The FDA Pesticide Residue Program

2016 MRL Harmonization Workshop
California Specialty Crops Council
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Chris A. Sack, Residue Expert
Food and Drug Administration

CSCC Mission

To foster a positive regulatory environment focusing on pest management and stewardship that supports the success of CSCC growers

FDA Mission and Objective

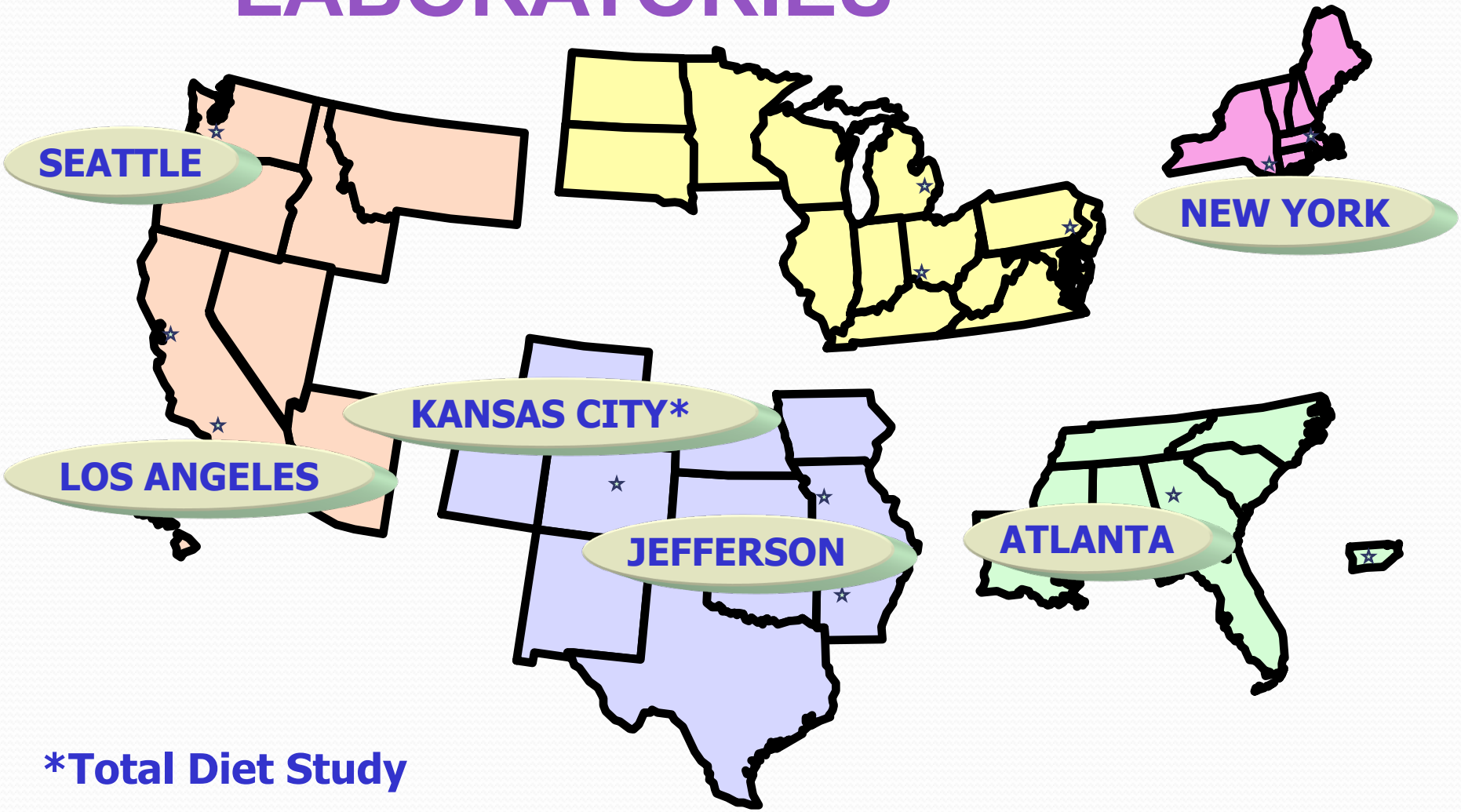
Mission - Promote and protect the health of the American consumer

Objective (Pesticide Program) - Enforce the MRLs established by EPA

Our Challenge

- Food and feed matrices
  - Imports: > 15 million per year
  - Domestic: ???
- Pesticides and other contaminants
  - 1000s that are known
  - Range: 10 ppb - ???
- Analyses
  - Up to 50 samples per day per lab
  - Timeframe: 1 day for imports

