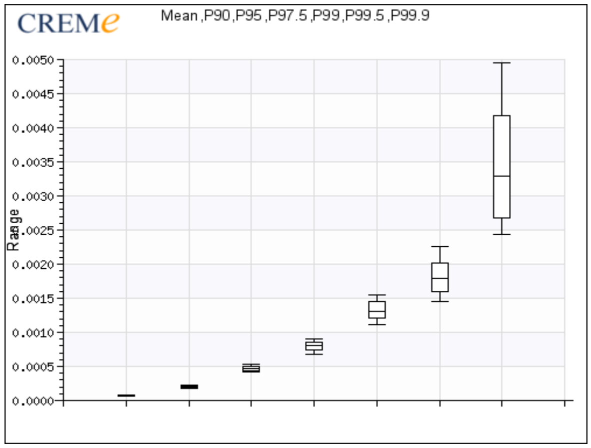


Figure B.80 Nitrofuran intakes in NHANES adult females (mg/kg/day)

Figure B.80 shows box-plots for the likely mean nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th , 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 adult female consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

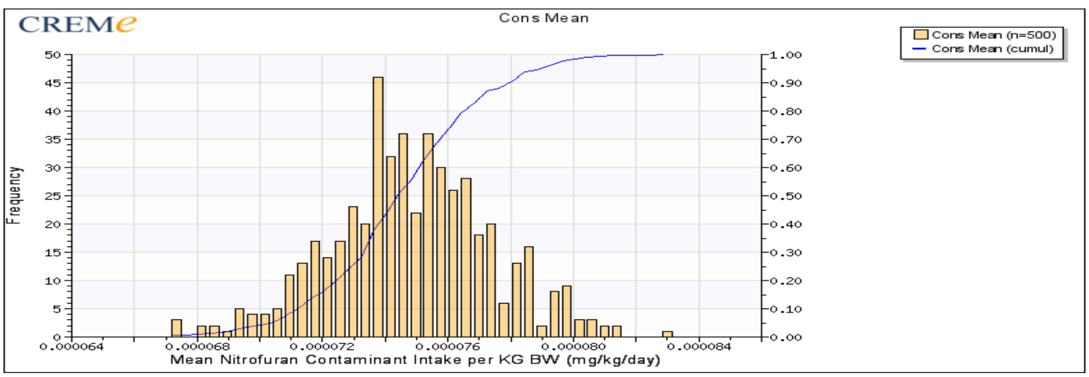


Figure B.81 Mean nitrofuran intakes in NHANES adult females (mg/kg/day)

Figure B.81 shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 adult female consumers.

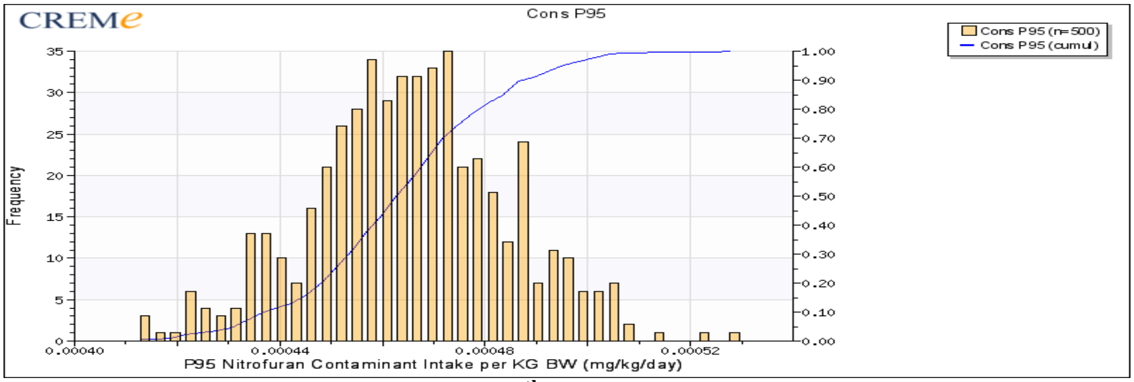


Figure B.82 Nitrofuran intakes in 95th P of NHANES adult females (mg/kg/day)

Figure B.82 shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 adult female consumers.

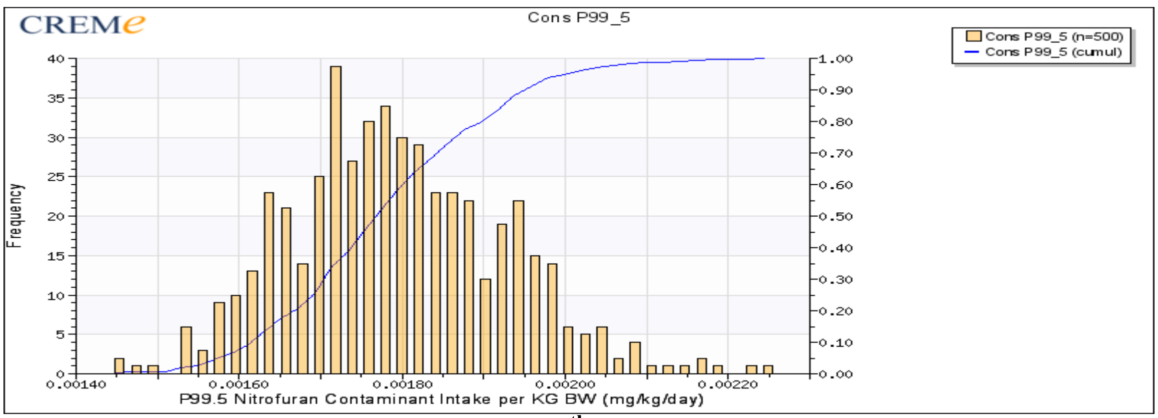


Figure B.83 Nitrofuran intakes in 99.5th P of NHANES adult females (mg/day)

Figure B.83 shows the distribution for the likely mean nitrofuran contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 adult female consumers.

