

Agricultural Chemical Residues and Tolerances - A Look At What's On The Horizon

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- I. Role of the Food and Drug Administration (FDA)
- II. Recent Events of Interest
- III. Role of the Environmental Protection Agency (EPA)
- IV. Concluding Remarks

Food and Drug Administration (FDA)

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- As it relates to agricultural chemical (pesticide) residues in food, the FDA is the enforcement agency.
- Unlike for other contaminants in foods, FDA does not set the standards of acceptable levels of pesticide residues in food.
- Under the Federal Food, Drug and Cosmetic Act (FFDCA) that role is reserved to the U.S. Environmental Protection Agency (EPA).

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- FDA can examine a food, and if they identify a pesticide residue for which there is no tolerance or exemption from tolerance, or the residue present exceeds the established tolerance, it can take enforcement action.
- For an imported product this can result in denying entry into the U.S.
- Additionally, if the problem appears to be persistent, the FDA can implement a “Detention Without Physical Examination” (DWPE) approach to address future potential imports of the commodity.

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- Typically only about 1-2% of the foods imported into the U.S. are sampled by FDA.
- Generally, FDA takes into account a variety of factors in making sampling decisions.
- FDA will conduct on occasion “focused sampling”. It is implemented where FDA believes there may be a problem and the Agency wants more information collected, but collected in a way that if a problem exists, enforcement action can be taken.

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- Typically FDA's laboratories rely on multi-residue methods (MRMs) to analyze for pesticide residues in food. The MRMs can generally analyze for the presence of hundreds of pesticides and their metabolites.
- Historically, the violative rate for imports is three to four times that for domestically produced food.

Recent Events of Interest

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- Carbendazim in Orange Juice
- Pesticides in Chinese Tea
- Arsenic in Rice

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- Carbendazim is a fungicide. It is not currently registered for use on citrus in the U.S.
- In the U.S., there is no tolerance for residues of carbendazim in orange juice.
- The European Union has established a maximum residue level (MRL) of 200 parts per billion for carbendazim in oranges and grapefruit.

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- Brazil is one of the largest exporters of orange juice, including orange juice concentrate, orange juice from concentrate and orange juice not from concentrate into the U.S.
- Carbendazim is registered for use on citrus in Brazil and several other countries to address a fungal disease.
- On December 28, 2011, FDA received reports from a U.S. orange juice manufacturer that it found low residues of carbendazim in its and its competitors orange juice.

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- FDA requested EPA to conduct a risk assessment of the safety of orange juice products containing carbendazim.
- In early January 2012, EPA completed its risk assessment. That assessment noted that assuming a residue value of 80 parts per billion (ppb) in juice and assuming 100% of the U.S. juice supply contains carbendazim there is no safety concern for acute, chronic or cancer effects.
- FDA did state that, on the basis of the EPA risk assessment, there was not a safety concern with the U.S. juice supply and no recall of existing juice products was required.

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- FDA was going to continue to require testing of imported juice and refuse entry where there were quantifiable levels of carbendazim identified.
- Quantifiable residues in this case meant that based on the analytical method, greater than or equal to 10 ppb.
- FDA advised that the EPA risk assessment had no applicability in considering whether to allow entry of imported juice.
- This differs from the approach which FDA uses for assessing other environmental contaminants such as lead or heavy metals in juice concentrates.

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- Those contaminants can render a food adulterated when present in an amount that may render the food injurious to health. In that case, the FDA by law can conduct a safety assessment and take into account the level of the contaminant in the food as consumed.
- The FFDCA does not provide FDA a basis to consider the food form of the product bearing the residue in determining whether the food is adulterated.
- Rather, if the residues are identified i.e., reliably quantified, the food is subject to enforcement action.

Pesticides in Chinese Tea

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Banned pesticides found in teas produced by popular Chinese tea brands

Press release - 2012-04-11

A Greenpeace investigation has found pesticides banned for use on tea in the products marketed by some of China's top tea companies. Some of the firms, which include China Tea, Tenfu Tea and China Tea King, export tea products to Japan, the US and Europe.



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- Greenpeace asserted that 12 of the 18 samples contained at least one pesticide banned for use on tea.
- In response, the Tea Association of the USA acknowledged that it was taking action with the US government to address this issue.
- Specifically, the association stated:

Statement Regarding Greenpeace Investigation of Chinese Tea

- This statement refers to the recent publicity regarding the Greenpeace investigation of pesticide residues on China-origin teas sold for consumption in China.

The Tea Association of the USA is taking all appropriate actions domestically and internationally to minimize the presence of agricultural residues on tea.

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Further, the Tea Association is working in conjunction with the United States Environmental Protection Agency (EPA) and the Food & Drug Administration (FDA), as well as with IR4 and within the framework of the Food Safety Modernization Act (FSMA), to build a global network of tea producers to ensure compliance with all rules regarding the importation of tea into the U.S. Based on the valid scientific analyses commissioned by the Tea Association of the USA, which show that the low levels of the most common agricultural residues found on tea pose a negligible risk to consumers, the tea industry has gained the support of global agencies in its work to ensure the safe production of tea.

Consumers should continue to consume and enjoy the many varieties of tea for its health promoting and protective effects as well as its delicious taste.

April 17, 2012

*Tea – Lovely? Or Laced with Pesticides?

Sunday, February 5th, 2012 at 1:08 am

Tea is one of the most popular drinks on the planet. Drunk daily by millions the world over, tea has the potential to restore and calm. Unfortunately the use of pesticides on many tea plantations means this delicious drink should be drunk with caution – unless you choose organic tea.

