



MRL and Trade

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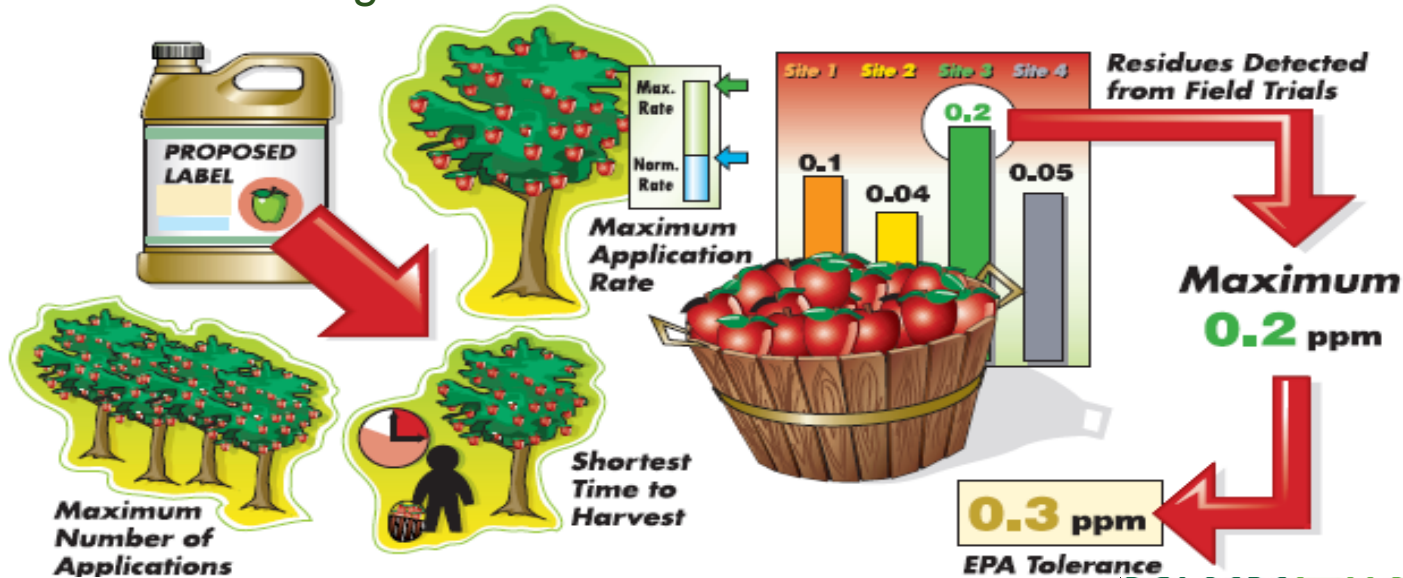
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DETERMINING THE MRL

FIELD RESIDUE TRIALS:

- Look at the spread in the residue trials –
- Take the data and put it into the OECD MRL calculator – *which*
- Statistically determines the upper limit from that data.
 - If data has a broad spread then the MRL will be quite a bit higher than the highest residue



TIER 1: MAXIMUM APPLICATION

Dietary Risk Assessment

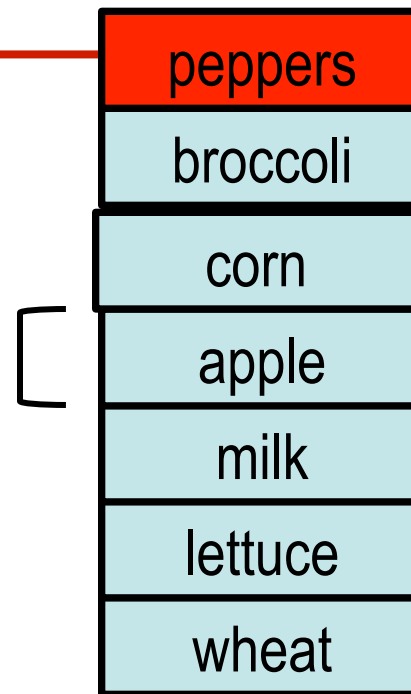
Hazard Assessment

NOAEL from Animals

UF (100X)

