Overview of Oxalate Oxidase Peanut Risk Assessment

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Background

The EPA Office of Pesticides regulates the sale, distribution, and use of all pesticides in the U.S. in order to protect human health and the environment.

<u>Including</u>: GE Plant-Incorporated Protectants (PIPs), such as the *Sclerotinia* resistant peanut

Coordinated Regulation

- **U.S. Department of Agriculture**
  - **Evaluate potential risks to agriculture and the environment.**
- **U.S. Food and Drug Administration**
  - **Food and feed safety**
- **U.S. Environmental Protection Agency**
  - **For GE plants that produce pesticides, EPA evaluates human and animal health and environmental risks, and sets food tolerance levels for all pesticides**

Sclerotinia on Peanut

Sclerotinia in Peanuts

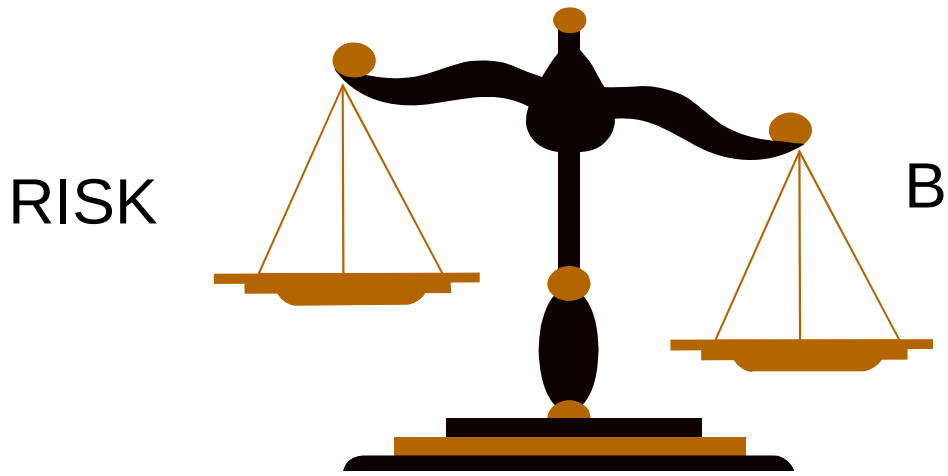
- ***Sclerotinia minor*** **infects peanuts (*Arachis hypogeae*) and other dicots**
  - **Pathogen is necrotroph and produces oxalic acid as pathogenicity factor**
- **Typically not a disease of cereals**
- **Oxalate oxidase is in the germin family (cupin superfamily)**
- **OxOx provides protection from disease**

EPA Regulation of PIPs

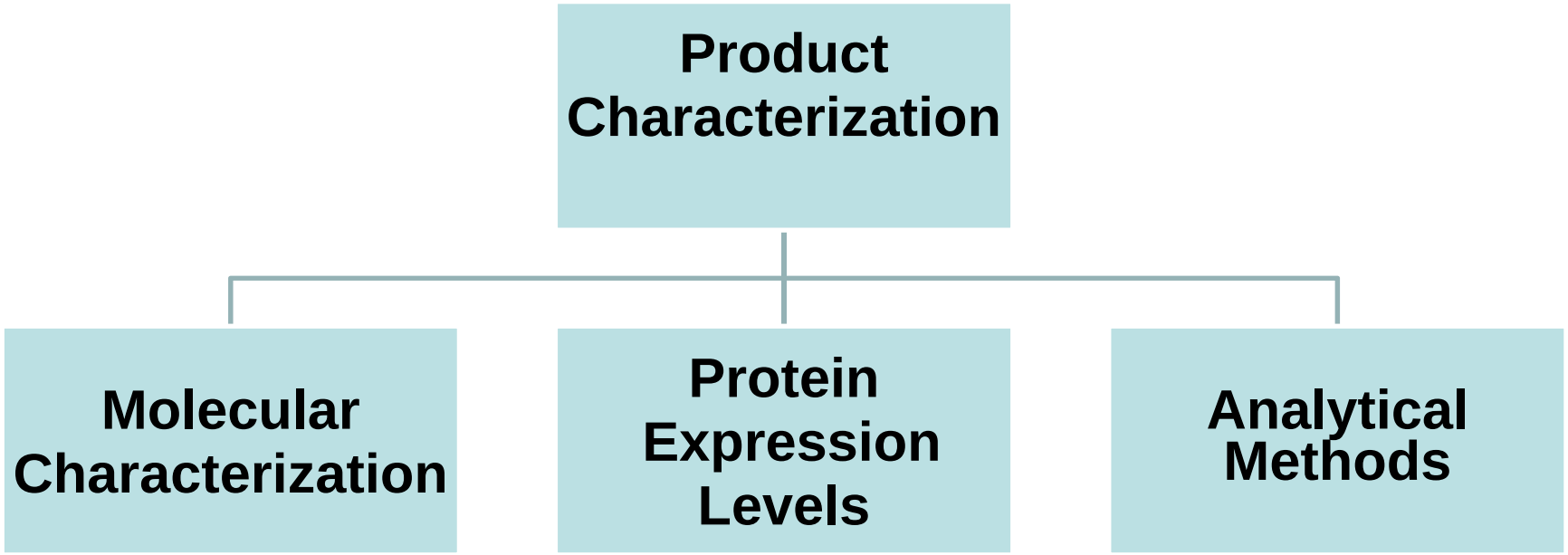
- **EPA regulates the gene and its product**
- **Inert ingredients are also considered**
- **EPA does not regulate the plant itself**
- **Regulation continues as long as the product is in commerce (licensing)**
- **Food / feed safety and environmental assessments are performed for all PIPs**