Pesticides such as [DDT](#), [hexane](#), [HCH](#), [Dicofol](#), [Fenvalerate](#), [Methamidophos](#) and [Acephate](#) are still used on tea plantations in some countries, despite being banned in other countries.

*Source: OrganicWish

Inorganic Arsenic in Rice

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Arsenic in your food

Our findings show a real need for federal standards for this toxin
Consumer Reports® magazine: November 2012

“Our analysis found varying levels of arsenic in more than 60 rices and rice products.

Organic rice baby cereal, rice breakfast cereals, brown rice, white rice—new tests by Consumer Reports have found that those and other types of rice products on grocery shelves contain arsenic, many at worrisome levels.



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Arsenic not only is a potent human carcinogen but also can set up children for other health problems in later life.

Following our January investigation, "[Arsenic in Your Juice](#)," which found arsenic in apple and grape juices, we recently tested more than 200 samples of a host of rice products. They included iconic labels and store brands, organic products and conventional ones; some were aimed at the booming gluten-free market."



St. Louis Post-Dispatch

S. Korea halts U.S. rice imports in arsenic scare

September 23, 2012 12:00

South Korea suspended bidding for U.S. rice imports Friday after the U.S. Food and Drug Administration and Consumer Reports magazine found elevated levels of inorganic arsenic in rice....

Seoul's Agriculture Ministry said it also suspended the sale of U.S. rice. It says the sale and bidding may resume after more studies are conducted. Last year, the country took in 101,490 tons of rice from the U.S. and planned to import 90,901 tons this year, according to a statement....

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The findings by Consumer Reports suggest that rice from Arkansas, Louisiana, Missouri and Texas generally contains higher levels of total and inorganic arsenic than rice samples from India, Thailand and California....

The geographical differences may be linked to the historical use of lead arsenate as a pesticide in certain areas, according to Consumer Reports senior scientist Michael Hansen....

Some infant rice cereals had five times the inorganic arsenic found in alternatives such as oatmeal, according to the group....

The FDA found no evidence in its preliminary study that the rice is unsafe. Also last week, pediatricians voiced concern about rice consumption....

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"I think a prudent position for the next few months or years ... is that parents avoid rice or at least avoid any rice that comes from Texas, Louisiana or Missouri, and when in doubt go with barley or oatmeal," said Dr. Philip Landrigan, a professor of pediatrics at Mount Sinai Hospital School of Medicine, on CBS' "This Morning."

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Gerber Foods said in a statement that it had "decided to exclusively use California rice in the production of our rice-containing infant nutrition products ... because California rice has the lowest naturally occurring arsenic levels for rice grown in the United States."

Role of the EPA

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- U.S. law does not specifically differentiate a tolerance as an “import” tolerance or a “domestic” tolerance. It reflects a situation where a tolerance is established for a particular residue that may be on an imported food when there is no corresponding U.S. pesticide registration for such use.
- With the passage of the Food Quality Protection Act in 1996, all tolerances, whether applicable to a raw agricultural commodity or its processed food are established under section 408 of the FFDCA.

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- Section 408 of the FFDCA requires that to establish a tolerance, EPA must determine that the levels of the chemical proposed in the tolerance are “safe.” Safe means a reasonable certainty of no harm to human health.
- EPA will consider the potential risks from exposure to the pesticide chemical residue on sensitive populations, particularly infants and children. The agency will also consider cumulative effects from exposure to pesticides with a common mechanism or mode of action or toxicity.

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- Section 408(b)(4) of the FFDCA requires EPA to determine whether a Codex MRL has been established for the pesticide chemical residue in the particular food commodity.
- To make its determination, EPA will generally want to review data regarding the toxicity of the pesticide, the expected chemical residues in the treated food, and information concerning consumption patterns, i.e., how much of the treated food is consumed by the specific populations of interest.

- EPA together with the Pest Management Regulatory Authority of Canada (PMRA) developed a “NAFTA Import Tolerance Guidance” document to help identify the product chemistry, residue chemistry, and toxicology data requirements to establish tolerances in the U.S. or MRLs in Canada.
- EPA wants to be certain that the residue data it receives is credible and reflects the maximum conditions of use i.e., the maximum rate that the pesticide is used on the crop, the maximum number of applications, the shortest pre-harvest interval, etc.

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- Available data submitted to foreign regulatory authorities may be considered.
- EPA has established a “crop grouping” process for purposes of establishing a tolerance. For spices this is:

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Crop Subgroup 19A. Herb subgroup. Basil (fresh and dried) and chive.

Crop Subgroup 19B. Spice subgroup. Black pepper; and celery seed or dill seed.

Angelica; balm; basil; borage; burnet; camomile; catnip; chervil (dried); chive; chive Chinese, clary; coriander (leaf); costmary; culantro (leaf); curry (leaf); dillweed; horehound; hyssop; lavender; lemongrass; lovage (leaf); marigold; marjoram (*Origanum* spp.); nasturtium; parsley (dried); pennyroyal; rosemary; rue; sage; savory, summer and winter; sweet bay; tansy; tarragon; thyme; wintergreen; woodruff; and wormwood.

Allspice; anise (seed); anise, star; annatto (seed); caper (buds); caraway; caraway, black; cardamom; cassia (buds); celery (seed); Cinnamon; clove (buds); coriander (seed); cilantro (seed); cumin; dill (seed) fennel, common; fennel, Florence (seed); fenugreek; grains of paradise; juniper (berry); lovage (seed); mace; mustard (seed); nutmeg; pepper, black; pepper, white; poppy (seed); saffron; and vanilla.