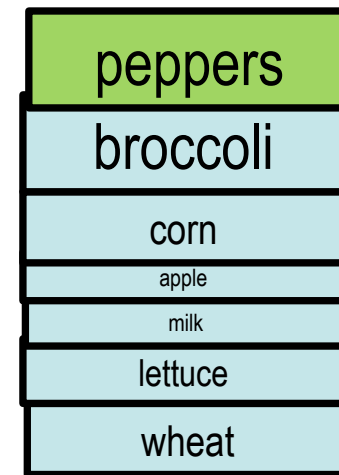
SAFETY THRESHOLD

CRUDE
Apple MRL
from field
residue trial



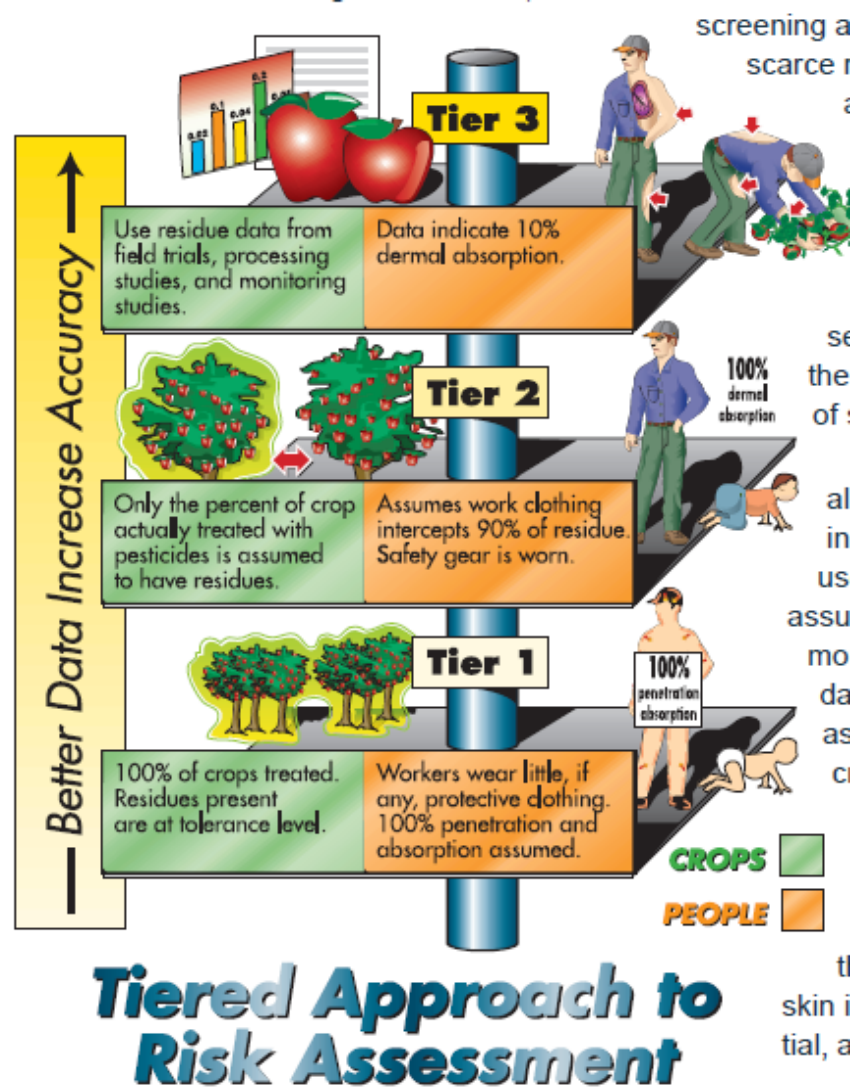
Tier 1 Estimate

REFINED
Actual residue
data based on
real-life use/
processing etc



Tier 3/4 Estimate

EPA Tiered & Refined Risk Assessment



Used to refine exposure for the risk assessment

NOT to change the MRL



WHAT IS THE MRL?

**MRL= Maximum legal limit of a residue
in/on food=US Tolerance**



What it is

From residue studies of maximized use pattern to set upper bound for local enforcement of GAP using **OECD** calculator