Fluoroquinolone Exposure (in mg/day) among the Elderly

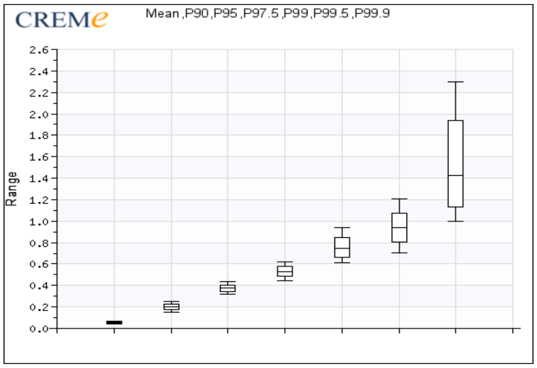


Figure B.84 Fluoroquinolone contaminant intakes in the elderly (mg/day)

Figure B.84 shows box-plots for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 50th, 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 elderly consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

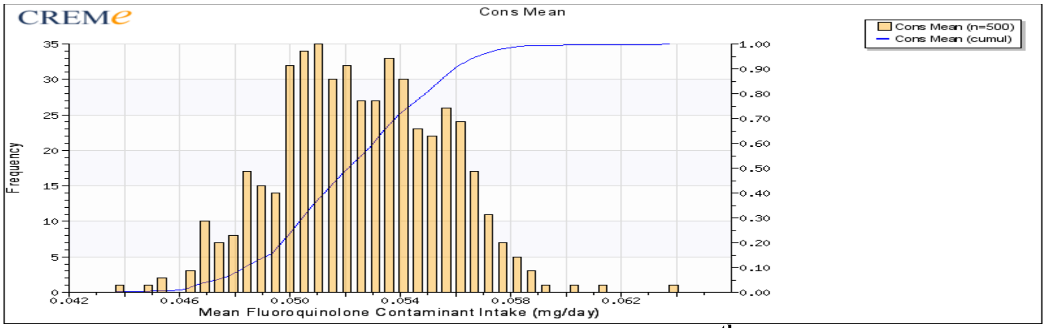


Figure B.85 Fluoroquinolone contaminant intakes in 50th P of the elderly (mg/day)

Figure B.85 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 elderly consumers.

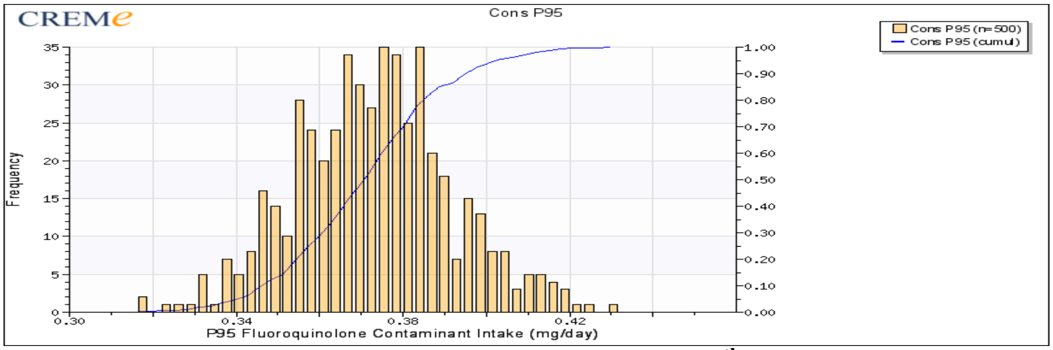


Figure B.86 Fluoroquinolone contaminant intakes in 95th P of the elderly (mg/day)

Figure B.86 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 elderly consumers.

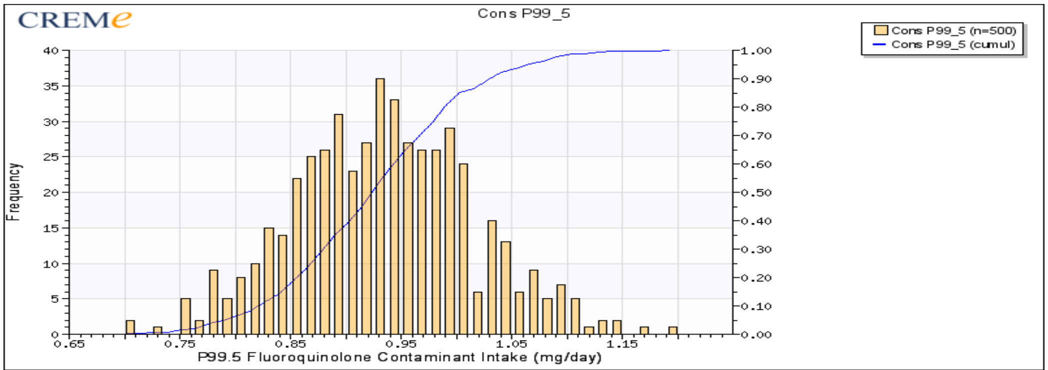


Figure B.87 Fluoroquinolone contaminant intakes in 99.5th P of the elderly (mg/day)

Figure B.87 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 elderly consumers.

Fluoroquinolone Exposure (in mg/kg/day) among the Elderly

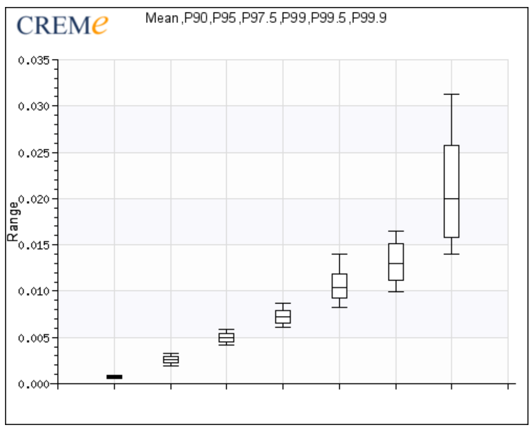


Figure B.88 Fluoroquinolone contaminant intakes in the elderly (mg/kg/day)

Figure B.88 shows box-plots for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th, 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 elderly consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

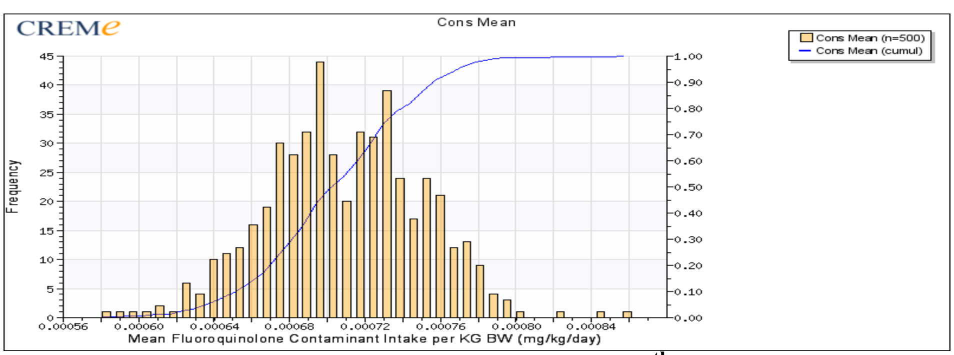


Figure B.89 Fluoroquinolone contaminant intakes in 50th P of the elderly (mg/kg/day)

Figure B.89 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 elderly consumers.