6 PESTICIDE LABORATORIES



*Total Diet Study

Three-fold Approach

- Regulatory Monitoring
- Special Assignments
- Total Diet Study

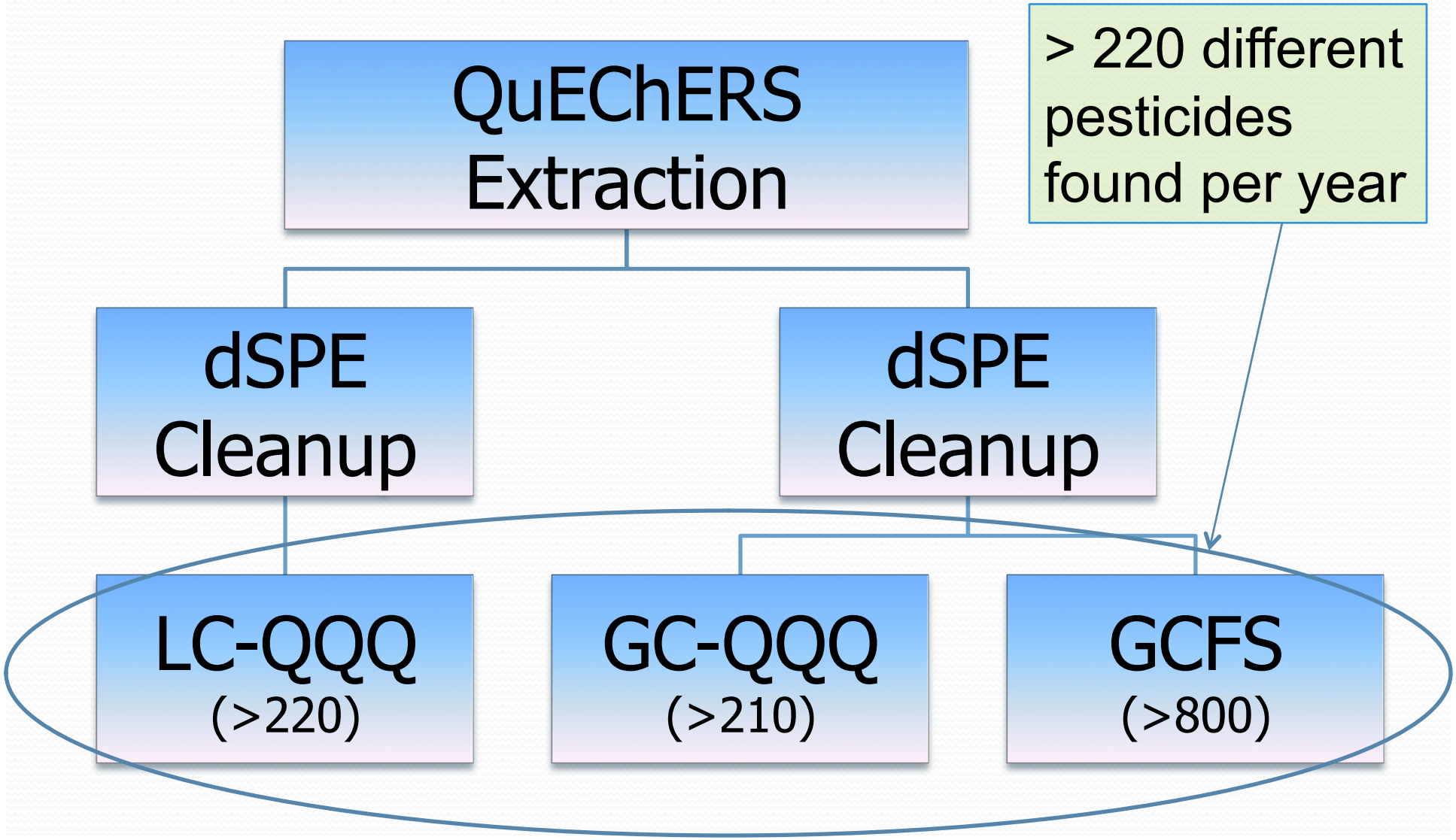
Regulatory Monitoring

- Sample types:
  - Raw agricultural products
  - Processed foods (limited)
  - Spices/botanicals
  - Animal feeds
  - ???
- Samples per year: 5000 – 8000
- Matrices per year: ~ 1000

Regulatory Monitoring

- Sample collection – primarily targeted
  - Violation history
  - State/USDA monitoring reports
  - Pesticide usage reports
  - Dietary significance
  - Toxicity
  - Origin
  - Foreign office reports
- Random

Pesticide Multiresidue Method (MRM)