Upper bound to check compliance with labeled use

Set in context of acceptable dietary risk/safety assessment

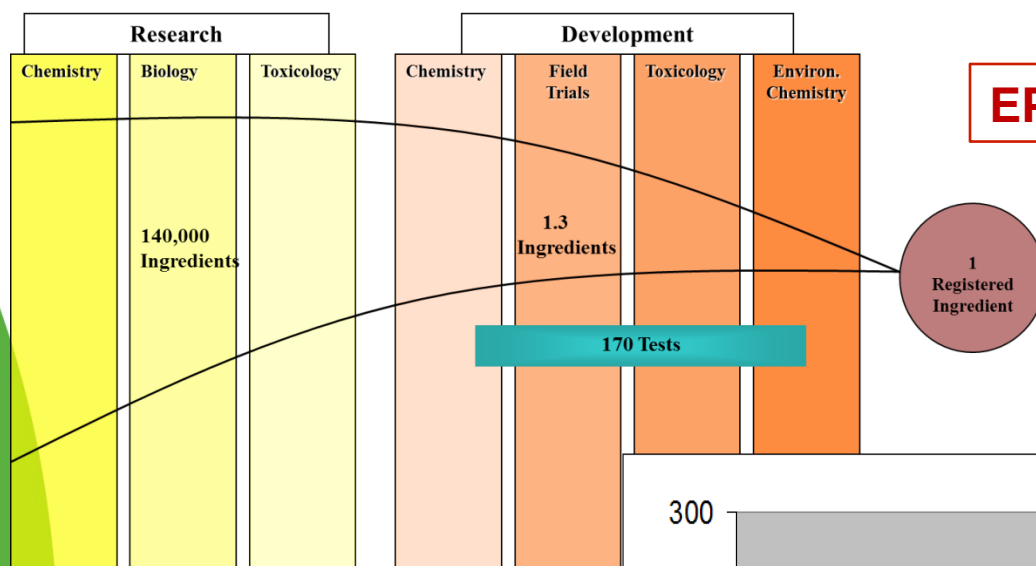
Over conservative exposure input in dietary safety assessment

What it is not

Stand-alone health standard; it is not a safety threshold.

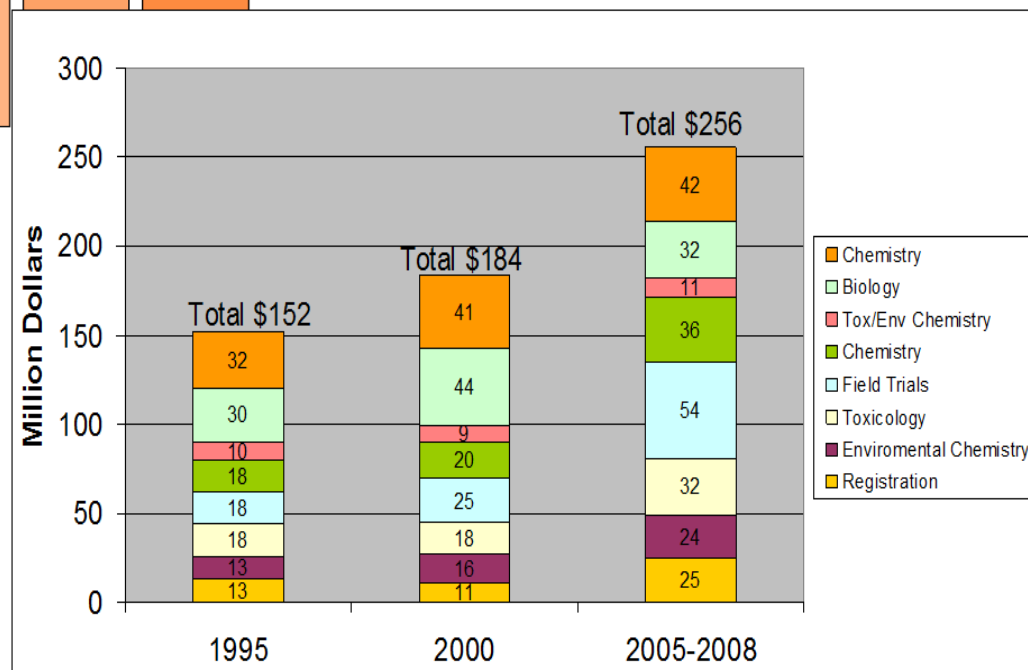
Realistic measure of typical exposure – **but PDP is**

FOLLOWING THE LABEL – WHY DO WE CARE?