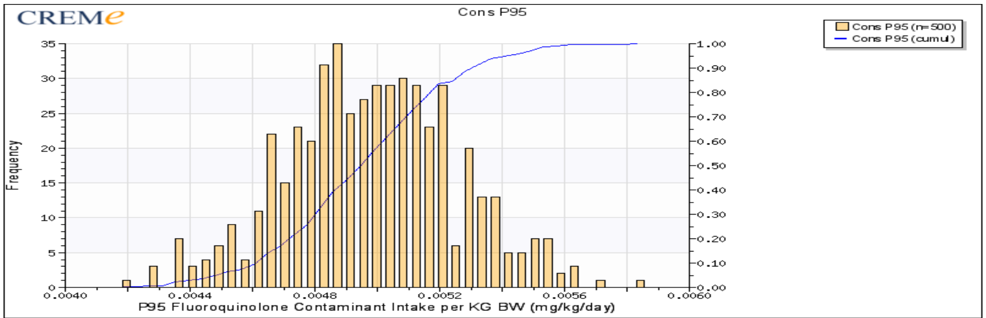


Figure B.90 Fluoroquinolone contaminant intakes in 95th P of the elderly (mg/kg/day)

Figure B.90 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 elderly consumers.

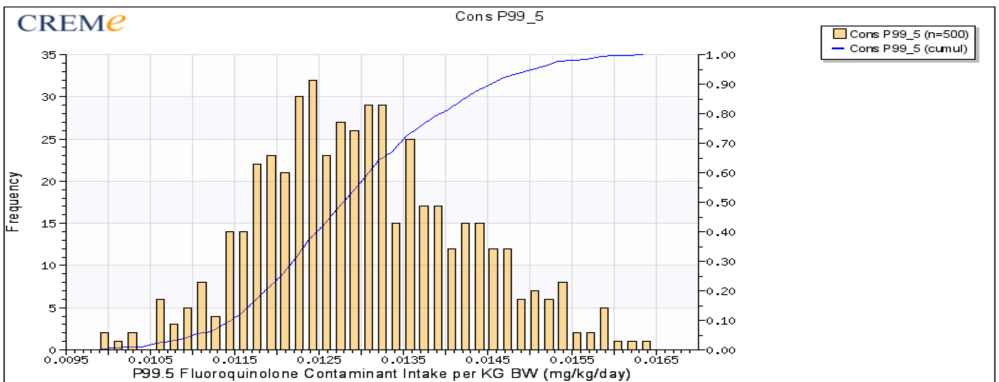


Figure B.91 Fluoroquinolone contaminant intakes in 99.5th P of the elderly (mg/kg/day)

Figure B.91 shows the distribution for the likely mean fluoroquinolone contaminant exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 elderly consumers.

Gentian Violet Exposure (in mg/day) among the Elderly

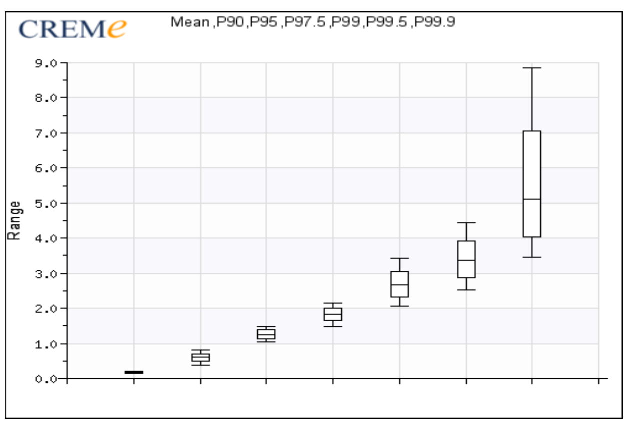


Figure B.92 Gentian violet contaminant intakes in the elderly (mg/day)

Figure B.92 shows box-plots for the likely mean gentian violet exposure (in mg/day) that would have occurred among the upper 50th, 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 elderly consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

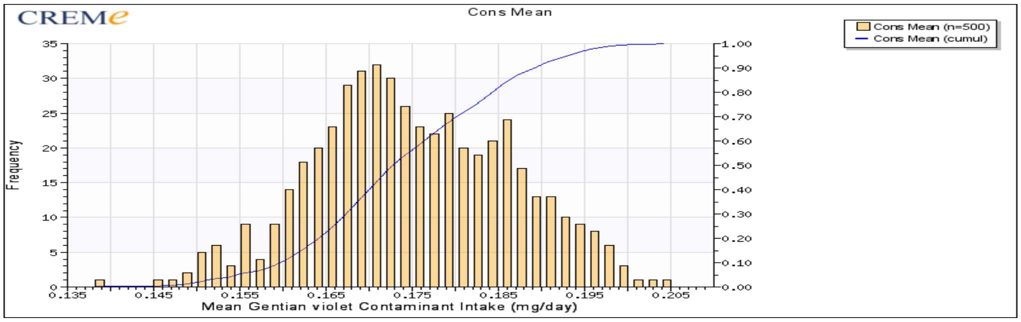


Figure B.93 Gentian violet contaminant intakes in 50th P of the elderly (mg/day)

Figure B.93 shows the distribution for the likely mean gentian violet exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 elderly consumers.

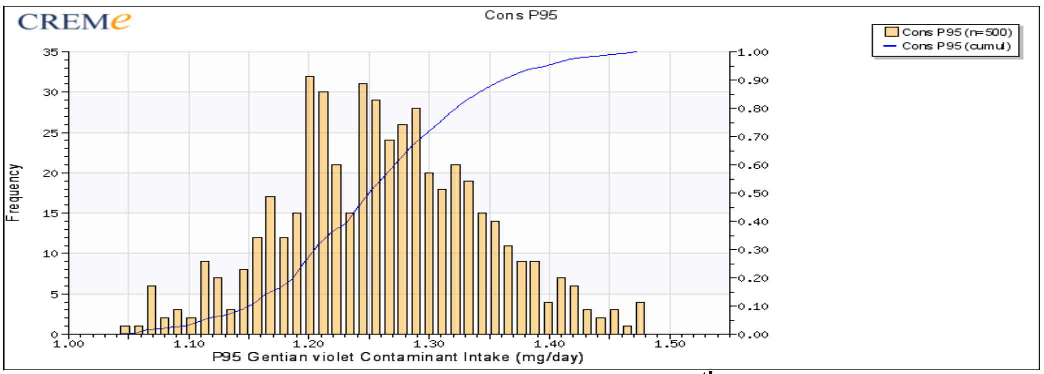


Figure B.94 Gentian violet contaminant intakes in 95th P of the elderly (mg/day)

Figure B.94 shows the distribution for the likely mean gentian violet exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 elderly consumers.

