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Case Study: Phosmet (Imidan)

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Overview

- Basic Information about Phosmet
- Use description and label information
- Regulatory History
- Database
- Importance in agriculture
- Biological opinion # 3 and opportunities for input from stakeholders
- Concluding remarks

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Basic Information about Phosmet

- First registered for use in 1966
- 99% sold as a wettable powder in water soluble bags 70-W, a 5% Dust only for use on Sweet Potatoes in the South
- Controls pests by both contact and ingestion activity
- Broad spectrum control of worms, beetles, flies and other pests.
- Broad label –most fruit and nut crop groups and a few row crops.
- Not systemic but Phosmet is absorbed into the wax layer of the leaf in the plant, this provides better residual and reduced wash-off
- Phosmet degrades rapidly in soil

Registered For Use On

USA Crops

- Pome Fruit
- Stone Fruit
- Potato
- Citrus
- Tree Nuts
- Cranberries
- Blueberries
- Grapes
- Alfalfa
- Peas

Label Statements: Environmental

ENVIRONMENTAL HAZARDS

- This chemical can contaminate surface water through aerial and ground spray applications. Under some conditions, it may also have a high potential for runoff into surface water after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas overlaying tile drainage systems that drain to surface water.
- This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.
- This product is highly toxic to bees exposed directly to application residues on crops. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. Protective information may be obtained from your Cooperative Agricultural Extension Service.

Label Statements: Spray Drift

SPRAY DRIFT MANAGEMENT

Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals. Avoiding spray drift is the responsibility of the applicator. The interaction of many equipment and weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making applications.

For overhead chemigation:
Apply only when wind speed is 3-10 mph.

For ground boom applications:
Apply with nozzle height no more than 2 feet above the ground or crop canopy, and when the wind speed is 3-10 mph at the application site as measured by an anemometer. Use a coarse or coarser spray (ASABE definition S572) for standard nozzles, or a volume mean diameter (VMD) of 385 microns or greater for spinning atomizer nozzles.

For airblast applications:
Do not direct spray above trees and vines, and turn off outward pointing nozzles at row ends and when spraying the outer 2 rows. Apply only when the wind speed is 3-10 mph at the application site as measured by an anemometer.

For aerial applications:
If the application includes a no-spray buffer zone, do not release spray at a height greater than 10 feet above the ground or crop canopy. Apply only when the wind speed is 3-10 mph. Use a coarse or coarser spray (ASABE definition S572) for standard nozzles, or a volume mean diameter (VMD) of 385 microns or greater for spinning atomizer nozzles. Aerial applicators must consider flight speed and nozzle orientation in determining droplet size. The boom width must not exceed 75% of the wingspan or 90% of the rotary blade. When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind.

The applicator also must use all other measures to control drift.

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Label Statements: Spray Drift

SPRAY DRIFT RESTRICTIONS

Do not apply this product in a manner inconsistent with the Best Management Practices summarized below:

1. Use the largest drop size consistent with acceptable efficacy. Formation of very small droplets may be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible and by avoiding excessive spray boom pressure.

2. For aerial applications, release spray at the lowest height consistent with efficacy and flight safety. For applications other than those on potatoes, if the application site is within 50 feet of a permanent water body, do not release spray at a height greater than 10 feet above the ground or crop canopy. For applications to potatoes, if the application site is within 150 feet of a permanent water body, do not release spray at a height greater than 10 feet above the ground or crop canopy.

3. For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy.

4. Make aerial or ground applications when the wind velocity favors on-target product deposition. Apply only when the wind speed is 3 to 10 mph. For all non-aerial applications, wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application.

5. Do not make aerial or ground applications into areas of temperature inversions. Inversions are characterized by stable air and increasing temperatures with increasing distance above the ground. Mist or fog may indicate the presence of an inversion in humid areas. Where permissible by local regulations, the applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface.

6. Low humidity and high temperatures increase the evaporation rate of spray droplets and therefore the likelihood of increased spray drift. Avoid spraying during conditions of low humidity and/or high temperatures.

7. All aerial and ground application equipment must be properly maintained and calibrated using appropriate carriers.

8. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy.

9. For ground-boom, chemigation, orchard or other airblast applications, do not apply within 25 feet of permanent water bodies (rivers, natural ponds, lakes, streams, reservoirs, marches, estuaries, or commercial fish ponds).

10. For aerial application to crops other than potatoes, do not apply within 50 feet of permanent water bodies. For aerial applications to potatoes, do not apply within 150 feet of permanent water bodies.

