

Establishing Tolerances for the Tea Industry: A Collaborative Approach

Peter F. Goggi – President MRL Harmonization Workshop May 2018











Tea Association of the USA, Inc. Tea Association Tea Association of the U.S.A. Inc. Formed in 1899 to protect the Tea Industry in the USA from harm For over 119 years it has defended the industry Tea Council -Formed in 1950 to Generically Promote Tea Since 1991 actively promoted Tea & Health Specialty Tea Institute –



Established Tea Education Arm in 2002, which has become an Industry Standard



Tea Association of the USA, Inc.

Vision

To enable sustainable growth of the US Tea Market as a whole while guiding our membership through an ever changing external environment.

Mission

The Tea Association of the USA is the recognized independent authority on Tea, acting as the official voice for its members on issues related to the tea industry.

Values

Our Core Values are to be ethical, knowledgeable, collaborative and forward looking in all our activities.





2016 - 2020 Strategy

Regulatory

Ensure the Industry is made fully aware of applicable U.S., EU, etc., Regulations and their impact .

Guidelines

Propose and implement Standards for the Tea Industry in areas not governed under current U.S. Regulations, as well as in white spaces created by new products, forms and consumer trends.

Membership

Drive Association, STI and Council to be an invaluable resource to its members.

Ensure Financial Viability of the Tea Association by maximizing membership.

Education

Be the premier choice for education by those seeking to learn about tea.

Be the recognized source of tea knowledge for those in the Specialty Tea space.

Communication

Enhance communication to all members by leveraging technology, industry networks, membership collaborations and global industry experts.

Tea Assoc

of the U.S.A. Inc.

Ensure Tea & Health Messaging remains focused, rooted in science and undiluted.

Talent & Staffing

Have the right people with the right skills in place to support the Association.

Leverage the expertise of the Association's Membership to drive tea.

Growth of the Tea Market in U.S. Dollars

1990 \$ Value by Type

- ► Traditional \$ 0.87 Billion
- ▶ RTD 0.20 "
- ► Food Service 0.50 "
- ▶ Special 0.27 "
- ► Total \$1.84 Billion

2017 \$ Value by Type (Est)

- ► Traditional \$ 2.58 Billion
- ▶ RTD 6.00 "
- ▶ Food Service 1.50 "
- ▶ Special 2.50 "
- **▶** Total **\$12.50 Billion**

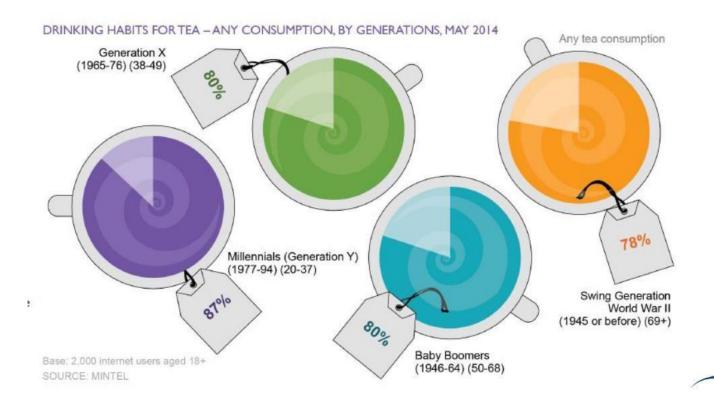
Green \$20 Million

- Green \$1.65 Billion
- Tea continues to grow in both dollars and volume across all categories and types. Key trends are:
 - Health & Wellness
 - "Naturalness"
 - Variety and Availability
 - Transparency of Source
 - Sustainability across the Supply Chain
- Green Tea's growth has slowed after years of double digit advances



