

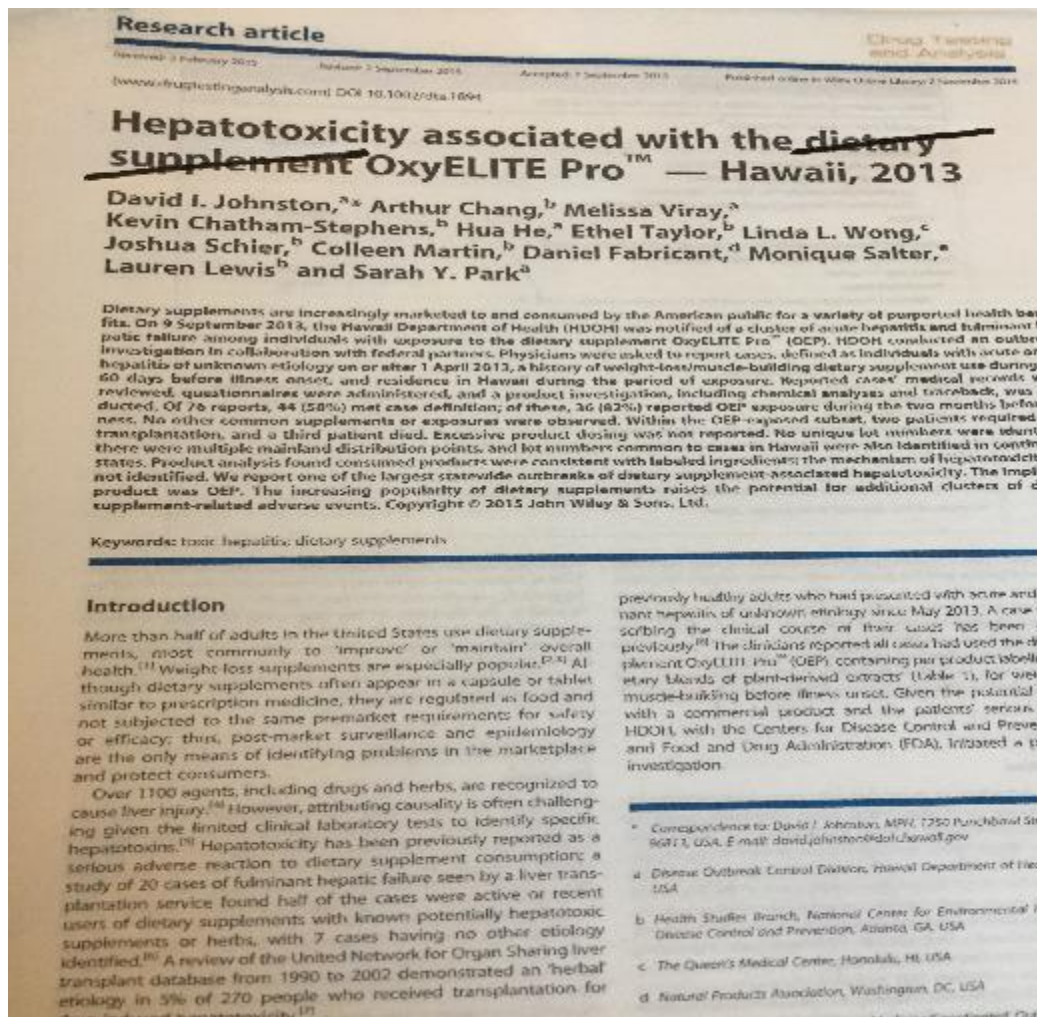


# **Dietary Supplements: State & Industry Efforts to Enhance Transparency (Industry Perspective)**

**Jen Johansen, VP of Quality, Regulatory & Government Affairs  
Cyanotech Corporation/Nutrex Hawaii  
(CWAG 2017, Honolulu March 15, 2017)**



# Who We Are NOT





## Who We Are

- **Natural Products Industry**  
(Safe, Effective, Non-GMO, Organic Products)
  
- **Dietary Supplements**  
(2/3 of Americans use Dietary Supplements)  
  