EPA MANDATES TESTING

**FIFRA:
NO UNREASONABLE
HARM**

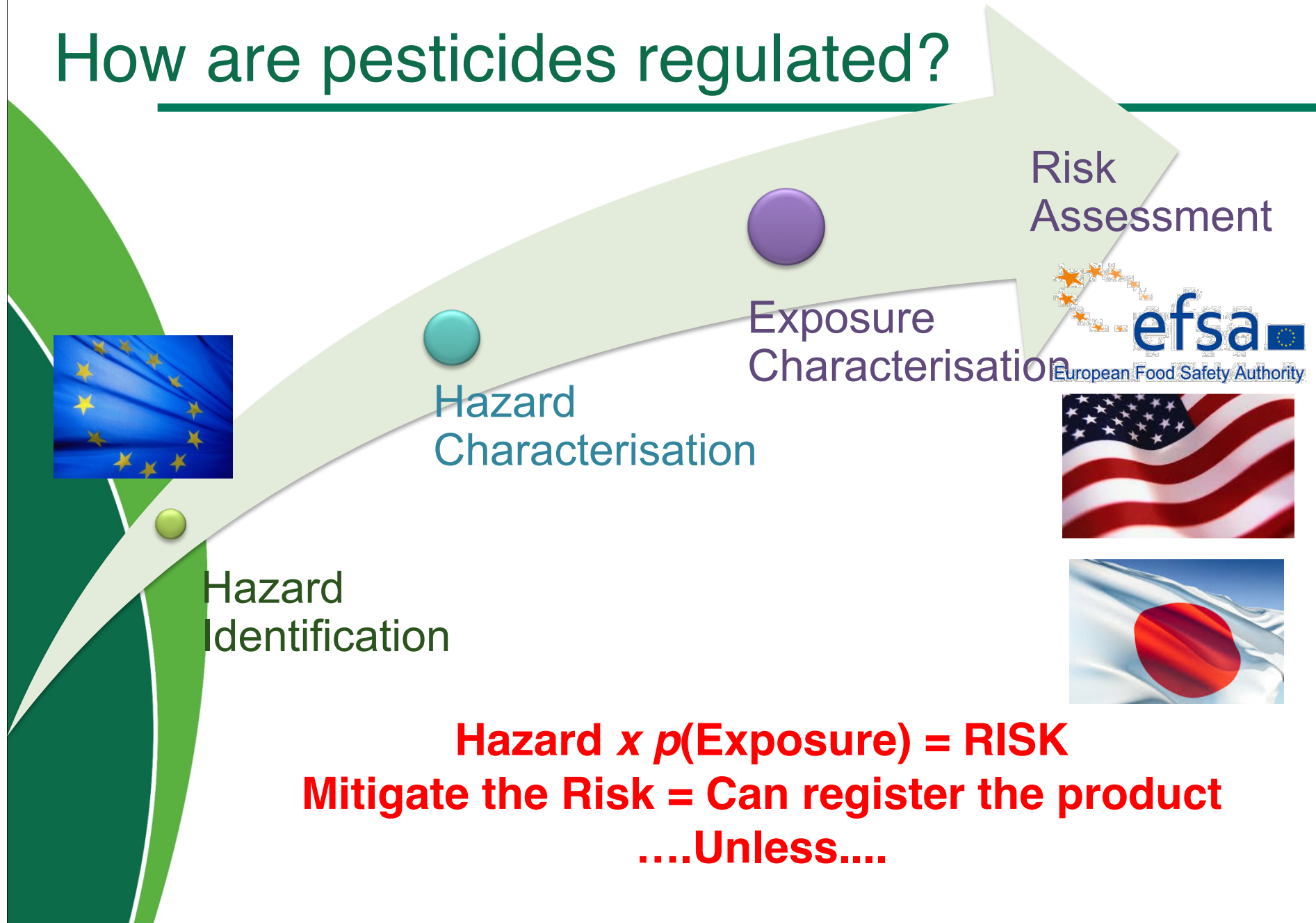


The Economics: WHY DO YOU CARE?

- **Agriculture and beyond:** manufacturing, food services, construction and transportation
- **\$33bn** in wages for more than **1.05 million** Americans
- **\$82bn** in crop value at the farm gate
- **40%** saved on food bills
- Feeding a growing global population
- Allow farmers to engage in conservation tillage:
 - 22.2 billion pounds of carbon dioxide emissions/year



How are pesticides regulated?



UNLESS.....

WITH HAZARD BASED CUT OFFS

- Categorize compounds based on hazard
- Cut them off from use in the EU market
- Establish default MRL of 0.01mg/kg
- Import MRL = Internal MRL (MS vote)

Example: endocrine disruptors



Active Substance	Number of MRLs
Insecticides	
Thiacloprid	18
Deltamethrin	336
Dimethoate	52
Herbicides	
2,4-D	112
Metribuzin	18
Picloram	3
Tepraloxymdim	4
Triflusulfuron-methyl	5
Fungicides	
Tritconazole	14
Triadimenol	9
Thiram	4
Tetraconazole	16
Prothioconazole	25
Propiconazole	111
Metiram	2
Myclobutanil	76
Folpet	2
Difenoconazole	124
Tebuconazole	88
Metconazole	57
Mancozeb	64
Iprodione	48
Fenbuconazole	40
Cyproconazole	4

SOOOO...How does the US evaluate ED?