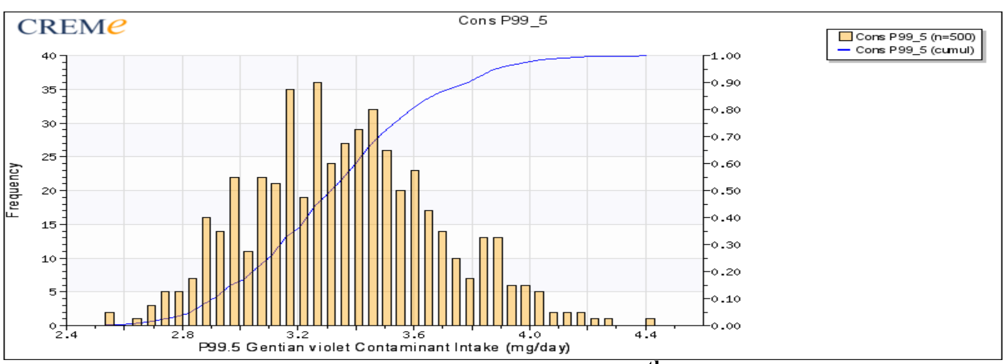


Figure B.95 Gentian violet contaminant intakes in 99.5th P of the elderly (mg/day)

Figure B.95 shows the distribution for the likely mean gentian violet exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 elderly consumers.

Gentian Violet Exposure (in mg/kg/day) among the Elderly

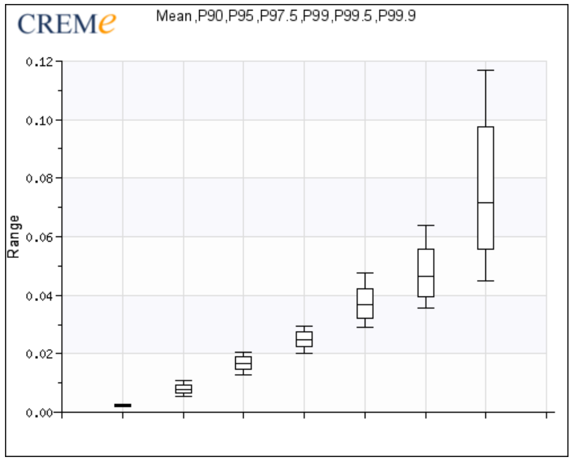


Figure B.96 Gentian violet contaminant intakes in the elderly (mg/kg/day)

Figure B.96 shows box-plots for the likely mean gentian violet exposure (in mg/kg/day) that would have occurred among the upper 50th, 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 elderly consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

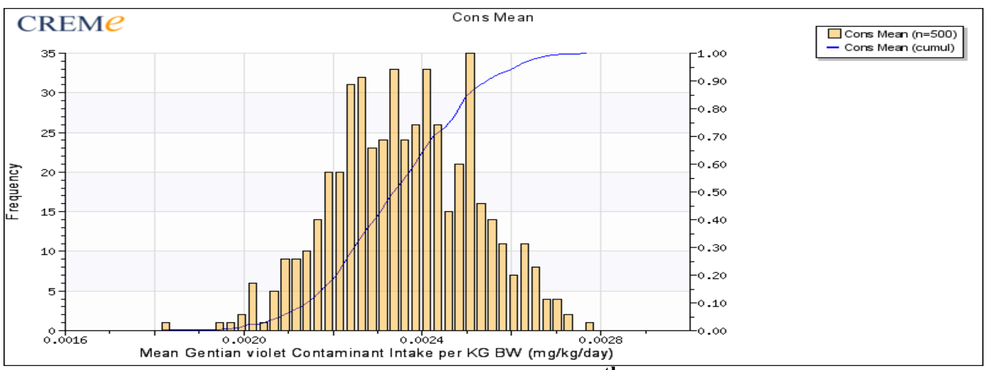


Figure B.97 Gentian violet contaminant intakes in 50th P of the elderly (mg/kg/day)

Figure B.97 shows the distribution for the likely mean gentian violet exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 elderly consumers.

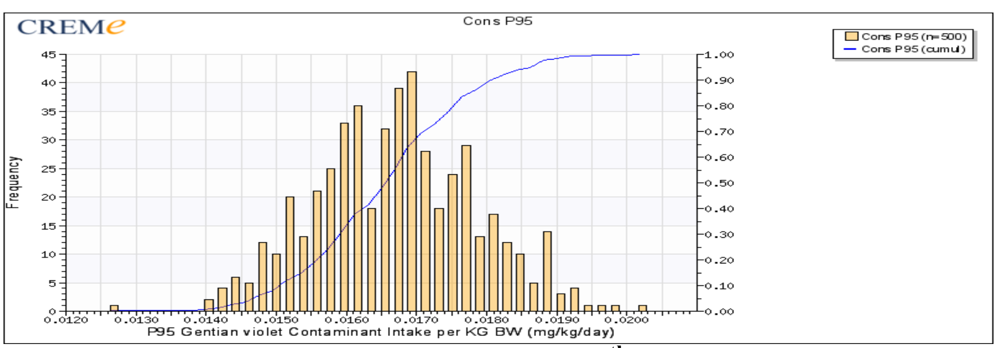


Figure B.98 Gentian violet contaminant intakes in 95th P of the elderly (mg/kg/day)

Figure B.98 shows the distribution for the likely mean gentian violet exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 elderly consumers.

