The Human Health Assessment Branch (HHA) has two major functions: review of toxicology studies and preparation of risk assessments to estimate the potential adverse health effects in humans associated with pesticide use in California. DPR requires registrants of pesticide products to submit data on a product’s potential chronic, sub-chronic, and acute health effects. The Data Review Section (DRS) reviews the submitted toxicology data for adequacy and indications of possible adverse health effects. The results of these reviews are combined with risk assessment and exposure monitoring/modeling to develop a risk characterization document (RCD). The RCD outlines the key findings and inform the risk manager in public health decisions.

Imidacloprid is a neonicotinoid insecticide to control insect pests on agricultural and nursery crops, structural pests and parasites on companion animals. The effects of imidacloprid chronic exposure on human health depend on many factors such as the exposure dose, length/frequency of exposure, and the inter individual variability. The cumulative efforts of HHA informs policy makers and other DPR branches of the potential effects of imidacloprid on human health.

Data review staff scientists review the data for new active ingredients and new products containing currently registered active ingredients, label amendments on registered products including major new uses, and re-evaluation of currently registered active ingredients.

### What Type of Data is Needed?
- **Formulated Products:** Acute six-pack studies (acute oral, acute inhalation, acute dermal, primary eye and skin irritation, and dermal sensitization)
- **New A1:** The type of A1 (i.e., chemical, biochemical, microbial, antimicrobial) dictates study requirements: acute, subchronic, animal metabolism, neurotoxicity, chronic, genotoxicity, immunotoxicity, etc.
- **Adverse Effects Reports**

### Review Toxicity Studies

#### Toxicity Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Acute oral</th>
<th>Acute dermal</th>
<th>Acute inhalation</th>
<th>Acute dermal sensitization</th>
<th>Subchronic oral</th>
<th>Subchronic dermal</th>
<th>Subchronic inhalation</th>
<th>Subchronic dermal sensitization</th>
<th>Chronic oral</th>
<th>Chronic dermal</th>
<th>Chronic dermal sensitization</th>
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<tbody>
<tr>
<td>Category I</td>
<td>&gt;15mg/kg</td>
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<td>&gt;15mg/kg</td>
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<td>Category II</td>
<td>3-15mg/kg</td>
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<td>30-150mg/kg</td>
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<td>Category III</td>
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<td>Category IV</td>
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<td>0-0.3mg/kg</td>
</tr>
</tbody>
</table>

#### Developmental Toxicity

**Insecticide**

- **Tempidril:** READY-TO-SPRAY
  - **Neonicotinoid Insecticide**
  - **Use Restrictions**
  - **Signal words:** DANGER, WARNING, CAUTION
  - **Precautionary language:** Personal Protective Equipment (PPE)
  - **Reentry Interval (REI):**
  - **First Aid Statements:**

#### Chronic No-Observed Effect Levels (NOELs) of Imidacloprid

<table>
<thead>
<tr>
<th>Chronic Study</th>
<th>NOEL mg/kg/day</th>
<th>Toxic Effects</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat Oral 5 days</td>
<td>5.3</td>
<td>Mutilated pellets in forebrain (males, 65%*** hematoxylin)</td>
<td>Bicker and Kubisz, 1991; Ens, 1991</td>
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<tr>
<td>Mouse Oral 47 days</td>
<td>47</td>
<td>Reduced body weight (10%* index)</td>
<td>Wataha-Gebert, 1991; 1992</td>
</tr>
<tr>
<td>Dog Oral 2 weeks</td>
<td>15</td>
<td>Low notal disturbances</td>
<td>Allen et al., 1989</td>
</tr>
</tbody>
</table>

#### Data Review of Imidacloprid

**Toxicity Summary of Imidacloprid**

- **Species:** Rat, Rabbit
- **Exposure:** Oral
- **NOEL:**
- **Study Description:**
  - **Rat:** 25 days dose
  - **Rabbit:** In-dose bone
  - **Species:** (IDG-0, 33-day in-dose bone)
  - **Study:** Developmental Toxicity of Imidacloprid in the Rat and Rabbit

**Further Toxicity Studies**

- **Developmental Toxicity of Imidacloprid in the Rat and Rabbit**
  - **Study Period:** 14 days
  - **Exposure Route:** Oral
  - **NOEL:**
  - **Study Description:**
    - **Species:** Rat, Rabbit
    - **Exposure:** Oral
    - **NOEL:**
    - **Study Description:**
      - **Species:** Rat, Rabbit
      - **Exposure:** Oral
      - **NOEL:**
      - **Study Description:**
        - **Species:** Rat, Rabbit
        - **Exposure:** Oral
        - **NOEL:**
        - **Study Description:**
          - **Species:** Rat, Rabbit
          - **Exposure:** Oral
          - **NOEL:**
          - **Study Description:**

**Further Toxicity Studies**

- **Developmental Toxicity of Imidacloprid in the Rat and Rabbit**
  - **Study Period:** 14 days
  - **Exposure Route:** Oral
  - **NOEL:**
  - **Study Description:**
    - **Species:** Rat, Rabbit
    - **Exposure:** Oral
    - **NOEL:**
    - **Study Description:**
      - **Species:** Rat, Rabbit
      - **Exposure:** Oral
      - **NOEL:**
      - **Study Description:**
        - **Species:** Rat, Rabbit
        - **Exposure:** Oral
        - **NOEL:**
        - **Study Description:**
          - **Species:** Rat, Rabbit
          - **Exposure:** Oral
          - **NOEL:**
          - **Study Description:**

**Toxicity studie...