Tea is a popular beverage for the majority of consumers

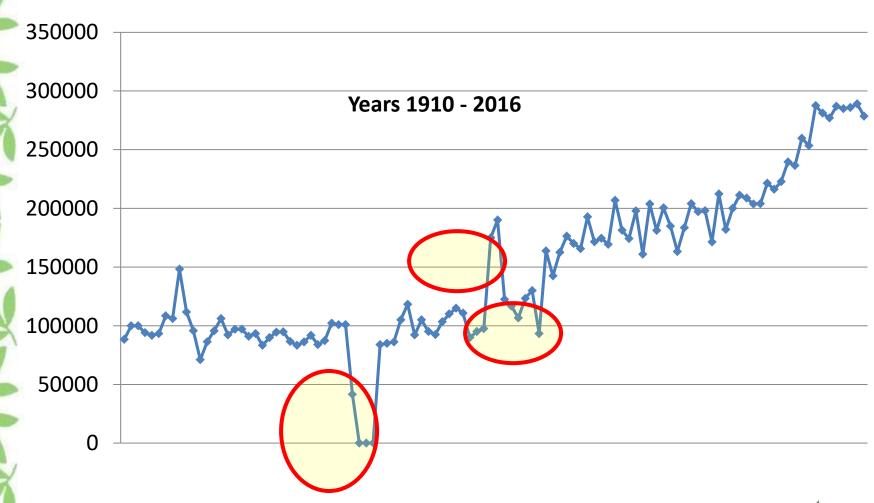
- Approximately four in five of all consumers drink tea, with Millennials being the most likely
- Due to the large number of consumers across generations, there is an opportunity to target many different markets and avenues





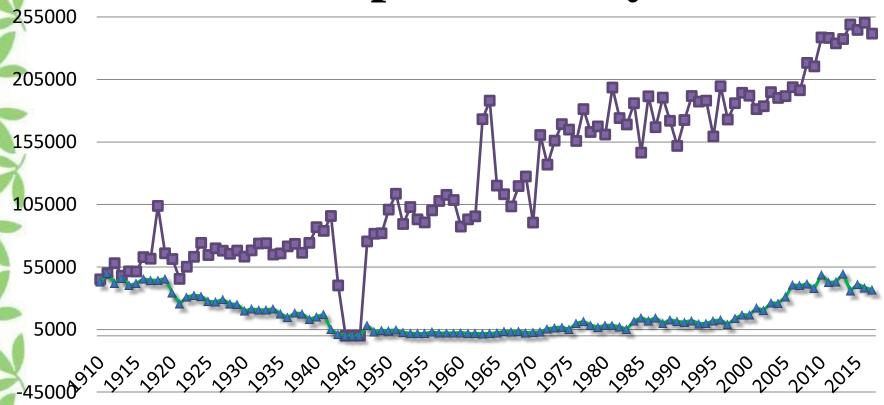
Total Tea Import History

Imports '000 pounds





Total Tea Import History



Black Tea Imports

→ Green Tea Imports

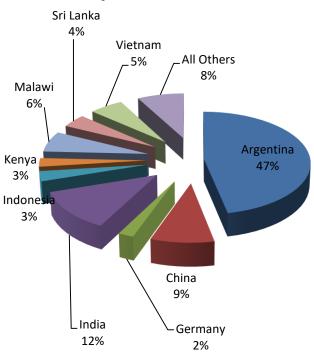


Green Tea Imports: '000 lbs

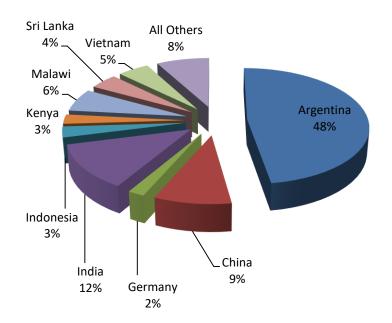


Current Facts - Black Tea

% Average Total Black Tea Imports 2014-2016

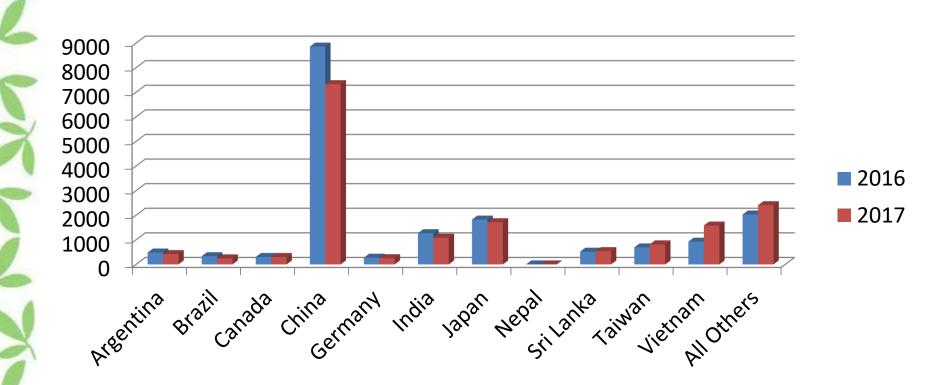


% Average Total Black Tea Imports 2015-2017





Current Facts - Green Tea





Pesticide Issue - Background

- 2008 Few MRL tolerances established for tea
 - Only 3 in the USA
 - Over 99% of the tea consumed in the USA is imported