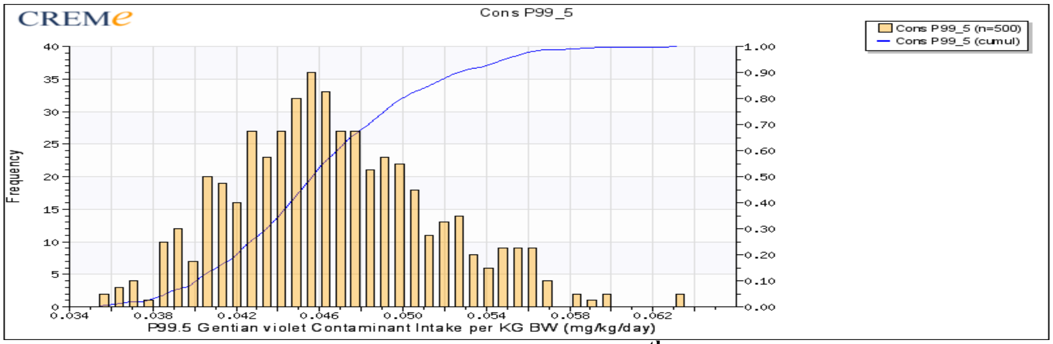


Figure B.99 Gentian violet contaminant intakes in 99.5th P of the elderly (mg/kg/day)

Figure B.99 shows the distribution for the likely mean gentian violet exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 elderly consumers.

Malachite Green Exposure (in mg/day) among the Elderly

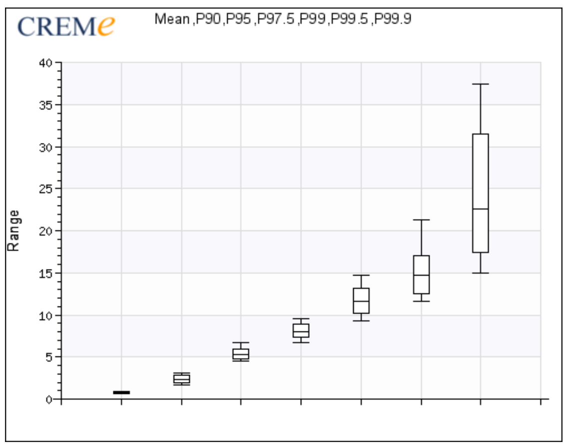


Figure B.100 Malachite green contaminant intakes in the elderly (mg/day)

Figure B.100 shows box-plots for the likely mean malachite green exposure (in mg/day) that would have occurred among the upper 50th, 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 elderly consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

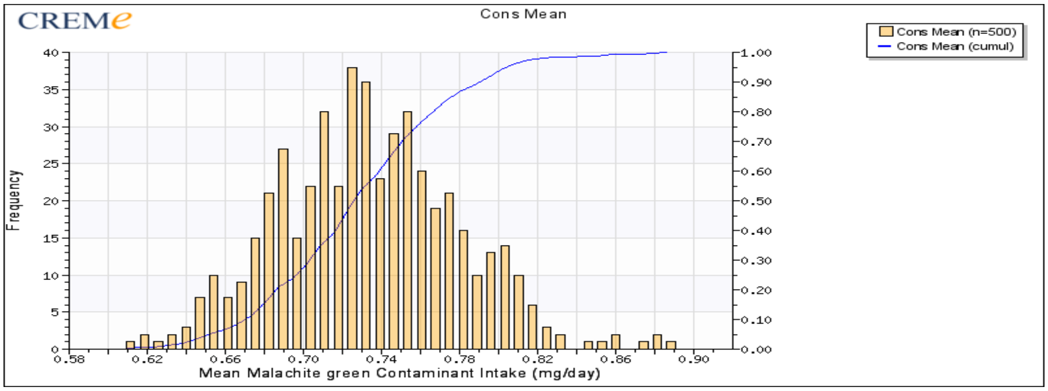


Figure B.101 Malachite green contaminant intakes in 50th P of the elderly (mg/day)

Figure B.101 shows the distribution for the likely mean malachite green exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 elderly consumers.

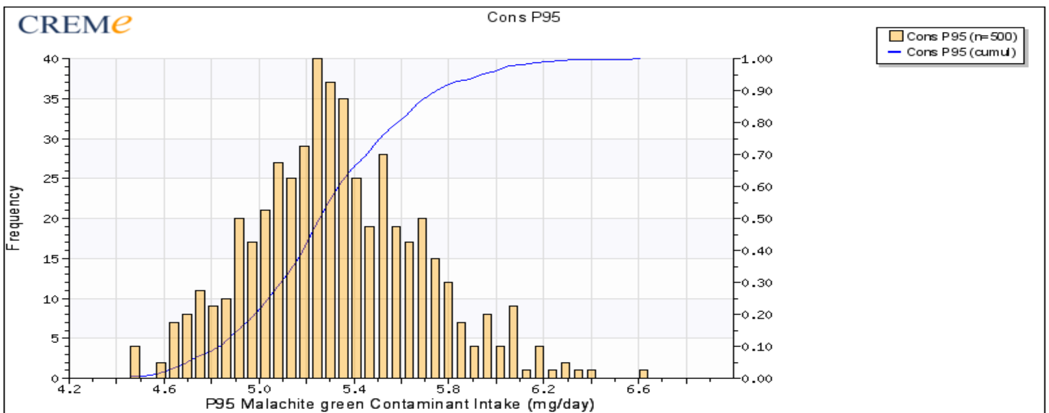


Figure B.102 Malachite green contaminant intakes in 95th P of the elderly (mg/day)

Figure B.102 shows the distribution for the likely mean malachite green exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 elderly consumers.

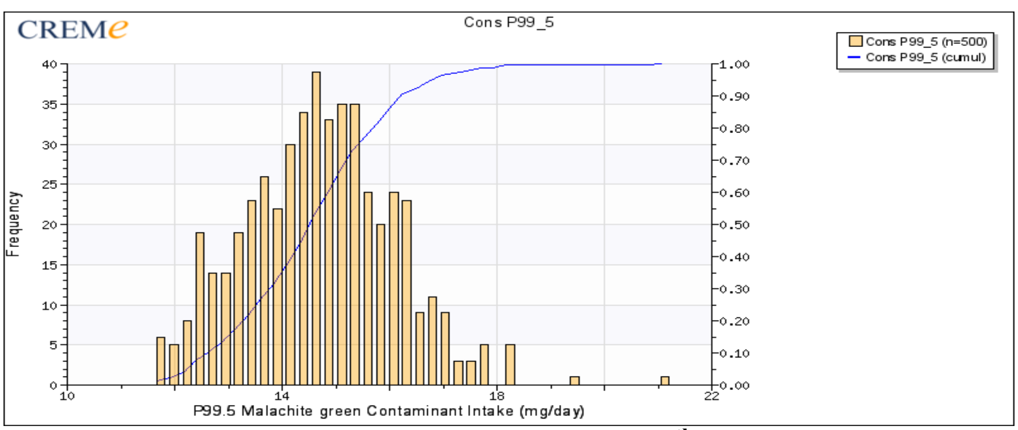


Figure B.103 Malachite green contaminant intakes in 99.5th P of the elderly (mg/day)

Figure B.103 shows the distribution for the likely mean malachite green exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 elderly consumers.