Risk Assessment Process

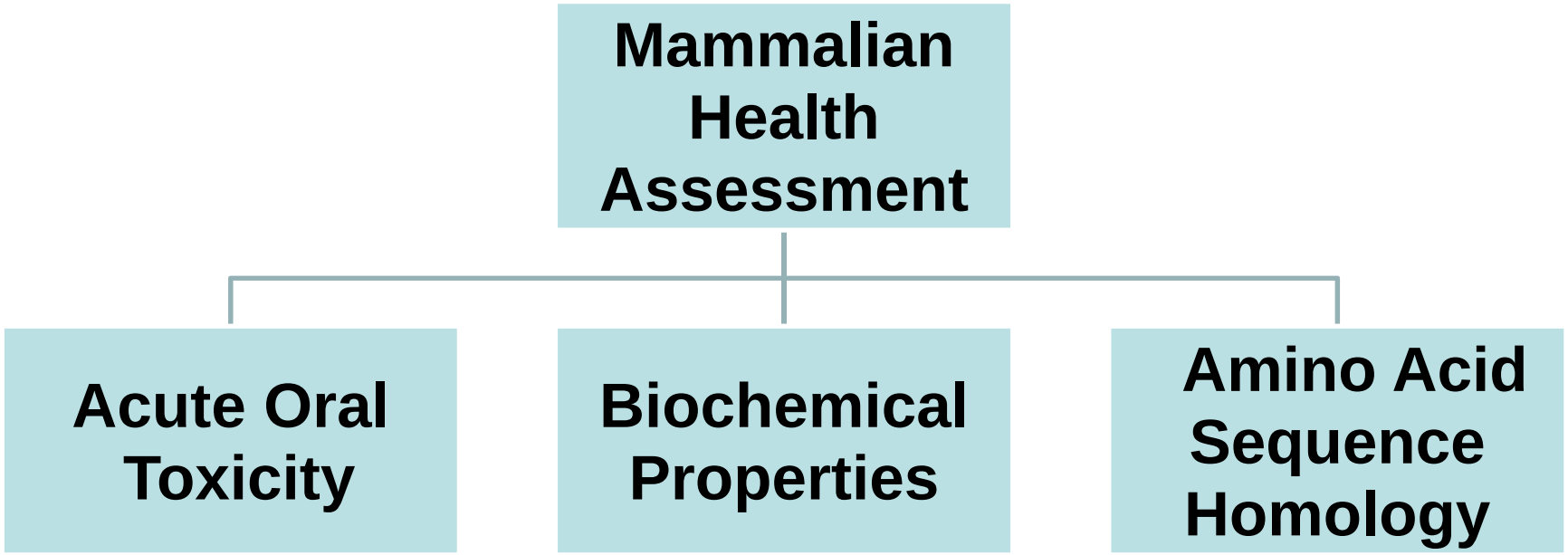
Risk = Hazard x Exposure



How EPA characterizes PIPs



How EPA Assesses Mammalian Dietary Effects for PIPs



Sclerotinia Blight Resistant Peanut

- *Arachis hypogeae*
- DNA sequences from oxox gene of barley
- Particle bombardment transformation
- Toxin inactivation mechanism
- Toxicity endpoint addressed if in food
- Cupin family contains allergens
- Germination/defense expression