 - Repeal of the Tea Importation Act of 1897, March 1996
 Tea was imported under the authority of the U.S. Tea Examiner
 - Organoleptic Evaluation only
 - No MRL's required
- 2008 Multiple containers of tea detained
 - Levels of lead and chemical residue
 - 30 Containers in which USTA was asked to intervene
 - Number escalated to 40
 - Importation of tea came to virtual standstill
- Detection
 - 3 chemicals were detected:
 - λ-cyhalothrin
 - Bifénthrin
 - Fenvalerate
- The Association commissioned a scientific study demonstrating that the 3 pesticides posed zero risk to human health Immediate Penalties Imposed
 - FDA rejected the 30 containers of tea that had been inspected
 - FDA rejected based it being a matter of law not public safety FDA released the 10 containers that had not yet been inspected
- Agreement Reached with the FDA
 - FDA officials agreed to use enforcement discretion provided we put forth good faith efforts to fix the problems Our legal bill for 2008 exceeded \$80,000
- Worked with FDA/EPA and created relationship with IR-4
 - Successful registration of multiple Pesticides



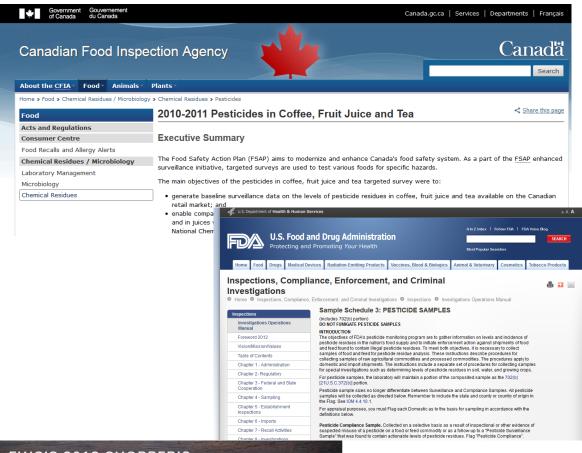
External Pressures

Media & Government



Media & Government















Food Babe

Yesterday at 1:40pm · 🚱

Do you drink these? Black Tea honestly contains more than just tea. With natural flavors, companies can mass produce products for less money, and give their products a special "kick" that homemade food and drinks don't have. That extra kick can have addictive qualities, driving us to consume more of their products. A

Sodium Omg	0%
Total Carb. 0g	0%
Protein 0g	
No. 9 significant source of sa choles fiber, total sugars, adde calcium, for and potas.	t. fat, <i>trans</i> fat, ed sugars, vit. D,
INGREDIENTS: ORGANIC BREV (FILTERED WATER, FAIR TRADE ORGANIC BLACK TEA LEAVES), NATURAL FLAVORS, CITRIC ACI	CERTIFIED "

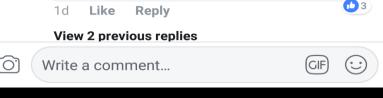






Tony Mendola

Filtered Water in the US is still toxic! You can't remove the gas, fluorine, by filtration. It combines with H2O (water) and makes fluoirides that have such a high boiling / evaporation point that just boiling the water further concentrates the fluorides! Hydrofluorosilicic acid is formed when the fluorine gas is utilized for industrial processes. It is more poisonous than lead! Th the municipalities buy that waste and put it in the water in the US. Then you brush your teeth with it, eat food contaminated with it (tap water, in the u.S.), bathe in it, buy foods that are soaking in it (pickles, sodas, etc...use teas in a convenient size! Some people even drink it! Even the Food Bane people act like they don't know! For instance, the above ad for hippy freedom, and not real Freedom! So Coca Cola Bottling Company triple filters the water! It is to make sure there are no rat droppings or mouse carcasses! No amount of filtering gets rid of the (what I like to call) fluoro-toxin! The ad didn't point out the real poison, the fluorine!





Diana S. Jones

And isn't citric acid something like a gmo mold and not derived from citrus??