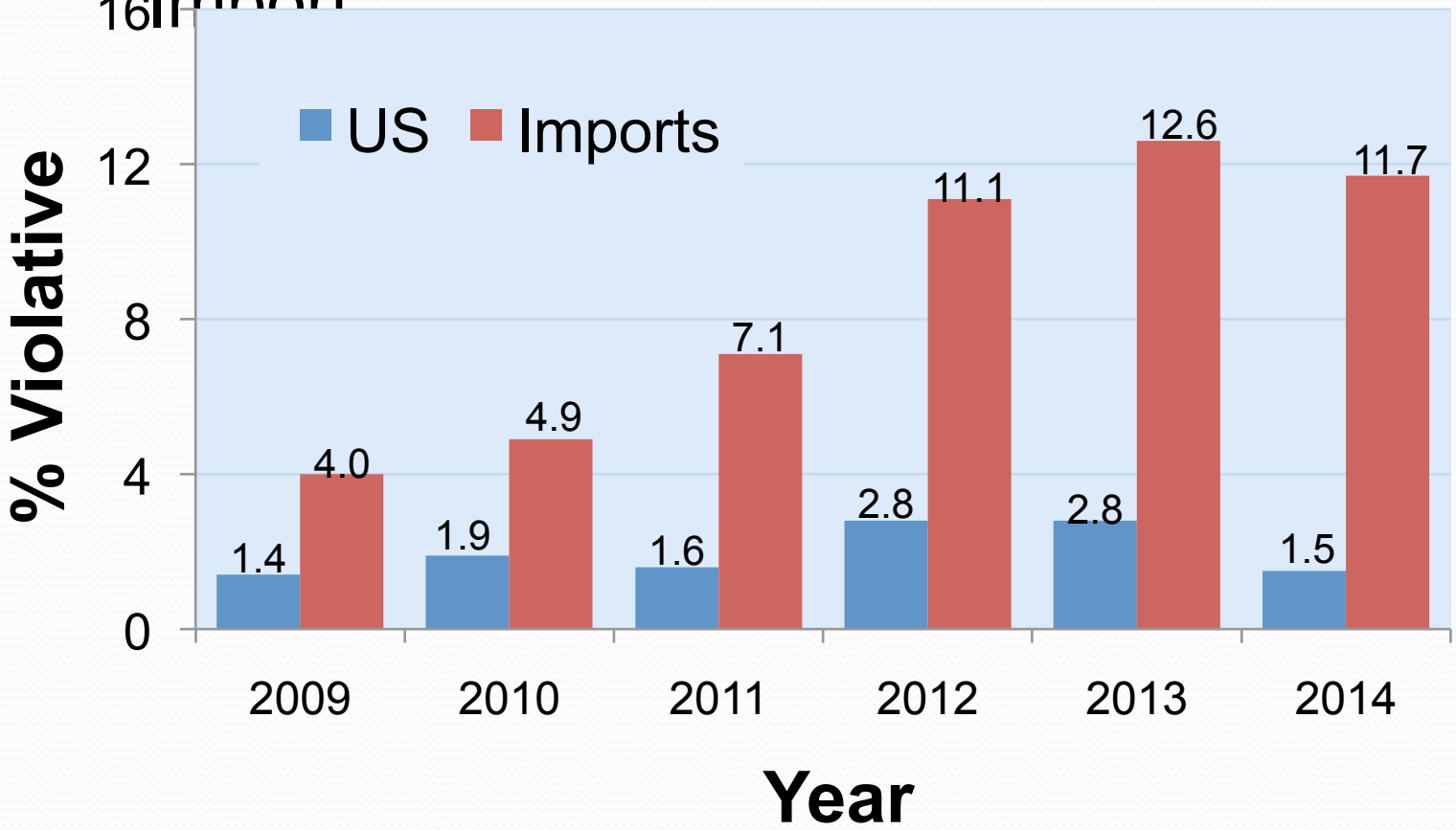


Regulatory Monitoring

Year	Violation Type (%)	
	No MRL	Exceeds MRL
2009	96.8	3.2
2010	94.5	5.5
2011	96.0	4.0
2012	96.8	3.2
2013	97.2	2.8
2014	96.3	3.7

Regulatory Monitoring

Violation Rate (%) - Domestic Vs. Import



Regulatory Monitoring

Most commonly found violative residues (2010–13)

Carbendazim	Buprofezin	Prochloraz
Tricyclazole	Pirimiphos methyl	Imidacloprid
Chlorpyrifos	Procymidone	Tebuconazole
Permethrin	Thiophanate-methyl	Difenoconazole
Triazophos	Cypermethrin	Acetamiprid
Ethion	Lambda-cyhalothrin	Monocrotophos
Profenofos	Pyrimethanil	Isoprothiolane