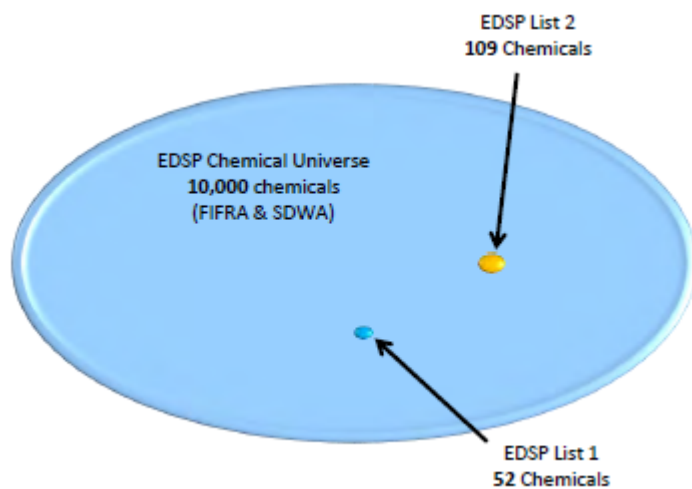
US EPA EDSP – Estrogen, Androgen and Thyroid axes

➤ TIERED APPROACH

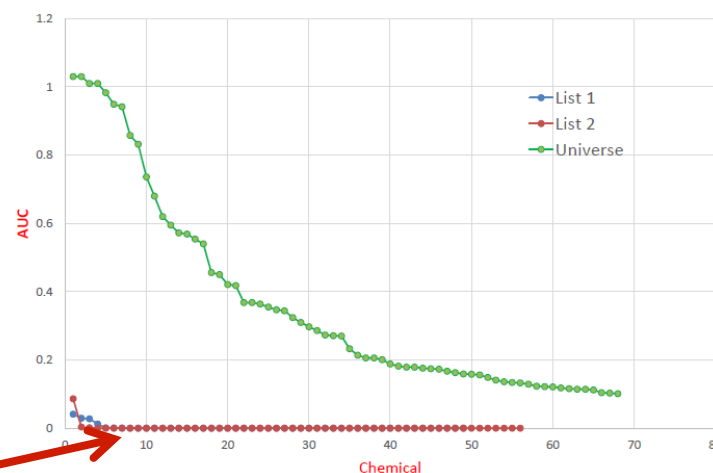
$$\text{Risk} = p(\text{Exposure}) \times \text{Hazard}$$

➤ RISK BASED

EDSP21 = EXPOCAST + TOXCAST

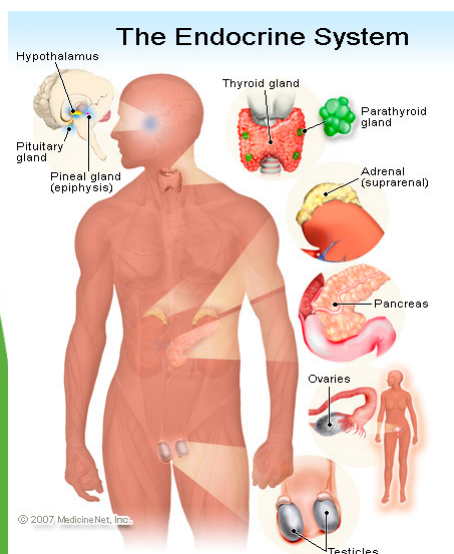


ToxCast Estrogen Activity



STOP!!!! - WHAT IS AN ENDOCRINE DISRUPTER???

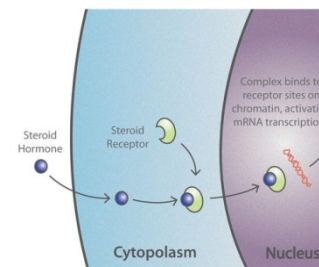
WHAT IS THE ENDOCRINE SYSTEM???



- It is comprised of glands
- Which secrete chemicals called hormones
- Which interact with cells in the body using receptors

How does it work?

- Like a lock and key
- As an interactive signaling system
- With feedback loops to balance things - like sugar levels in the blood



Why do we have one?

- For interacting with our environment
- For growth and development
- For reproduction



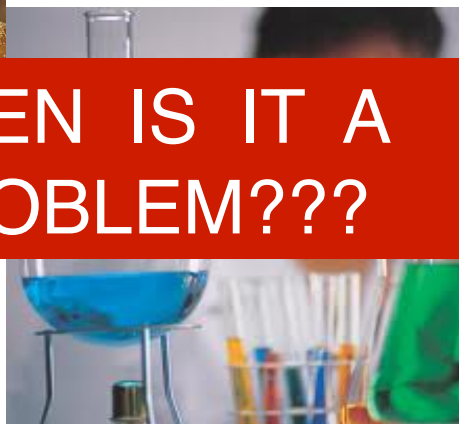
Endocrine Disruption

What is an Endocrine Disruptor (ED)?

