



The Pesticide Labeling Process

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for MAMCA Feb. 2012*



Presentation Objectives

- *I WILL NOT*

- Teach you HOW TO READ (or write) a label
- Cite the LABEL PARTS

- *I WILL*

- Describe HOW a registered label comes to be
- DECONSTRUCT a label into HAZARD and RISK, and explain the difference
- Reinforce READ THE LABEL FIRST

The Registration Standard, briefly

- Composition supports the claims;
- The pesticide will perform its intended function when used in accordance with commonly recognized practice *without unreasonable adverse effect on human health or the environment*

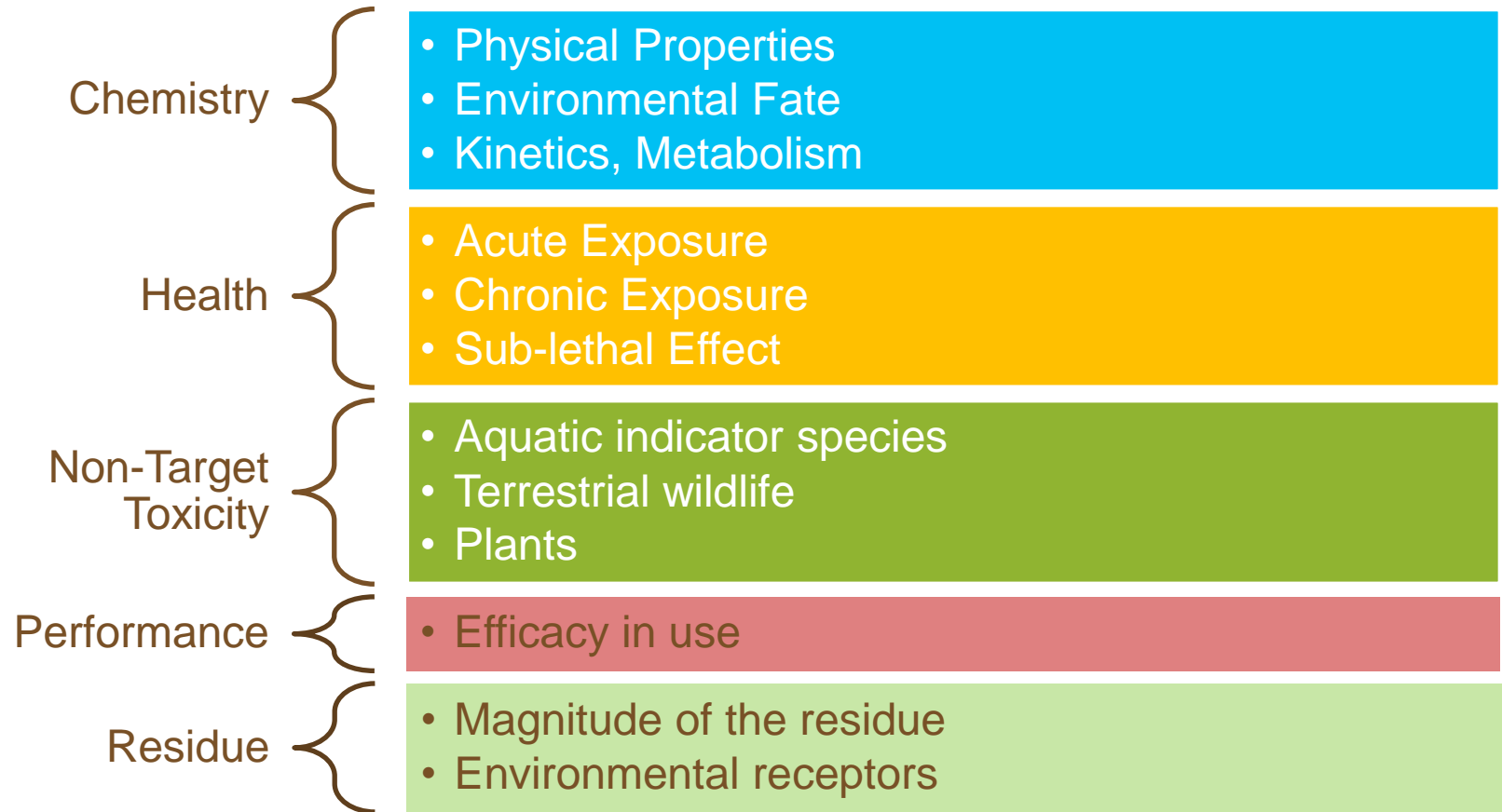
THE REGISTRATION PROCESS

Process inputs
include variables,
environment,
constraints, and
assumptions



Process outputs
include work product,
deliverables,
outcome

Science-based Assessment



The Pesticide Label

- Translates the results of scientific evaluations into a set of conditions, directions and precautions, such that the pesticide product
“can be used with a reasonable certainty of no harm”
- Provides critical information about how to safely handle and legally apply pesticide products
- Unlike most other types of product labels, pesticide labels are enforceable