Like Reply 11h





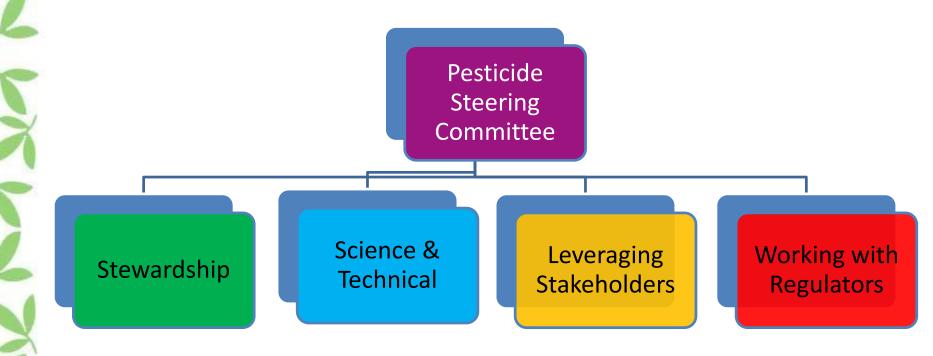
of the U.S.A. Inc.



- Good Faith Efforts Agreement with FDA
- **❖ IR-4 Engagement**
- EPA Engagement/Minor Crop Activities
- ❖ Industry Wide Meeting in March of 2012
- Key Actions:
 - Formation of Pesticide Steering Group
 - Formation of Work Stream Driven Sub-Committees



Agreed Structure





Pre-Meeting Proposed Actions

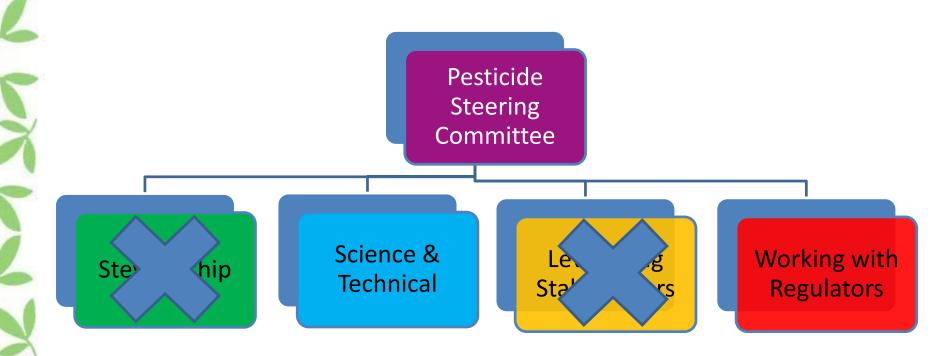
Harmonization

(Cross Acceptance of MRL's and testing Methodologies)

- **≻**How
 - ➤ Urge Regulatory Bodies to utilize Codex Standards
 - ➤ Sharing Risk Assessment/Test Data
 - ➤ Join with other organizations, e.g., ETC, Producer Tea Associations
 - ➤ Open relationship with regulatory bodies:
 - Allow for cross product usage if MRL"s established for other like products (e.g., Asparagus)
 - ➤ Sharing of data packages
 - ➤ Leverage fact that Codex MRL's are now adopted by Europe
- ➤ Understand that Regulators need science based data to set MRL's to avoid litigation



Agreed Structure





Actions:

Certify More Pesticides

>How

- ➤ Continue working with IR4/EPA/Manufacturers to minimize costs by combining with other registrations
 - **≻**IR-4
- ➤ Prioritize Chemicals
- ➤ Maintain FDA Relationship
- ➤ Register import tolerances in USA

➤Also:

- >Communicate what chemicals should be eliminated at origin
- ➤ Communicate that we are in need of Import tolerances



Actions

Drive Compliance with Producers

- >How
 - ➤ Continue to work with key importing countries
 - ➤ Argentina
 - **≻**India
 - ➤ Sri Lanka
 - **≻**Kenya
 - ➤ Malawi, etc.
 - **≻**FAO-IGG
 - ➤ Work Streams
 - **≻**Engagement



Registrant Engagement

- Direct Engagement
 - Bayer
 - Syngenta
 - **❖**BASF
 - **❖**Gowan
 - ❖ Nisso
 - **❖**Etc.
- CropLife
 - Food & Beverage Committee