Almost anything!!



WHEN IS IT A
PROBLEM???



**WHEN EXPOSURE TO THE ENDOCRINE ACTIVE
COMPOUND CAUSES HARM**

***Function of* (EXPOSURE X HAZARD)**



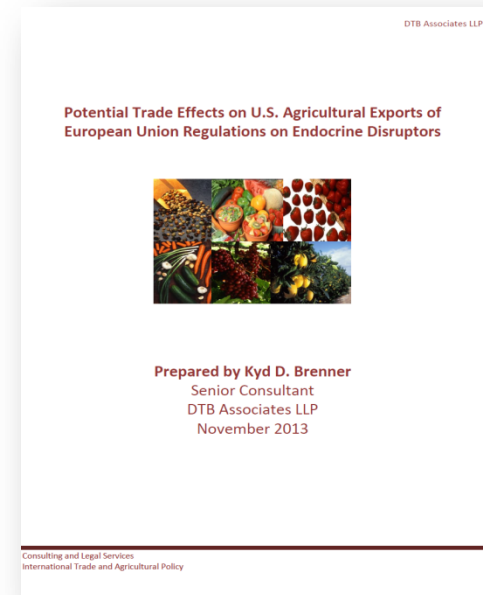
Potential Trade Effect On U.S. Agricultural Exports Of EU Regulations On Endocrine Disruptors

Kyd Brenner
Senior Consultant DTB
Associates

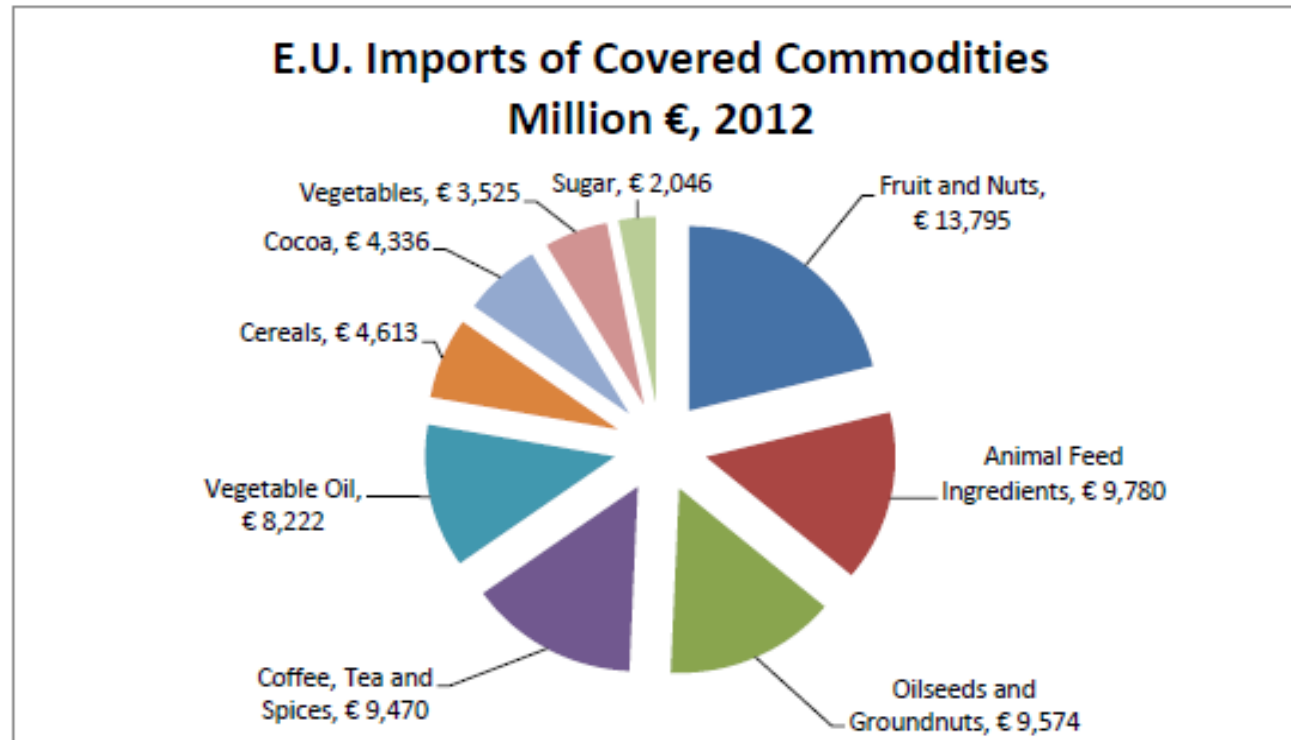
Hazard Based Cut-Offs

- How many compounds?
- How many MRL?
- What happens to trade?