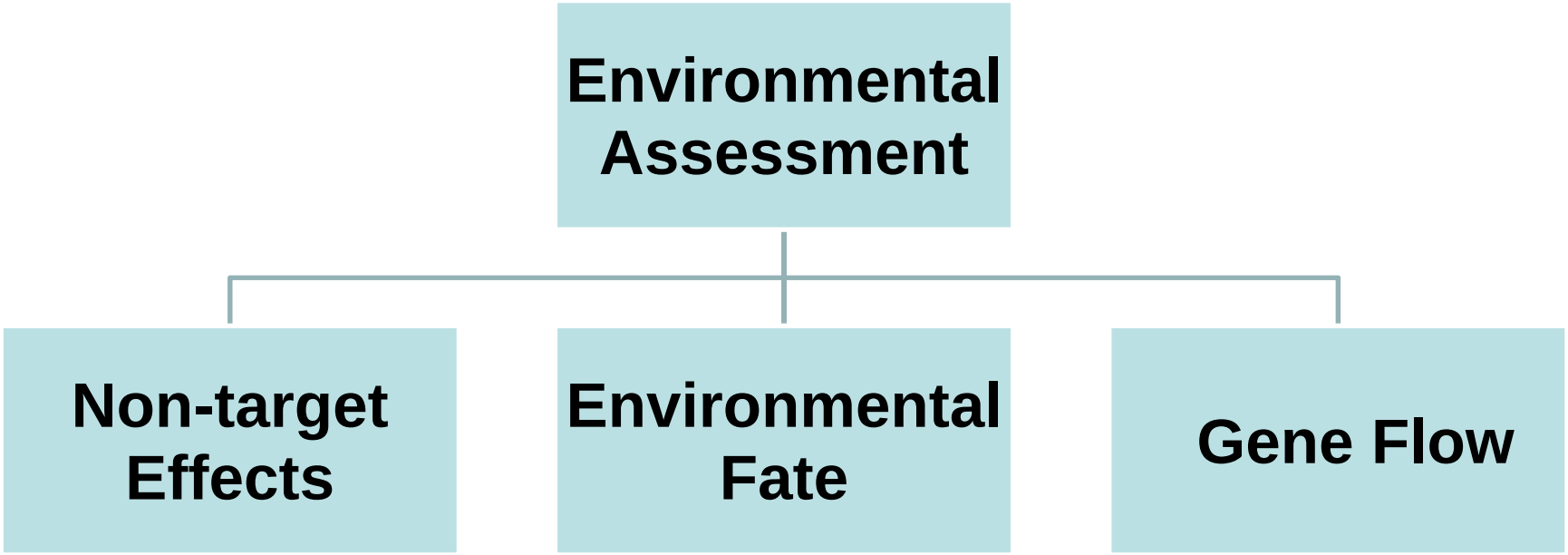
OxOx Peanut

- **No detailed formal submission**
- **Active- promoter + OxOx gene + terminator**
- **Marker – resistance gene**
- **Insert number not definitive**
- **Last conversation indicated still in screening process for final selections based on field performance.**

Regulatory Considerations

- Trait with history of consumption and exposure
- Protein has no homology with known toxins or allergens –but protein family with allergens
- Food tolerance exemption for DNA and marker protein
- No information on OxOx stability to protesases, heat or environmental factors
- No initial cross pollination issues based upon primarily self pollinating

How EPA Assesses Environmental Effects for PIPs



Environmental Assessment

- **Wild mammal toxicity**
- **Aquatic invertebrate toxicity**
- **Freshwater fish toxicity**
- **Non-target arthropod toxicity**
- **Honeybee toxicity**
- **Estuarine / Marine organism toxicity**
- **Microbial community testing**

Regulatory Considerations

- **No initial gene flow issues based upon ploidy differences with native species <u>but</u> not confirmed**
- **No information on OxOx stability to protesases or environmental factors**
- **No information on possible effect on microbial cycling processes**

Useful websites

- **http://www.epa.gov/oppbppd1/biopesticides/pips/index.htm**
- **http://www.epa.gov/pesticides/biopesticides/reg_of_biotech/eparegofbiotech.htm**