(Vitamins, Minerals, Herbs, Botanicals - Mircoalgae)





## Who We Are

- **Cyanotech Corporation / Nutrex Hawaii, Inc.**  
(Kona, Hawaii)
- **Brands**  
Hawaiian Spirulina Pacifica®  
BioAstin® Hawaiian Astaxanthin®
- **Grow microalgae on 90 acres @ NELHA since 1984**



## Who We Are

(First Crew in Kona circa 1984)



# Who We Are

(1st Spirulina Manufacturing Facility)



# Who We Are

(Cyanotech Manufacturing Facility – Present Date)



# Consumer Protection

(Proactive Measures for Industry & manufacturers)

- **FDA Regulated**  
(3<sup>rd</sup> Party GMP Inspected & Certified since 2007)  
Mandatory Compliance 2009
- **Registered Food Facility under Bioterrorism Act**
- **State of Hawaii Department of Health Inspected**
- **Consumer Complaint Monitoring–Trend Reporting**



# Consumer Protection

(Proactive Measures for Industry & manufacturers)

- **Quality Assurance / Quality Control Dept.**  
(10% of Total Company)
- **Generally Recognized as Safe (GRAS)**
- **New Dietary Ingredient Notification (NDIN)**
- **Supply Chain Integration & Transparency**  
(GMP Agreements with contract manufacturers)  
(Risk Assessment of new Ingredients)

# Consumer Protection

(Proactive Measures – 3<sup>rd</sup> Party Certifications)

- **Non-GMO Project Verification**



- **Gluten Intolerance Group – Gluten Free Certification**



- **3<sup>rd</sup> Party GMP Certification**  
(NPA-UL, NSF, Silliker)

**NSF Sports Certification**  
(Banned Substances)

# Consumer Protection

(Proactive Measures – 3<sup>rd</sup> Party Certifications)

- **United States Pharmacopeial (USP) Dietary Supplement Verification Program** (BioAstin<sup>®</sup> products in process)



- **USP Monographs – Public Standard Setting Process**  
(Cyanotech - Spirulina Monograph Development, 2013)

# Consumer Protection

(Proactive Measures – Industry Relations)

- **Lobbying**  
(Designer Anabolic Steroid Control Act of 2014)  
(Fund FDA) – (Fund HDOH)
- **NAXA – Ingredient Trade Organization**  
(Know Your Source, safe, effective Astaxanthin from algae)  
(Monitor Market Place – Supply Chain)
- **GOED – Ingredient Trade Organization**  
(Global Organization for EPA and DHA Omega-3s)

# Consumer Protection

(Proactive Measures – Industry Relations)

- **United Natural Products Alliance (UNPA)**  
(Cyanotech – Anchor Company in Hawaii)  
May 2016 – Annual Members Retreat, Mauna Lani



<b>Banned Ingredients</b>	<b>No-Sale Policy Effective Date</b>
B-methylphenethylamine (BMPEA)	April 9, 2015
Bulk-powdered caffeine for retail sales	Feb 24, 2015
Kratom ( <i>Mitragyna speciosa</i> )	May 1, 2014
1,3-dimethylamylamine, methylhexanamine or geranium extract (DMMA) – OXYELITE PRO	May 1, 2013
Ephedra or ma huang	May 1, 2005

## **Consumer Protection**

**(Reaction – Post Market Surveillance)**

- **Banned Ingredient Lists** (CRN, NSF, UNPA)
- **FDA Import Alerts – FDA Inspections**
- **Adverse Event Reporting**  
(Safety Call Medical Consult)
- **Recall Notification – Retailers are KEY**  
(COMMUNICATION – COLLABORATION)

## **Consumer Protection**

**(Reaction – Post Market Surveillance)**

- **Industry - A Resource for Regulators & Local Officials**  
(2-Way Alert System for Safety Risks & Recalls)  
(Ingredient or Test Methods Assessments)  
(Labeling & Regulatory Review & Resources)

CONSUMER PROTECTION  
A SHARED GOAL



# MAHALO