Malachite Green Exposure (in mg/kg/day) among the Elderly

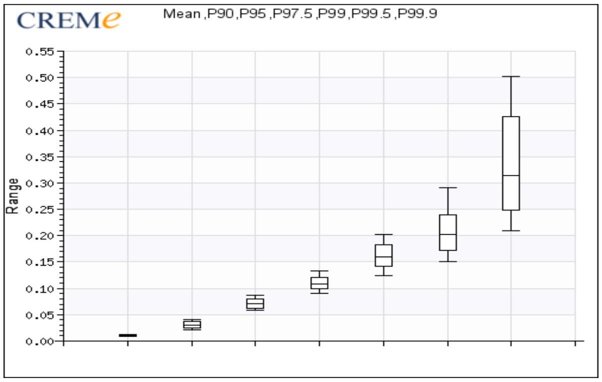


Figure B.104 Malachite green contaminant intakes in the elderly (mg/kg/day)

Figure B.104 shows box-plots for the likely mean malachite green exposure (in mg/kg/day) that would have occurred among the upper 50th, 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 elderly consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

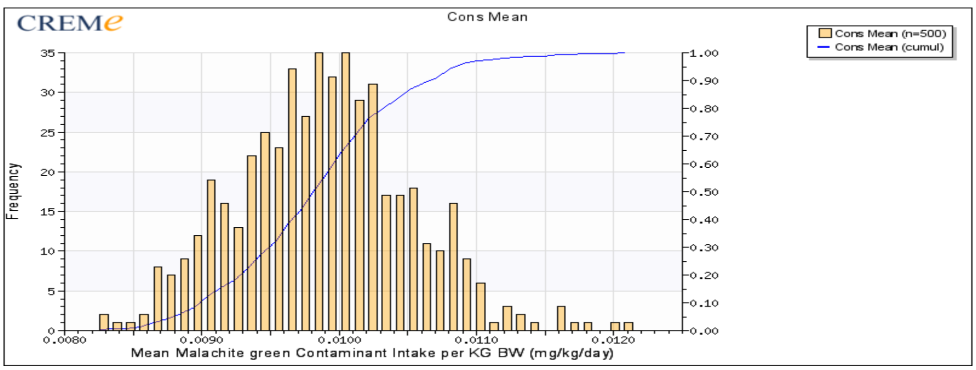


Figure B.105 Malachite green contaminant intakes in 50th P of the elderly (mg/kg/day)

Figure B.105 shows the distribution for the likely mean malachite green exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 elderly consumers.

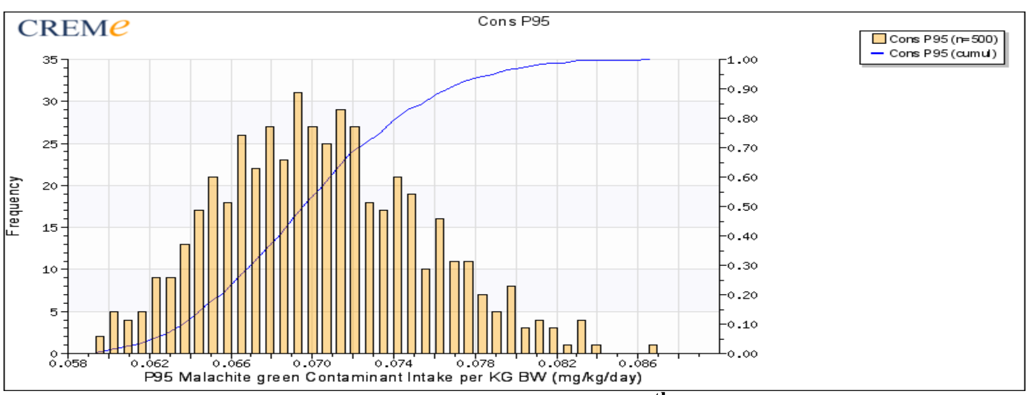


Figure B.106 Malachite green contaminant intakes for 95th P of the elderly (mg/kg/day)

Figure B.106 shows the distribution for the likely mean malachite green exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 elderly consumers.

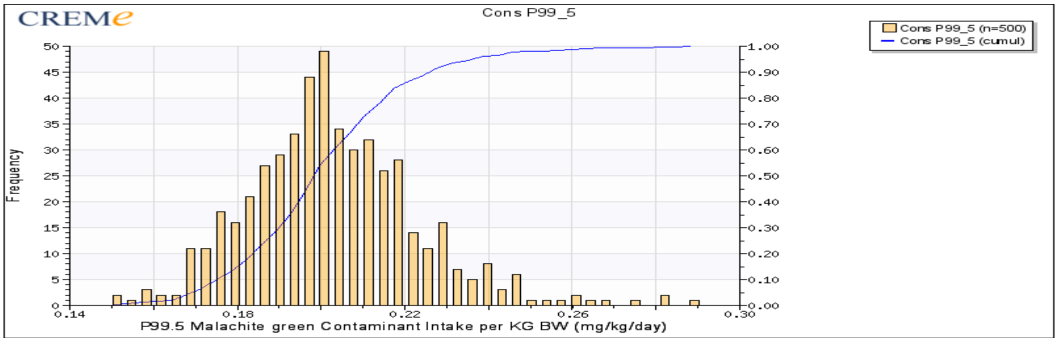


Figure B.107 Malachite green contaminant intakes for 99.5th P of the elderly (mg/kg/day)

Figure B.107 shows the distribution for the likely mean malachite green exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 elderly consumers.