USTA as Registrant - Activities

- ❖ PRIA (Pesticide Registration Improvement Act Process)
 - Opportunity to reduce fees
 - ❖ Worked with EPA Ombudsman
 - ❖Tea Association granted Small Business Waiver
- ❖ Partnered and Leveraged IR-4 / CropLife
 - Leveraging Relationship to assist Registration Packet/Consultancy
- Funding / Co-Funding Registration Process
 - Membership Funded
- Consultant to Lead Process
 - **❖** Developed Core Competencies
 - ❖Intimate knowledge of US EPA pesticide regulations, especially with regard to MRL submissions. Previous experience interacting with EPA staff in response to regulatory submissions and ability to persuasively interact with EPA on data adequacy and submission fee issues.
 - Ability to interpret pesticide field trial data to determine if data will be sufficient to meet US EPA requirements for tea. Ability to possibly compile and submit US MRL petitions on behalf of USTA.
 - ❖Strong relationships with pesticide registrants to further USTA's mission of establishing additional US tea MRLs. Ability to persuade registrants to support our MRL needs and negotiate with registrants on possible work and/or fee sharing.
 - ❖Able to keep tea industry top of mind with registrants to ensure the development of a strong pipeline of MRL submission for new compounds.
 - Familiarity with Codex process
- ❖ Propiconazole Success
 - Small Business Waiver granted
 - Submission completed
 - Only two issues with screening that were answered
 - ❖Tolerance Granted in 2015
- **❖**Looking to leverage success for Hexythiazox





- 1. Networking Relationships
 - I. FDA
 - a. Enforcement Discretion
 - b. Continued to Engage
 - II. EPA
 - a. Minor Use
 - b. Pilot Program
 - III. IR-4
 - IV. FAO IGG
 - a. Global Harmonization
 - V. CropLife
 - a. Food & Beverage Committee
 - VI. Registrant



<u>Chemicals Authorized for Use – Prior to 2008</u>

Chemical	PPM	Most Recent Federal Register Date
Glyphosate		
Tea: Dried	1	10/1/1980
Tea: Instant	7.0	10/1/1980
Propargite	10	8/1/2007
Pyriproxyfen	.02	8/22/2007



Chemicals Currently Authorized for Use on Tea in the USA

Chemical	PPM	Most Recent Federal Register Date
Acequinocyl	40	1/18/2017
Acetamiprid	50	2/10/2010
Azoxystrobin	20	5/1/2015
Bifenthrin	30	9/14/2012
Buprofezin	20	10/17/2012
Carfentrazone-ethyl	.1	3/31/2004
Chlorantraniliprole	50	7/27/2011
Chlorfenapyr	70	1/26/2018
Clothianidin	70	3/29/2013
Cyantraniliprole	30	3/22/2017
Cyclaniliprole	50	8/3/2017
Dicofol: Tea Dried	50	3/25/2013
Dicofol: Tea Instant	30	3/25/2013
Dinotefuran	50	9/12/2012
Ethiprole	30	4/6/2011

Chemical	PPM	Most Recent Federal Register Date
Etofenprox	5	11/27/2013
Etoxazole	15	4/13/2011
Fenazaquin	9	5/25/2017
Fenpropathrin	2	11/28/2012
Fenproximate/Fenpyroximate	20	12/12/2012
Flonicamid	40	5/11/2017
Fluazinam	6.0	5/11/2017
Flubendiamide	50	7/5/2017
Glyphosate: Tea Dried	1	10/1/1980
Glyphosate: Tea Instant	7.0	10/1/1980
Propargite	10	8/1/2007
Propiconazole	4	12/24/2015
Pyriproxyfen	15	2/22/2016
Spinosad	.02	12/5/2007
Spiromesifen	40	1/16/2013
Thiamethoxam	20	3/27/2013
Tolfenpyrad	30	1/9/2014



Pending Chemical Registrations in the USA

Chemical	Expected Tolerance Year
Abamectin*	2019
Avermectin*	2020
L-Cyhalothrin^	2020
Cyflumetofen*	2018
Cypermethrin^	2020
Imidacloprid*	2018
Methoxyfenozide*	2018
Permethrin^	2020
Pyrifluquinazon*	2019
Spinetoram*	2018

* Submitted

^ Not in PRIA Action

NOTE THESE CHEMICALS
SHOULD NOT BE USED ON
ANY_TEAPRODUCT
BOUND FORUSA

Chemicals With No Possibility of Approval in U.S.

