Tools for Prioritizing Food Safety Concerns: An Industry Perspective

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Chasing Zeroes

- Zero is a small number
 How we chase zero
 Problems this presents
- TTC as a prioritization tool

Zero is a Small Number

- 1950s & 1960s parts per thousand, ppm
- 1970s & 1980s ppm, ppb
- 1990's & 2000s ppt, ppq

Analytical technology has advanced quickly – but tools (or their application) for interpreting findings have not kept pace



Zero is a Small Number



How Small?

<u>Unit</u> Length	1ppm 1 in/16 mi	<u>1ppb</u> 1 in/16,000 mi	<u>1ppt</u> 1 in/16 million mi (6" trip toward the sun)
Time	1 min/ 2 yrs	1 sec/ 32 yrs	1 sec/ 320 centuries
Money	1ct/\$10,000	1ct/\$10 million	1ct/\$10 billion
Area	1 ft ² /23 acres	1ft ² /36 mi ²	1in² / 250 mi²
Volume	1 drop v'mouth in 80 L gin	1 drop/500 barrels gin	1 drop/pool of gin covering football field 43 feet deep <u>or</u> 1 drop in 520 30,000 gal tanker <u>cars</u>

How We Chase Zero

- Something new is found in food
- Zero = the current limit of detection (LOD)
- A new instrument or method drops the LOD
- The component is found again & new ones may appear for the first time
- Detection is often seen by the public as undenied risk, which is translated as "inevitable harm."
- Human nature has caused society to chase the receding "zero"



An Example of Chasing Zero

Chloramphenicol

- Antibiotic used by China in bee colonies 5 or so years ago now deemed carcinogenic
- Traces found in honey around the world
- "Can't set an acceptable level" acc. to regulators
- Each lot tested down to LOD of 0.5 ppb
- Canada improved LOD down to 0.05 ppb (50 ppt)
- Business shut down for weeks, loss of >\$1,000,000
- Chasing zero causes lots of problems



Problems Presented by Chasing Zeroes

- Consumer confidence in food is eroded
- Scarce resources do not always go to the most critical risks
- Disruption of business, international trade
- No end in sight...zero rushes ahead, just out of reach, with improvements in analytical sensitivity
- Not just advances in methods, but also global sourcing, sensitivity around food defense, decreasing scientific literacy, others...will make this issue more acute in future



Problems Presented by Chasing Zeroes

- Key point: do we have the resources to pursue all detections as major issues?
- Can society afford to continue to operate using the toxicology model of the mid-20th century? (Foreign chemicals are rare in pure food; when found, we chase to zero.)
- Can't toxicology guide us to agree on some threshold of concern?



Threshold of Toxicological Concern

The TTC concept was actually described in the early 1500s

Paracelsus: "All things [substances] are poison and nothing is without poison. Solely the dose determines that a thing is not a poison."

How to Change

 Over the past 50 years, TTC has been developed and applied to:

- Food packaging
- Flavors
- Pharmaceuticals
- Cosmetics

Proposition: TTC can be applied now to nearly any trace finding in foods, whether naturally occurring, formed during cooking, or via addition from the environment



Problem is Larger than Just Chasing Zero

- Non-zero guidance needed on some compounds esp on newly discovered, when tox is incomplete
- For many, where guidance is set, there is continuing downward pressure
- Others have guidance levels that were developed through great expenditure of resources. Some might have benefited from application of TTC.

Some Examples of Low Level Findings in Food

Acrylamide

- Carcinogenic in animal tests at ppm levels
- Found in 2002 formed in heating sugars, carbohydrate, and amino acids – ppb levels
- Major international meetings
- Extensive product/process testing
- Regulatory agencies looking at interventions
- Toxicity tests still underway to determine relevance in humans
- Other heat formed toxicants:
 - Furan
 - Semicarbazide
 - PhIP
 - European Heat-Tox project 7 million Euros looking for more

Some Examples of Low Level Findings in Food

- Packaging residues BPA, ITX, butadiene, phthalates, etc.
- Processing residues chloropropanols from acidhydrolyzed vegetable proteins
- Heavy metals in foods Hg in fish; Cd in vegetables;
 Pb in chocolate, water
- Mold toxins AFB1, FMB, OTA, DON, in cereal grains, nuts, oil seeds
- Perchlorate in water military sites or naturally formed?
- Allergens? Starlink®?



Use of TTC

Benefits

- Puts resources where the biggest risks are
- Gives science-based guidance in place of unattainable zero level and zero risk
- Avoids "crying wolf"—public can take warnings seriously when they are saved for significant risks
- Maintains confidence in safety of foods
- Gives predictability to business, trade, regulation
- An honest approach based on science, not emotion