Nitrofuran Exposure (in mg/day) among the Elderly

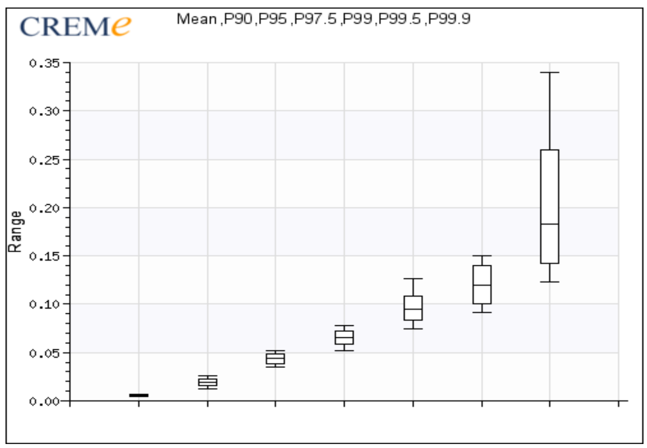


Figure B.108 Nitrofuran contaminant intakes in the elderly (mg/day)

Figure B.108 shows box-plots for the likely mean nitrofuran exposure (in mg/day) that would have occurred among the upper 50th, 90th 97.5th, 99th, 99.5th, and 99.9th percentiles of NHANES 2003-2004 elderly consumers. The box-plots show the likely exposures that would have resulted from imported Chinese aquaculture products (scenario 1).

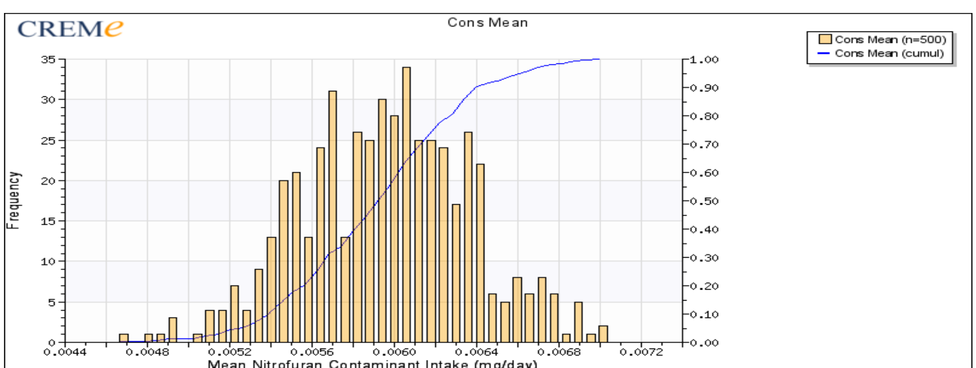


Figure B.109 Nitrofuran contaminant intakes in 50th P of the elderly (mg/day)

Figure B.109 shows the distribution for the likely mean nitrofuran exposure (in mg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 elderly consumers.

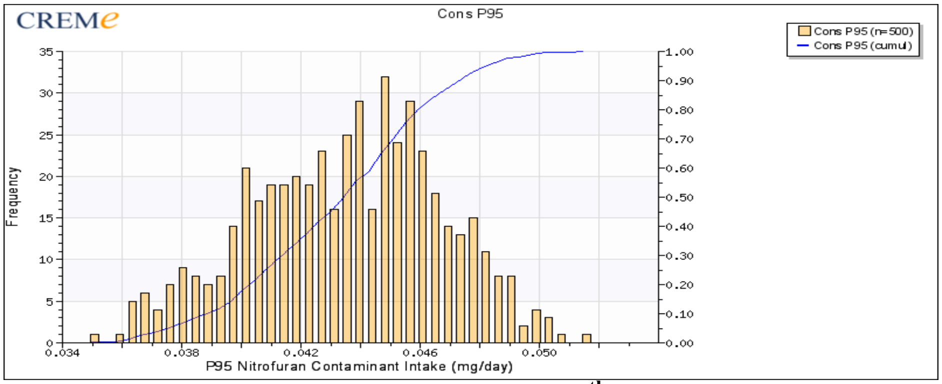


Figure B.110 Nitrofuran contaminant intakes in 95th P of the elderly (mg/day)

Figure B.110 shows the distribution for the likely mean nitrofuran exposure (in mg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 elderly consumers.

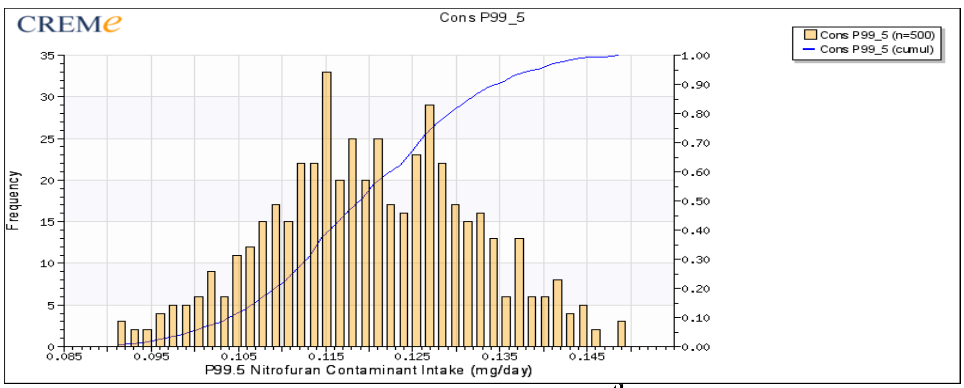


Figure B.111 Nitrofuran contaminant intakes in 99.5th P of the elderly (mg/day)

Figure B.111 shows the distribution for the likely mean nitrofuran exposure (in mg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 elderly consumers.

Nitrofuran Exposure (in mg/kg/day) among the Elderly

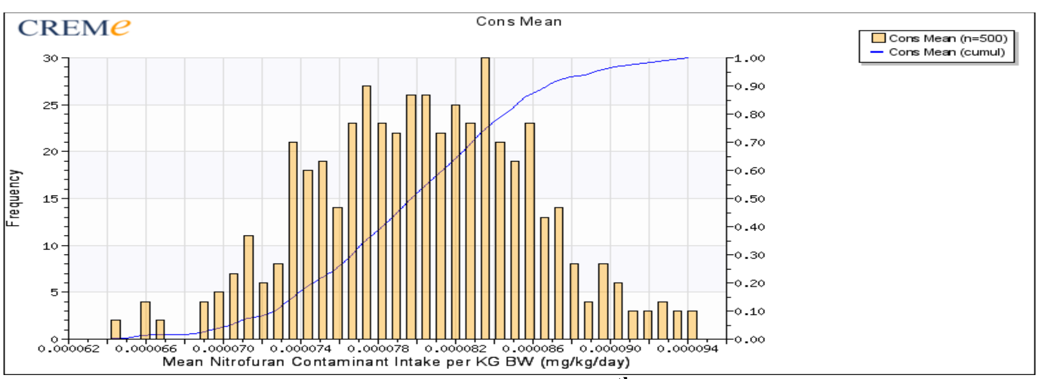


Figure B.112 Nitrofuran contaminant intakes in 50th P of the elderly (mg/kg/day)

Figure B.112 shows the distribution for the likely mean nitrofuran exposure (in mg/kg/day) that would have occurred among the upper 50th percentile of NHANES 2003-2004 elderly consumers.