THE REGISTRATION PROCESS



The Science is in the Label

REGISTRATION & LABELING

Directions
for Use

PPE

Regulation

RISK ASSESSMENT

Chronic

Fate

Exposure

Intervals

PRECAUTIONARY LABELING

Acute
Health

Non-Target
Indicators

Chemistry

$$\text{Risk} = f(\text{hazard}, \text{exposure})$$

- Hazard = what *can* go wrong, precaution
- If the elements of *hazard* and *exposure* are not both in play, there is no biophysical risk to health or the environment
- The magnitude and severity of risk are a function of the types of hazard and the extent and likelihood of exposure

The Deconstructed Label

Precautionary Labeling

- Hazard-based
- Advises of the *potential for hazard* or effect
- “may cause”
- Based on laboratory endpoints
- Broadly & qualitatively assumes exposure

Risk Mitigating Labeling

- Circumstances & conditions that *eliminate or minimize the potential for hazard*
- Quantitative Environmental & Health Risk Assessment
 - Toxicology (hazard)
 - Concentration (dose)
 - Duration, Frequency of exposure

The Deconstructed Label

Precautionary Labeling

- Chemical identity
- Signal Word
- Hazards to Health
- Environmental Hazards
- Physical Hazards

“may effect; take caution”

Risk Mitigating Labeling

- PPE, Engineering Controls
- Directions for use
 - Sites (exposure)
 - Rates, frequency (magnitude)
 - Weather, equipment (likelihood of exposure)

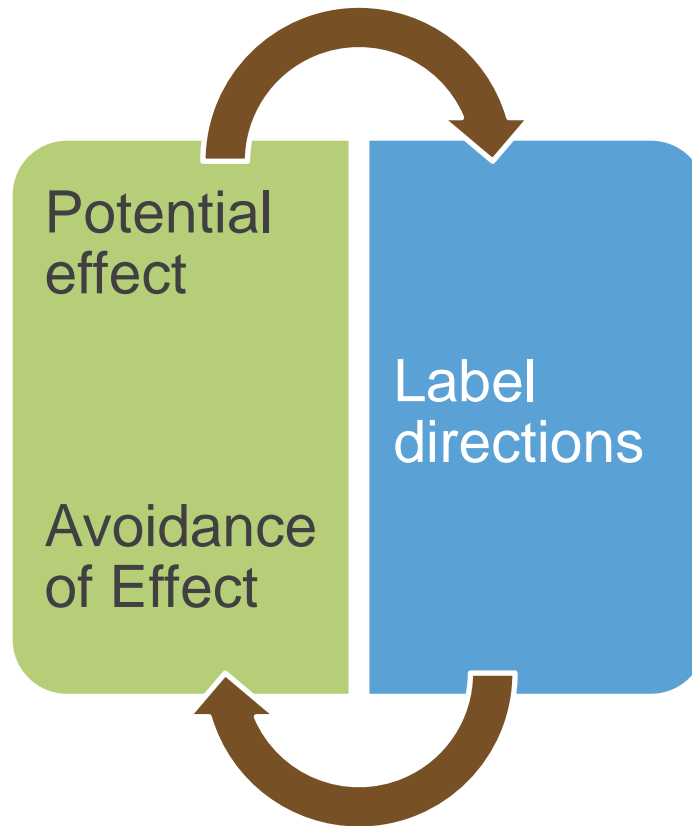
“reasonable certainty of no harm”

Hazard & Risk Mitigation Labeling

Dermal sensitization

Highly toxic to aquatic organisms

Toxic to bees



PPE

Droplet size; wind & weather; equipment calibration; height; reapplication intervals; rate labeling

Application during periods of inactivity

Why so much variability among labels?

- While all registered pesticide labels are based on scientific conclusions of risk, products are not registered in isolation
- Nuances in labeling are created by
 - Variability in the underlying datasets, exposure models
 - U.S. EPA Agency division
 - State regulatory interpretations
 - Emerging external influence (politics, emotional)
 - Human elements (Registrant, Agency)
 - Time lapses in label maintenance

What's NOT in the label?

- Comparative risk
- “when used as” qualifying labeling
- DfE ineligible
- 3rd party endorsements
- OMRI, NOP

While these qualifiers may be useful to know, they are generally regarded as not communicative, *even distracting*, to the user on ‘how to safely use the product’

Why labels change!



- Registrant initiated
 - Pests, sites, rates
 - Industry science
 - Local need
 - Liability
- Agency initiated
 - Revised risk
 - Models
 - Assumptions
 - Cumulative assessments
 - Legislation
 - Harmonization
 - Consumer initiatives
 - Enforceability



Thank you for your time.