Registered in over 20 countires

- Gowan is supporting the label with registrations in more than 20 countries with labeled uses similar to those in the US
  - North America
  - Europe
  - South America
  - Asia
  - Africa and Middle East
- Gowan is the sole supporter and registrant of agricultural uses in the US, Europe and other countries

Regulatory History

- 1966: First registered
- 1986: Issuance of Registration Standard and DCI (Data Call-In)
- 1990: Gowan assumes registrations
- 2001: Food Quality Protection Act (FQPA) Interim Reregistration Decision (IRED) issued
- 2004: PMRA Review
- 2006: FQPA Final RED
- 2007: EU Annex 1 inclusion
- 2008: JMPR – CODEX reevaluation
- 2009: Initiation of Registration Review
- 2010: Brazil Reregistration

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Regulatory Database

- Complete database
- New Part 158 requirements underway
  - Immuno tox, Passerine bird, vegetative vigor and seedling emergence
- Endocrine testing underway
- Complete Annex 1 and Annex 3 dossiers for the EU
- Fulfilling DCI requirements from Registration Review

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Importance to Agriculture

- Proven efficacy and crop safety
- One of the few broad spectrum insecticides left
- Broad label for tree fruit, nuts and berries
- MRLs in place around the world
- Registrations around the world

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Biological Opinion # 3

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Conclusions in BiOp Three -12 OPs

- Jeopardy – jeopardize the continued existence of the species – "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of listed species in the wild by reducing the reproduction numbers or distribution of that species." (50 CFR section 402.02)
- Phosmet: jeopardy for some species of salmon and adversely modify critical habitat for several species in certain areas
- A maximum concentration limit of .5 ug/l was suggested
- "NMFS reached this conclusion because predicted concentrations of these nine ais in salmonid habitats, particularly in floodplain habitats are likely to cause adverse effects to listed Pacific salmonids…"

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Specific Elements of the RPA (Reasonable and Prudent Alternative)

- Do not apply when wind speeds are greater than or equal to 10 mph as measured using an anemometer immediately prior to application
- For all uses, do not apply pesticide products when soil moisture is field capacity or when a storm event likely to produce run off from the treated area is forecasted by NOAA/NWS to occur within 48 hours
- EPA will implement NMFS approved risk reduction measures to insure maximum concentrations of the ais predicted will not exceed the maximum concentration limit: buffers, vegetated filter strip, reduction in max single or seasonal application rate, etc.
- Report all incidents of fish mortality that occur within 4 days of application within the vicinity of the treatment area to EPA (OPP) or to the registrant for 6(a) 2 filing.

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Opportunities for input from Stakeholders to refine conclusions

- Estimates about use
  - Typical use rate and number of applications
  - Timing of applications
- Labels and uses on labels
- Tank mixes
- Cultural practices
- Actual Data

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Biological Opinion # 3

Assumptions about use in BiOp

- The greatest use of phosmet occurs in apples (600,000 lbs/year), peaches (300,000 lbs/year), and almonds (200,000 lbs/year)
- Twelve other crops are estimated to receive more than 20,000 lbs of phosmet per year (EPA 2008c). The most recent pesticide use report available for California indicates that phosmet use between 1997 and 2007 was variable and ranged from a low of 342,000 lbs in 2003 to a high of 658,000 lbs in 2004.
- In 2007 over 421,000 lbs of phosmet was applied for agricultural uses in California
- Reported use of phosmet within the freshwater distribution of listed salmon ranged from 3,000 lbs (Northern California steelhead) to over 100,000 lbs (California Central Valley steelhead) based on county totals reported in California during 2001
- Use estimates were not provided for other states although the biological evaluation provided estimates of total areas that might be treated with phosmet within the distribution of listed salmonids in Idaho, Oregon and Washington