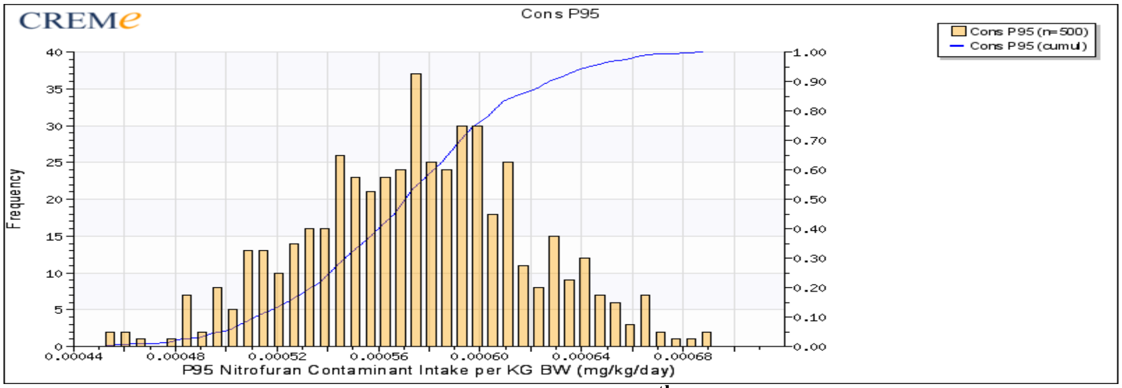


Figure B.113 Nitrofuran contaminant intakes in 95th P of the elderly (mg/kg/day)

Figure B.113 shows the distribution for the likely mean nitrofuran exposure (in mg/kg/day) that would have occurred among the upper 95th percentile of NHANES 2003-2004 elderly consumers.

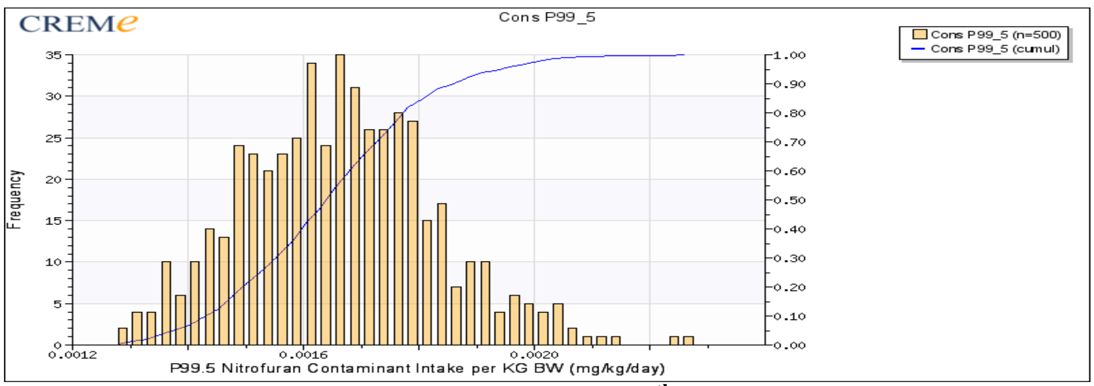


Figure B.114 Nitrofuran contaminant intakes in 99.5th P of the elderly (mg/kg/day)

Figure B.114 shows the distribution for the likely mean nitrofuran exposure (in mg/kg/day) that would have occurred among the upper 99.5th percentile of NHANES 2003-2004 elderly consumers.

Appendix C - Handout on Chemical Contaminants Provided at Final Presentation

Chemicals in Chinese aquaculture imports

- Malachite green,
- Gentian violet,
- Nitrofuran, and
- Fluoroquinolone

Malachite green:

- Water soluble
- Used as an antibiotics and antifungal in veterinary operations
- Metabolized into leucomalachite green
- Has carcinogenic and mutagenic properties
- Leucomalachite green:
    - Is highly lipophilic,
    - Has longer shelf-life, and
    - Is highly toxic
    - Bio-accumulates in tissues
    - Is heat stable: can withstand heating at 210°C for 2 hours
    - Causes :
        - Cancer of mammary glands in female
        - Cancer of the liver in male and female
        - Developmental toxicity, and
        - Reproductive toxicity

Gentian violet:

- Water soluble
- Used in controlling fungus and intestinal parasites
- Rapidly absorbed and metabolized into leucocrystal violet {half-life = 79 days}
- Carcinogenic and mutagenic in rodents

- Causes:
    - Abnormal multiplication of liver cells
    - Partial or complete wasting away of ovaries
    - Cancer of the connective tissues in the urinary bladder
    - Cancer of the uterus, ovaries, and vagina
    - Breakage of chromosomes and loss of genetic materials during cell division

Nitrofuran:

- Used as broad-spectrum antimicrobials
- Banned from use in animals & animal feed in 1991
- Compounds and derivatives have carcinogenic and mutagenic properties
- Derivatives are capable of causing chromosome aberration in cultured human cells

Quinolones:

- Are families of antimicrobials consisting of ciprofloxacin, enrofloxacin, norfloxacin, fluoroquinolone, etc.
- Are used in treating bacterial infections & boost production in animals
- Excessive use in humans can cause
    - Damage to the CNS,
    - Insomnia,
    - Paranoia,
    - Depression, etc.
- Continued excessive use can result in the development of bacterial resistance against antibiotics

The U.S. National Health and Nutrition Examination Survey

- Was created in 1956 with the signing of the *National Health Survey Act* by President Eisenhower
- Is a system of collecting data on the U.S. population health & nutritional status
- Is important in assessing the health status of the U.S. population
- Eight surveys have been done since its inception
- The CDC's National Center for Health Statistics designs the surveys and collects data

- Uses complex, stratifies, multistage probability-cluster sampling design to ensure adequate representation of entire U.S. population in the survey
- NHANES data is useful in developing and implementing new policies as well as in assessing:
  - the prevalence and trend of certain diseases,
  - risk factors for the diseases, and
  - the success of intervention strategies
- The NHANES survey has two components:
  - Interview
  - Examination
- The NHANES data is also useful in conducting research on emerging health issues
- This study exploited the available 2003-2004 NHANES food consumption data and the 2006-2007 FDA contaminant sampling data to answer the third research question.