Prohibited Chemicals	STATUS
DDT	Banned
Lindane	Banned
Endosulfan	Expired – will not be renewed
Ethion	Not Registered for ANY use in USA
Tetradifon	Not Registered for ANY use in USA
Triazophos	Not Registered for ANY use in USA



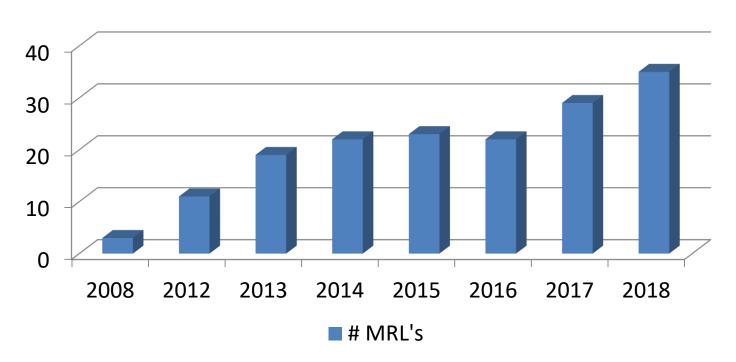


FDA AUDIT

- 12 Samples were violative
 - All had green tea from China
 - 1 Herbal
 - 2 Tea & Herbal
- 7 Brands
 - Multiple Samples of each



MRL's







Pesticide Priority List



USTA Priority List



USTA Communications

Requested of Origin Producers:

- 1. To review the list of authorized chemicals allowed in the U.S. and have their growers comply with our import regulations as established by FDA. (Attachment 1)
- 2. To send us a list of those chemical tolerances authorized for use on tea in their country so that we have an up-to-date database.
- 3. If any work is being done to develop and/or register new chemicals for use on tea in their origin, that they
 - a. Let us know.
 - b. Inform the chemical manufacturer that they should submit to EPA a request for an import tolerance to be established on that chemical in the U.S.A.
- 4. Support our efforts in increasing the number of MRL's in the United States and harmonizing them between the US and producer countries as well.

Engagement with PPP Industry:

To that end, we are looking to engage directly with Chemical Manufactures in order to address the following:

- 1. Register old molecules (that may be off patent) that are used on tea for import tolerances;
- 2. Provide the USTA with data package to allow us to register these older molecules:
- 3. Engage more effectively across international divisions, so that when international registration occurs, a corresponding tolerance application is completed in the U.S.
- 4. Determine how tea can become a higher profile within their scope of activity.



Going Forward -Networking

- FDA
 - Continually Update
 - Maintain Enforcement Discretion
- ❖ IR-4
 - Include Tea in new registrations
 - Maintain contacts
- ❖ EPA
 - Minor Use
 - Pilot Program
 - Advice and engagement
- ❖ PPP Industry
 - CropLife
 - Direct Engagement
- Global Influencers/Stakeholders



- Going Forward -

- Increase Number of MRL's for Tea
 - Continue to feed funnel of chemicals for Approval
 - Maintain contact with FDA/EPA for opportunities
 - Pilot Program
 - Minor Use
 - Continue engagement through CropLife
 - Continue to assess, update and act on Pesticide Priority List
 - Continue FAO-IGG Engagement
- Tea Association as Registrant
 - Use Learnings from Propiconazole submission and apply
 - Determine if additional funding necessary
 - Form cooperatives between Origin and USTA for submissions
 - ❖ E.g Japan, Vietnam, China
- Raise Awareness to Stakeholders
 - Continue Networking
 - FDA/EPA
 - ❖ GMA
 - ◆ FAO
 - **❖** IR-4
 - Origin Countries
 - TRI's
 - Tea Boards
 - Growers
 - Chemical Manufacturers
 - CropLife



EPA Pilot

Proposal

- Going Forward -

Current Facts

- Teas with minimal pesticide residues are safe
- Large portions of pesticide residues are not actually consumed low transferability
- Obtaining compliant tea is not always possible
- Domestic farmers and pesticide distributors do not have an incentive to obtain MRL's for a foreign crop
- Establishment of MRL's is Expensive and Time Consuming





- Tea is Safe
- Any Rejections have been legislative
 - None since 2008
- Research shows that Human Health is ultimately <u>enhanced</u> by Tea and that no risk to Human Health has EVER been demonstrated at current residual levels
- The Tea Industry is:
 - Aware of our responsibilities
 - Working in Partnership
 - Internally
 - Domestically
 - Internationally
 - Collaboratively with U. S. Government Agencies

JUNE is NATIONAL ICED TEA MONTH!!!