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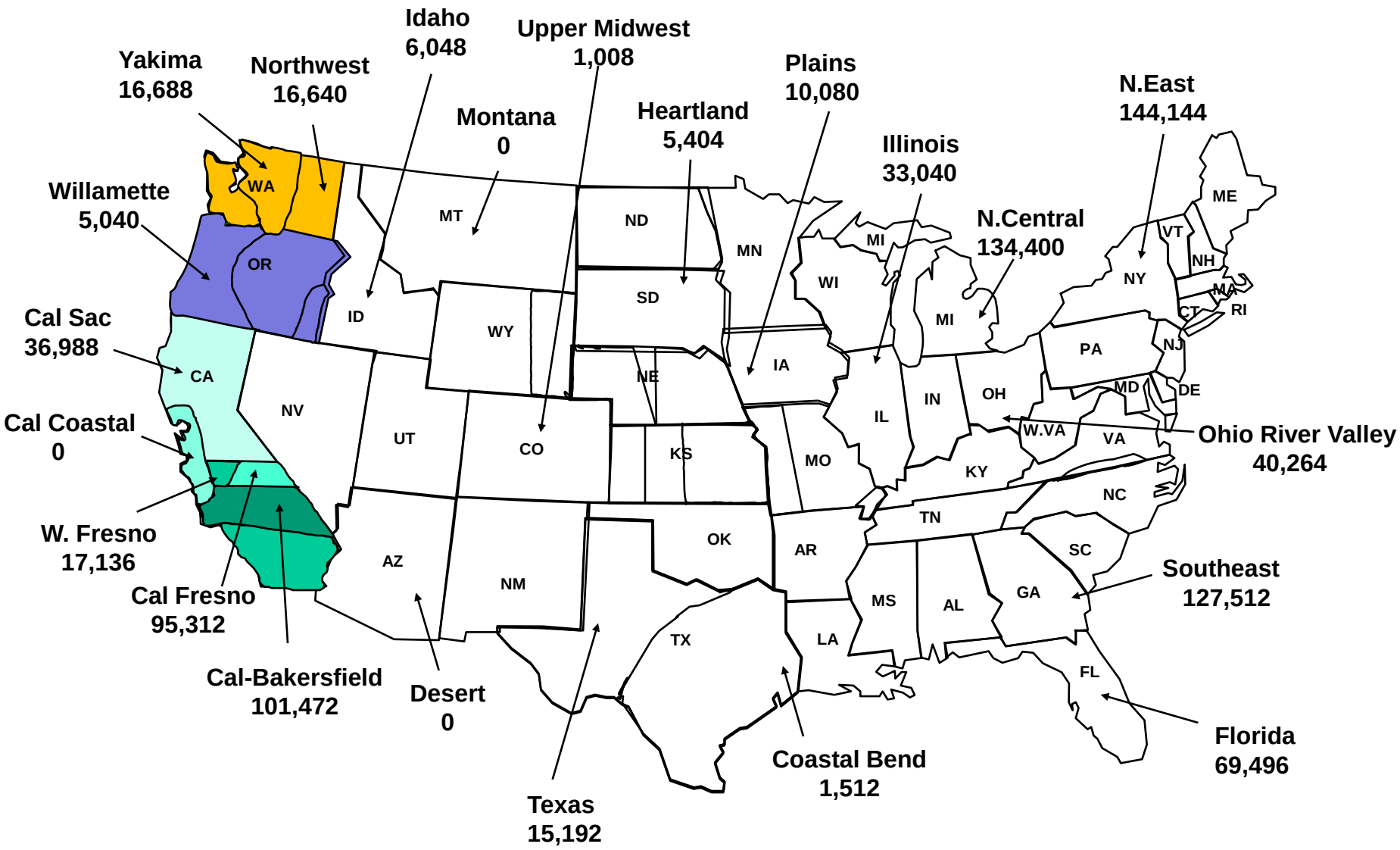
Confirmation of actual rates used per app, seasonal max and number of applications

- California 100% Use Reporting Data
- Data from other States and other gov't sources
- Sales Data from Registrants
- Private Data bases – GfK/Kinetic, CDMS, etc.

Sales Territories



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Assumptions about labeled uses

- Types of uses
  - Assumed –ag, non-ag, animal
  - Refinement – confirm changes already made –no homeowner use and scope of other uses
- Max number of applications
  - Assumed - not specified on all labels
  - Refinement –on ag labels in use in the US
- Max seasonal amount applied
  - Assumed - not specified on all labels
  - Refinement –on ag labels in use in the US
- Type of application method –air, ground, etc.
  - Assumed - all methods employed
  - Refinement – characterization of actual of air versus ground

Assumptions about Tank Mixes

- Assumption
  - "some labels encourage the use of more than one AChE inhibiting insecticide"
  - Multiple OPs in the tank mixes
- What we know and can document
  - No other OP is tank mixed with Imidan
  - If a tank mixer partner –a fungicide or miticide
  - No other AChE inhibiting product used with Imidan

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Actual Data

- Water Monitoring Data
  - Assumptions, modeling or estimations of levels of phosmet in water
  - Refinement - Actual monitoring data -5000 surface water data points (NAWQA, CDPR, WA, USDA PDP) -4 detections. Highest value seen in waters in salmonid range was .076 ug/l
- Exposure to salmonids
  - Assumed – 96 hours of constant exposure, all salmonids exposed to pesticides at same concentrations
  - Refinement – half life of phosmet in natural water is a few hours at most in some cases less – salmonids would not be exposed to 96 hours of the same concentration

Concluding remarks

- Thank you for the opportunity to engage and share information.
- Understanding the risk assessment process, the drivers of outcomes better allows for opportunities to provide information that can refine the assessments.
- Opportunities for discussion, input and refinements should exist since there are significant adverse consequences for agriculture based on mitigation.