Special Assignments in 2016

- Glyphosate and Glufosinate in Corn, Soybean, Milk and Eggs
  - Samples: corn & soy (300 each), milk & eggs (120 each)
  - Residues found thru April
    - No residues found in 51 milk and 81 egg samples
    - No violative levels of glyphosate and glufosinate

Commodity	Spls	Glyphosate		Glufosinate	
Corn	52	23	(0.002-0.117)	3	(0.002-0.006)
Soybean	44	34	(0.005-9.24)	3	(0.005-0.172)

Special Assignments in 2016

- Acid Herbicides in Selected Commodities
  - Samples > 1300 grains and root crops
    - Grains: barley, corn, oats, soybean, wheat, rice
    - Root crops: potato, sweet potato, turnip, radish, peanut, carrot
  - Residues tested: 35 acid herbicides

2,4-D	Mecoprop	Aminopyralid	Acifluorfen	Diflufenzopyr
2,4,5-T	Fenoprop	Clopyralid	Imazamethabenz	Fluroxypyr
2,4,5-TB	2,3,6-TBA	Picloram	Imazamox	Triclopyr
2,4-DB	2,4,5-TBA	Dichlorprop	Imazapic	Bromoxynil
4-CPA	Chloramben	Diclofop	Imazapyr	Dalapon
MCPA	Dicamba	Haloxyfop	Imazaquin	Pentachlorophenol
MCPB	Quinclorac	Quizalofop	Imazethapyr	Aminocyclopyrachlor

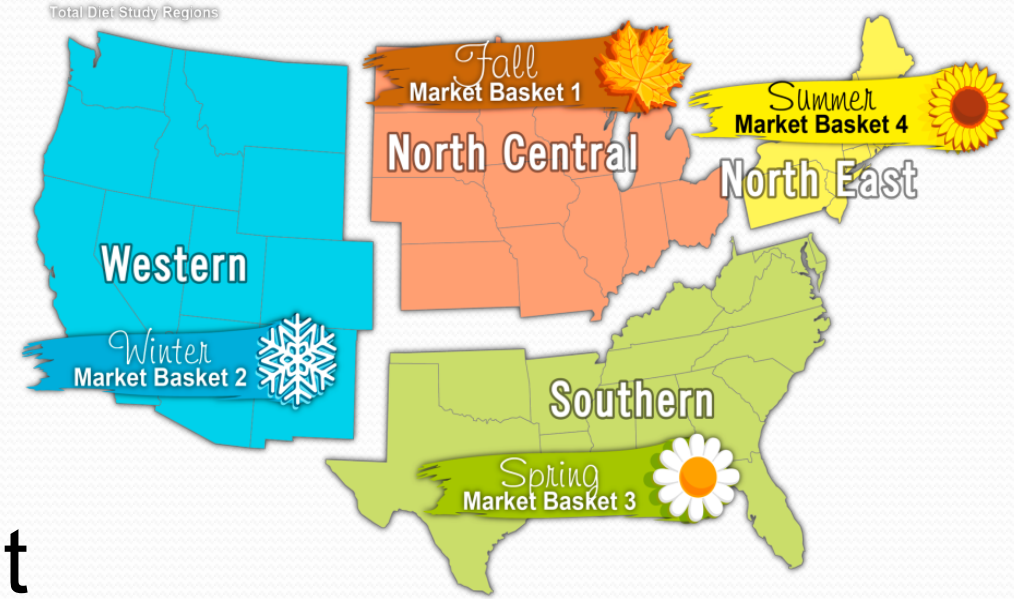
Special Assignments in 2016

Acid herbicide	Freq & Range	Commodities (Freq/Analyzed)
Total	242 samples tested (49 positive for at least one AcH)	
Clopyralid	24 @ 0.005-0.382	barley(8/19), wheat(6/12), sugar beet(4/10), oats(3/3), corn(3/63)
Quinclorac	11 @ 0.005-0.083	rice(11/17)
2,4-D	12 @ 0.005-0.020	wheat(4/12), soybean (5/55), barley (1/19) peanut(1/5), potato (1/8)
4-CPA	2 @ 0.009-0.010	peanut(2/4)
Dicamba	5 @ 0.011- 0.052	soybean(4/55), barley (1/19)
None	50	carrot(22), garden beet(10), radish(5), turnip(9), sweet potato(4)

Total Diet Study

- Definition: Analysis of “table-ready” foods for ultra-trace (0.1 ppb) residues
- Objectives:
  - Monitor contaminants and nutrients
  - Assess contaminant/nutrient trends and risk
  - Estimate exposures