MRL are not a safety threshold



AFFECTED COMMODITIES



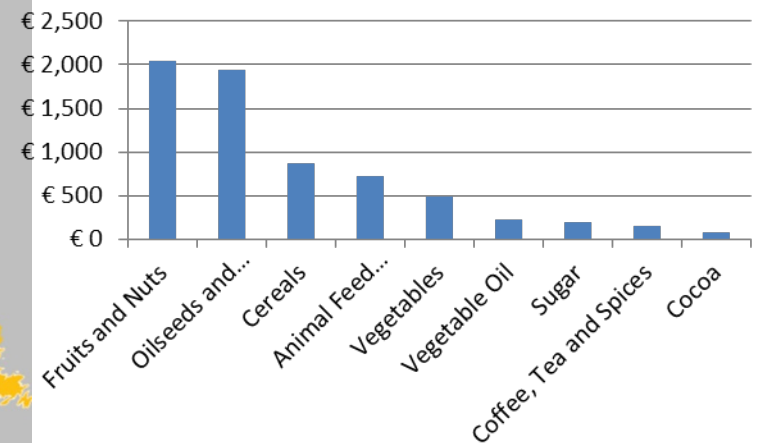
**GLOBALLY, 60% OF THE VALUE
OF ALL EU IMPORTED
COMMODITIES**



E.U. Imports of Covered Commodities and Three Largest Products by Country (€ 6,697 Mil)



Major Affected Commodity Groups North America and the Caribbean



■ Million Euro, Jan -..

Trade Impact Assessment Due to Endocrine Issue

- Impacts US exports **AND** EU Imports
 - source of raw commodities for the EU Food Processing industry
- **\$3.9 billion** of U.S. raw agricultural commodities
 - Tree nuts & fruits: \$1.577 billion
 - Soybeans & peanuts: \$1.516 billion
 - Grains: \$0.586 billion
 - Other: \$0.207 billion
- **>\$ 5 billion** total, including processed food and feed products

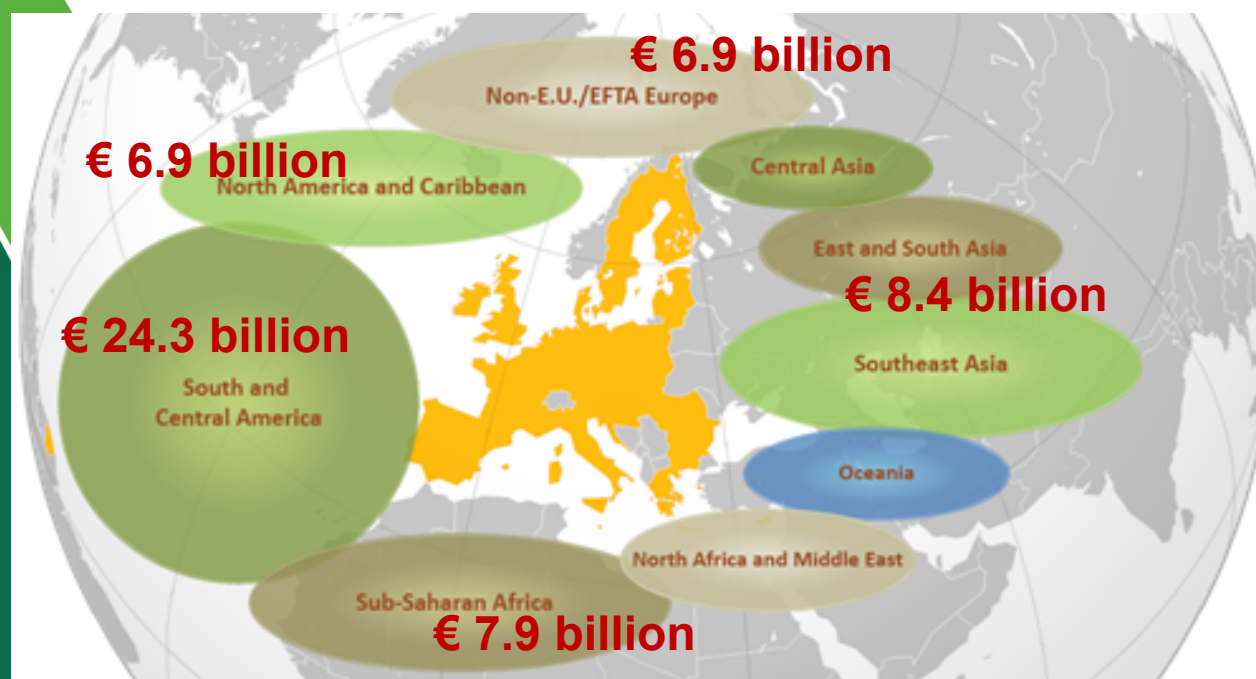
What is the global effect of default MRL's??

