# Hazard vs Risk Are your Tigers in the Cage?

2020 MRL Harmonization Workshop Jane Stewart and Brandy Riffle



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# HAZARD *VS* RISK

**RISK** consists of...

Hazard - the presence of a live animal capable of seriously injuring and even killing you

and

Exposure - the likelihood that the tiger will see you, be hungry, and attack you





# How do we try to understand the potential hazards to people???

### Mammalian Toxicology studies!!!

- Acute toxicity
  - What if I swallow it once? Or get it on my skin? Eye? Breathe it?
- Repeated exposure toxicity
  - What if I ate this for few days, weeks, or the rest of my life?
- Genotoxicity
  - Can this interact with my DNA? Cause my cells to mutate?
- Reproductive Toxicity and Teratogenicity
  - What if I'm pregnant? Or want to get pregnant?
- Neurotoxicity and immunotoxicity...
  - Everyone likes to be smart and no one wants to get sick



# To be a honorary toxicologist, here's what you must first understand.... "The dose makes the poison"

- There is a safe dose and a toxic dose for everything
- Everything will kill you eventually, the question is how much it will take

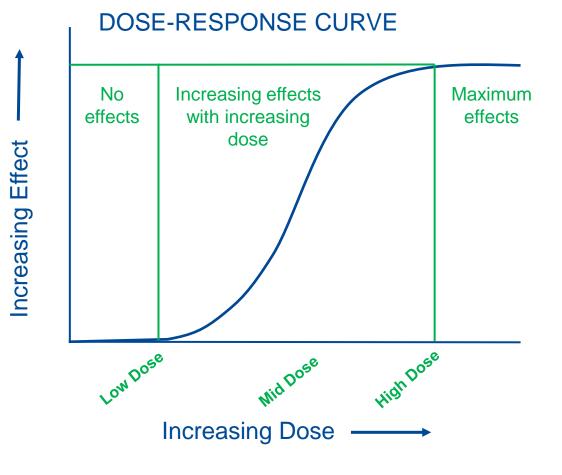




# But what exactly are you looking for in these studies???

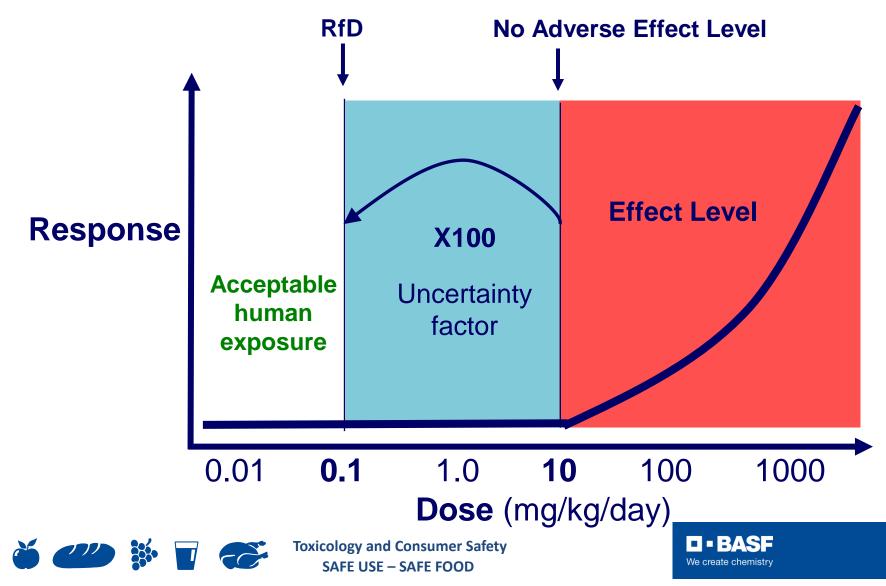
 The ultimate goal for toxicology studies is to identify a dose that will not cause any adverse effects while dosing high enough to fully characterize all of the adverse effects possible

No Observed Adverse Effect Level (NOAEL)





# And how do you figure out how MUCH we can be exposed to using Risk Assessment?



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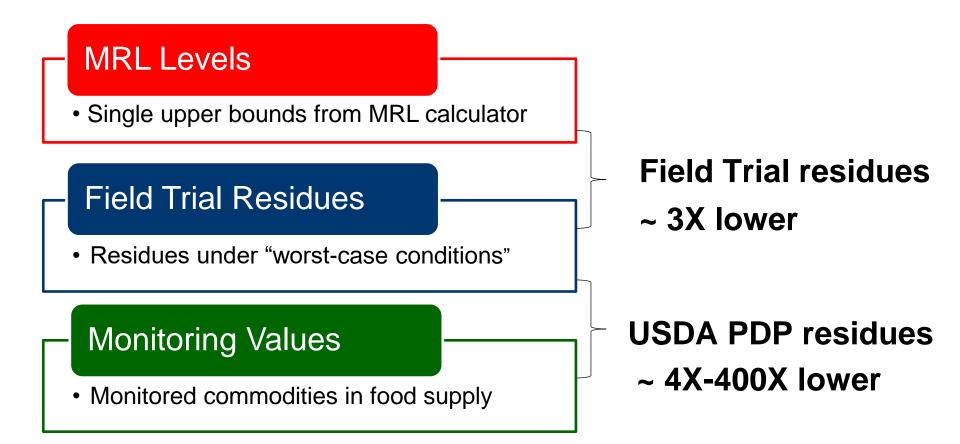
### How do we establish Exposure for pesticides?