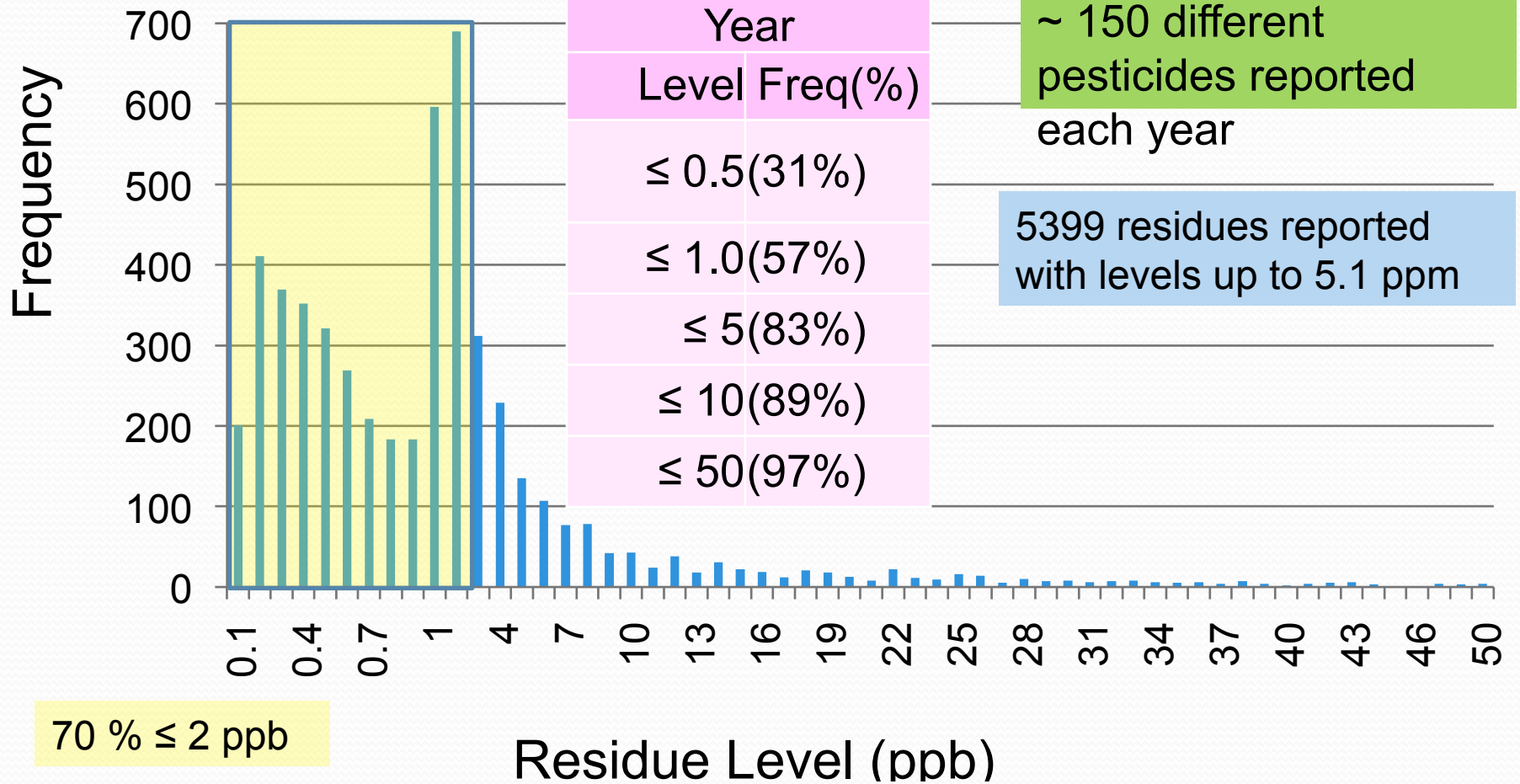
Total Diet Study



- 1 MB per region
- 4 regions
- 4 MBs per year
  - Market Basket

- 270 items
- 14 age/sex group diets
- Collect from 3 cities
- Make table ready and composite

Total Diet Study – Findings in One Year



Residues per Year	
Level	Freq(%)
≤ 0.5	(31%)
≤ 1.0	(57%)
≤ 5	(83%)
≤ 10	(89%)
≤ 50	(97%)

~ 150 different pesticides reported each year

5399 residues reported with levels up to 5.1 ppm

70 % ≤ 2 ppb

Total Diet Study - Findings

35 residues in strawberries (ppb)