Potential Trade Effects on World Agricultural
Exporters of European Union Regulations on
Endocrine Disruptors



Impact on Trade (€)

Globally, **€65 billion** of EU imports potentially affected by ED cut-off criteria



Category	€m (2012)
Fruit and Nuts	€ 13,795
Animal Feed Ingredients	€ 9,780
Oilseeds and Groundnuts	€ 9,574
Coffee, Tea and Spices	€ 9,470
Vegetable Oil	€ 8,222
Cereals	€ 4,613
Cocoa	€ 4,336
Vegetables	€ 3,525
Sugar	€ 2,046
Total	€ 65,362

[More information on methodology is available](#)

Total Trade Impact of 1107/2009?

More than just Endocrine Disruption

- Seven categories trigger hazard-based cut-offs

Candidates for Substitution

- Approved products can still be withdrawn from the market based on an unfavorable comparative assessment with other products on the market. (resistance problems??)

What will the buyers do??

AND

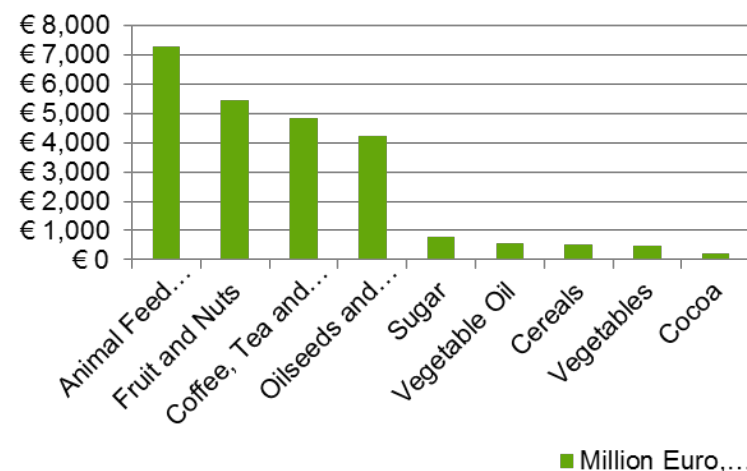
The \$4.6bn trade impact *does not include* the export of pesticides to the EU



E.U. Imports of Covered Commodities and Three Largest Products by Country (€ 24,324 Mil)



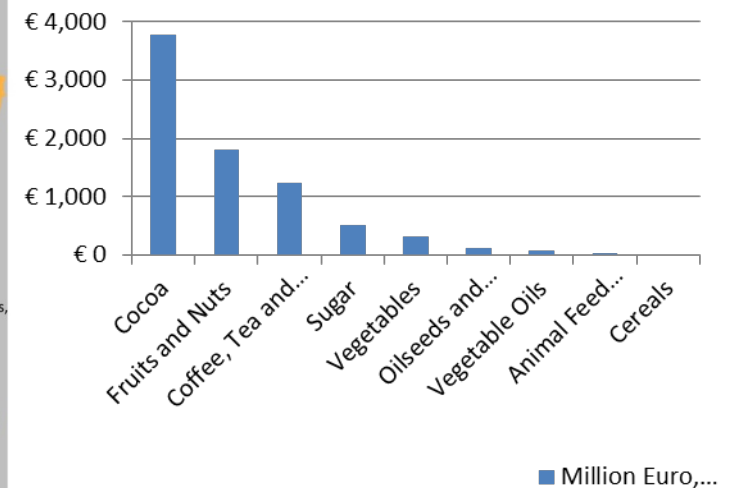
Major Affected Commodity Groups Central and South America



E.U. Imports of Covered Commodities and Three Largest Products by Country (€ 7,915 Mil)



Major Affected Commodity Groups Sub-Saharan Africa





THANKYOU!

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