## **Comparing MRL, Field Trial & Monitoring Residues**

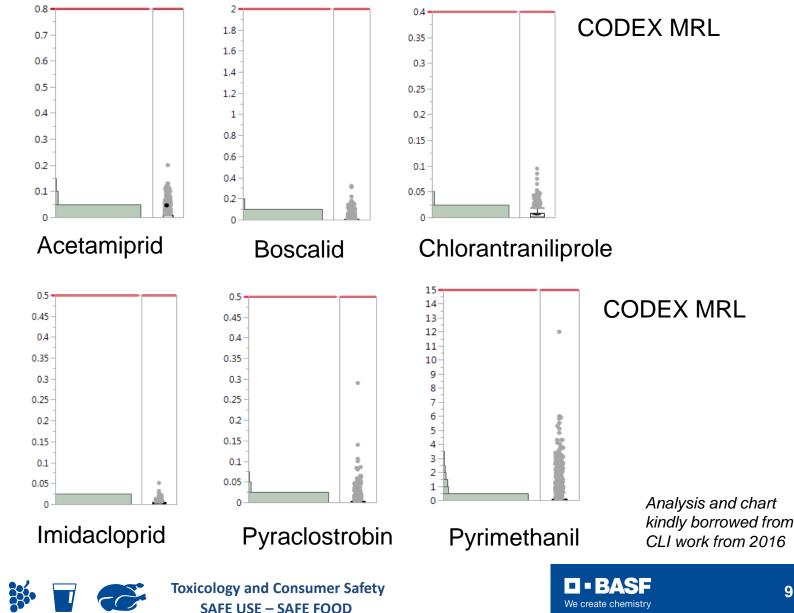


Reference: Szarka, A. Z., Hayworth C., Anderson, W., and Joseph, R., "Comparison of Pesticide Data Program and Registrant-Generated Residue Data Pesticide Exposure, International Society of Exposure Science Annual Meeting (October 2015)





#### USDA Pesticide Data Program for Apples (2009, 2010, 2014) **Distribution for 6 actives with highest residue % of MRL**



### **Exposure = Consumption x Residue in Food**



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#### National Health and Nutrition Examination Survey (NHANES)

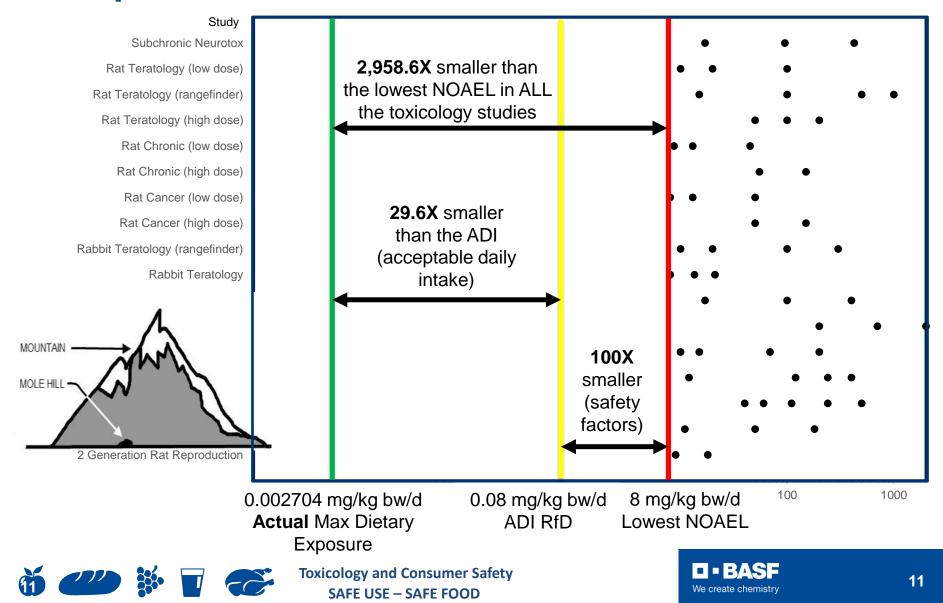
What We Eat in America (WWEIA) is the dietary interview component of the NHANES. WWEIA is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS).



Data from the survey are used for many purposes including nutritional status, disease prevention and basic health sciences research.



# Let's put hazard and exposure together with a real example.....



### But what about using a hazard assessment?

- Europe does risk assessment for most things but it does have cut off criteria for a few:
  - Classified mutagens, carcinogens, <u>reproductive and</u> <u>endocrine disrupting pesticides</u>
  - So what's the problem???
    - Those tricky endpoints like reproductive and endocrine effects..
    - Since those toxicology studies were dosed really high to see everything, they might have effects that really aren't due to the chemical itself but are due to the high dose
- Basically, they only are looking at the tiger (hazard) and aren't paying attention to the cage (exposure)





### A RISK – based approach still includes risk



Photo: courtesy of Netflix

We cannot guarantee 100% protection from all harm.

We cannot totally prevent misuse, abuse or illegal use of pesticide products.

#### We cannot stop people from sticking their arms into the tiger's cage.

US Food Quality Protection ACT (1996) – mandates that pesticides must pose "a <u>reasonable</u> certainty of no harm."





### Benefits are critical to every risk assessment

The **BENEFITS** of agricultural products should be recognized when doing risk assessment.

Benefits to consumers Benefits to growers and workers Benefits to society and food security

Photo courtesy of Ricepedia







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