THPI	48	Endosulfan II	7	Hexythiazox	2
Piperonyl butoxide	45	Thiamethoxam	7	Spiromesifen	1
Flonicamid	32	Malathion	7	Spinetoram	1
Cyprodinil	26	Acetamiprid	6	Fenbutatin oxide	0.9
Boscalid	26	Quinoxyfen	4	Thiophanate-methyl	0.8
Fludioxonil	19	Endosulfan sulfate	4	Methoxyfenozide	0.7
Novaluron	18	Carbendazim	4	Chlorantraniliprole	0.4
Fenhexamid	17	Endosulfan I	4	Cyflufenamid	0.4
Pyrimethanil	17	Myclobutanil	4	Metalaxyl	0.4
Fenpropathrin	16	Fenpyroximate	3	Clothianidin	0.3
Bifenthrin	16	Bifenazate	2	Azoxystrobin	0.2
Pyraclostrobin	13	Dichlorvos	2		

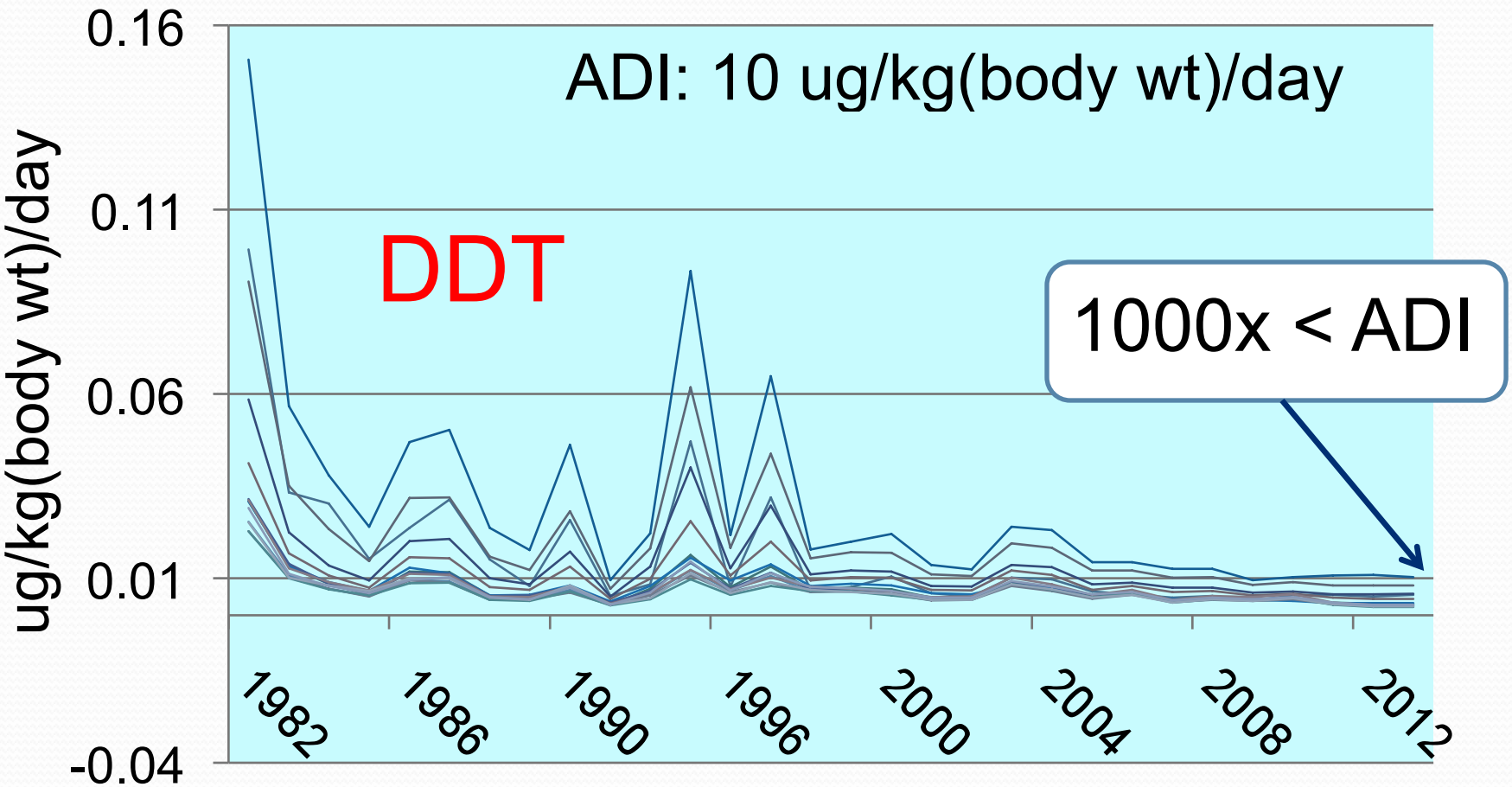
Total Diet Study - Findings

Acid Herbicides Found in 5 MBs

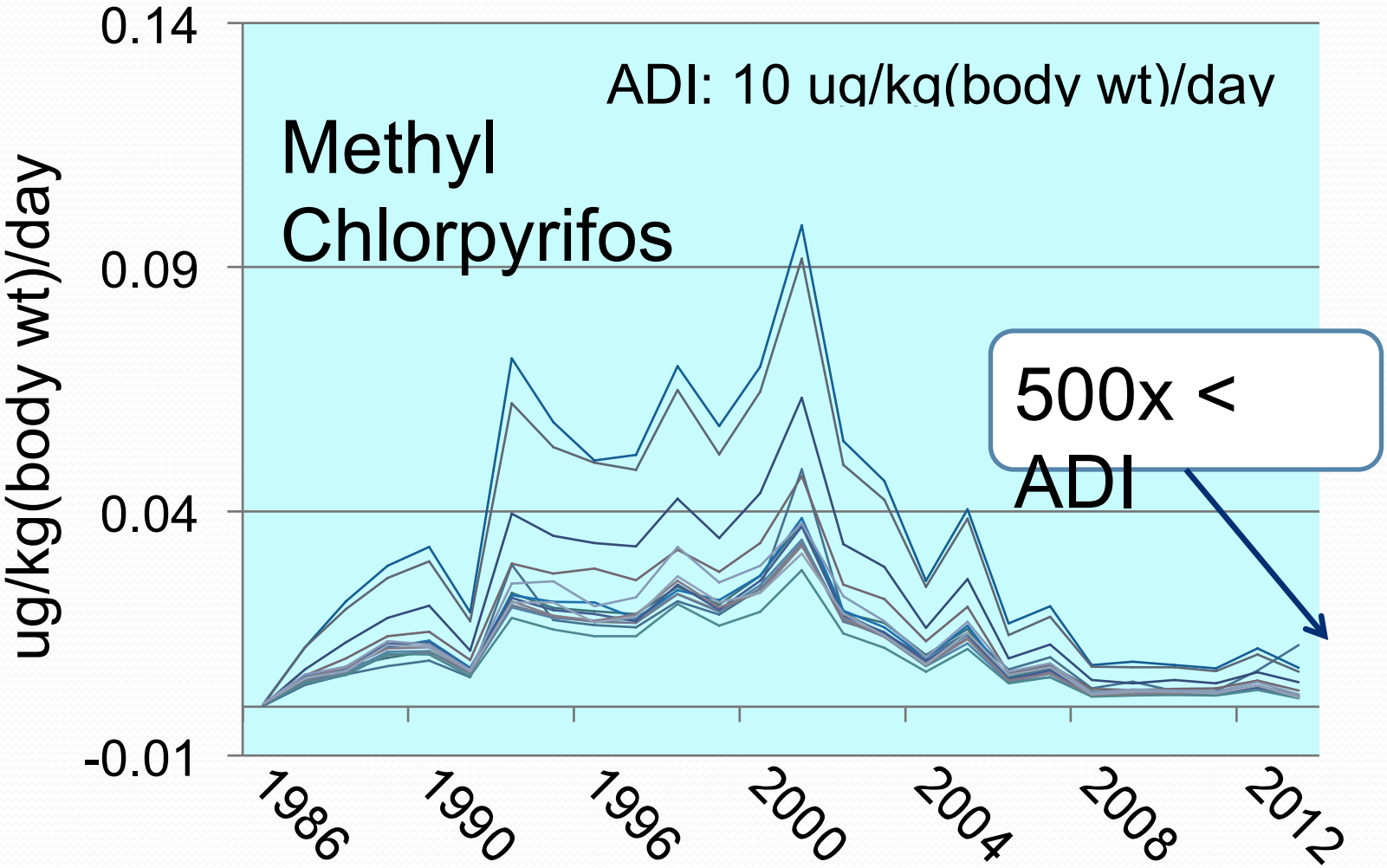
320 items analyzed (64 items analyzed per MB)

Herbicide	Freq	Items	PPB
2,4-D	74	30	2(0.3-12)
Clopyralid	62	20	10(0.4-39)
Imazamox	38	17	0.8(0.1-5)
Quinclorac	31	11	5(0.1-28)
Imazethapyr	13	8	0.2(0.1-0.3)
Triclopyr	13	7	0.3(0.2-0.5)
4-CPA	11	3	15(0.9-26)
Dicamba	6	4	6(3-11)
Acifluorfen	3	2	1(0.2-2)
Haloxyfop	2	1	4(0.2-8)
Imazapic	1	1	0.2(0.2-0.2)
Imazapyr	1	1	0.4(0.4-0.4)

Total Diet Study - Exposures

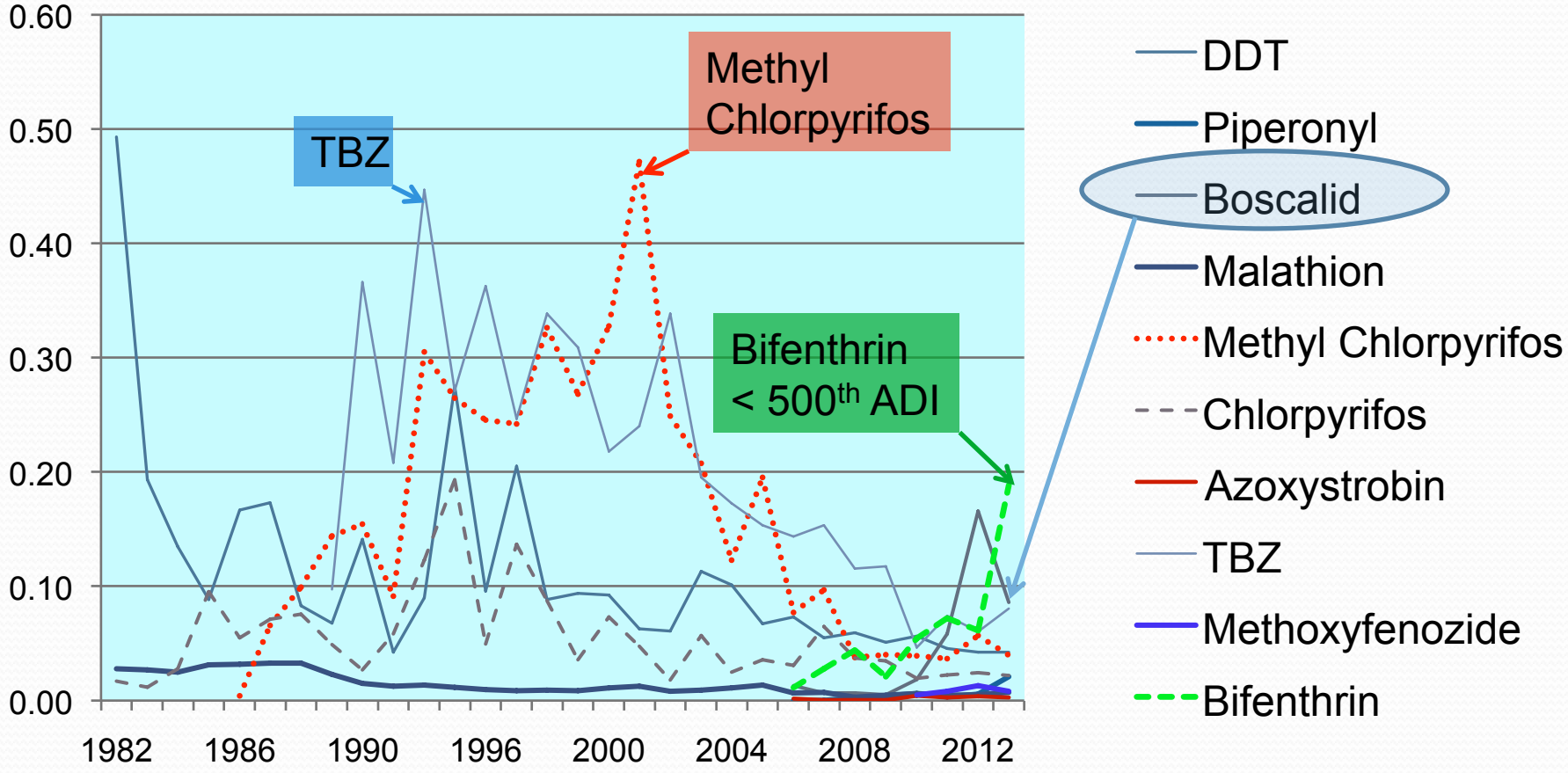


Total Diet Study - Exposures



Total Diet Study - Exposures

% ADI of Most Frequently Found Pesticides



Future

- Multiresidue Methods
  - Analyze over 1200 chemical contaminants by high resolution mass spectrometry
- Selective Residue Methods
  - Glyphosate – expand to routine screening
  - Acid Herbicides – expand matrices
  - Quats (paraquat, diquat, mepiquat, difenzoquat, …) – method under development
  - Dithiocarbmates (mancozeb, zineb, maneb, thiram, ziram, …) – research planned

Thank You!

Chris Sack

Center for Food Safety and Applied Nutrition

FDA