



Past, Present, and Future of Fungicides for FHB

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But you know all of this. I'd like to talk about the chemistries we use to help manage this disease.

One perspective on the campaign to limit the impact of FHB with fungicides

 Bayer CropScience has been a supporter of the Wheat and Barley Scab Initiative and the National Fusarium Head Blight Forum. (Inaugural meeting in 1997)

 Bayer AG was the inventor of tebuconazole, the active ingredient in Folicur.

(Mobay, then Miles, then Bayer CropScience)

Tebuconazole

- Registered in the US for broad-spectrum disease control on peanuts in 1994.
- Identified in mid-1990's as having activity on Fusarium graminearum.
- In 1997 ND, SD, and MN filed for Section 18 specific emergency exception – denied.
- ND, SD, and MN filed for Section 18 crisis exception.
- Time-limited tolerances were originally published in the Federal Register on June 20, 1997. (62 FR 33550) (FRL-5725-7)

Emergency Exemptions

Emergency exemptions can be requested by a state or federal agencies when a serious pest problem jeopardizes production of agricultural goods or public health but no pesticides are currently registered for that situation. They submit information describing the pest emergency and request permission to use a specific pesticide even though it is not currently registered for that use.

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the EPA to allow an unregistered use of a pesticide for a limited time if we determine that an emergency condition exists.

Specific Emergency Exemptions

- Requested when an emergency conditions exists, in order to avert a significant economic loss, ...
- Growers or agricultural research scientists identify a pest situation that registered pesticides will not alleviate.
- State pesticide agency requests an emergency exemption from EPA.
- We evaluate request and decide whether or not to authorize use.
- Specific exemptions may be authorized for up to one year.

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Crisis Emergency Exemptions

- Requested when there is an immediate need for a specific, quarantine, or public health exemption.
- Following communication with us and our clearance, state lead agency or federal agency may issue a crisis exemption allowing the unregistered use to proceed for up to 15 days.
- We confirm that the appropriate safety findings can be made.
- The request for a crisis exemption may be followed by a request for a specific, quarantine or public health emergency exemption request.

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- Tolerance petition and application for use on wheat was submitted to EPA on July 18, 1997

UWBSI Uniform Trials

- From 1998 to the present, products are tested across a broad geography on multiple types of wheat.
 - New and old products have been included
 - Some were less effective or ineffective
 - Some increased mycotoxins
- Tebuconazole (Folicur) was considered the most effective product available.
- However, not all cereal growers could use Folicur.

Folicur Regulatory Actions

- Between 1998 and 2008, multiple states filed for specific emergency exemptions.
 - Laborious process (lengthy petitions)
 - Cooperative process (pathologists, growers, etc.)
- Folicur could be used ONLY by growers in those states, and ONLY for Fusarium head blight suppression.
- 12 years of emergency exemptions.

Folicur Regulatory Actions

 Folicur was first registered for cereals in May of 2008.

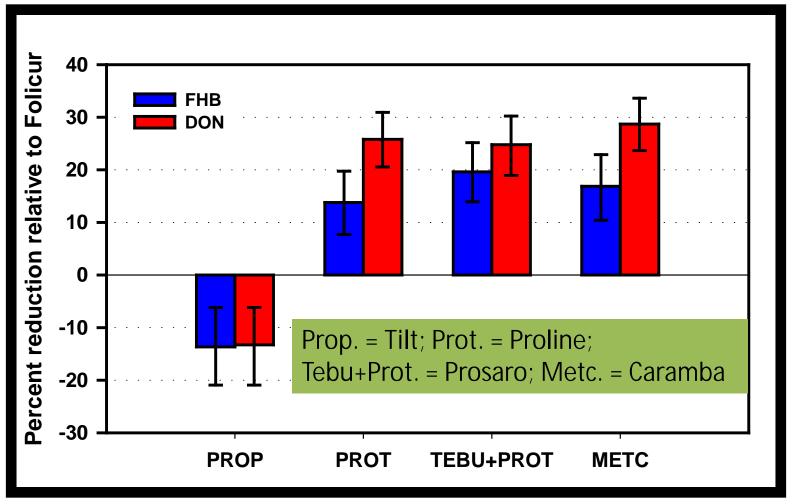
What happened in between 1997 and 2008?

- Priority system with EPA delayed the review.
- In 2000 EPA halted its review of petitions for new uses of triazole-containing products.
 - Concern about 1,2,4-triazole and its conjugates.
- In 2006 EPA determined the risk assessments were conservative and would be supported.

Changes in 2008

- Multiple products that contained triazole chemistries were registered.
 - Caramba in April
 - Folicur early in May
 - Prosaro late in May
- Now all cereal farmers had expanded options for disease control, especially FHB.

How do the options stack up to Folicur?



From Paul et al., Phytopathology 98:999-1011(2008); Summary over 12 states, multiple years

Current Standards and Practices

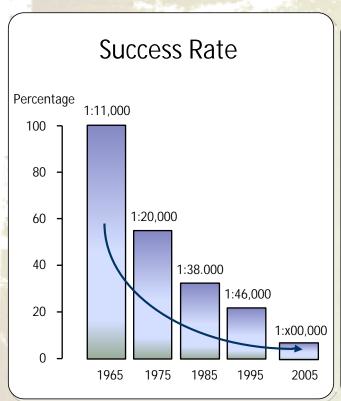
- Prosaro and Caramba are viewed as the best performing products against FHB*.
 - Prosaro = 52% FHB reduction; 42% DON reduction
 - Caramba = 50% FHB reduction; 45% DON reduction
- However, they should be viewed as a component of an FHB management program.
 - Utilize crop rotation to reduce inoculum
 - Plant resistant varieties
 - Vary varietal maturity
 - Timely and high quality applications

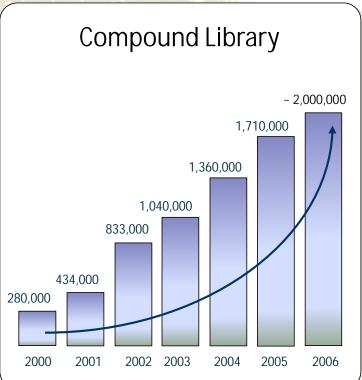
^{*}Paul et al., Phytopathology 99:999-1011 (2008)

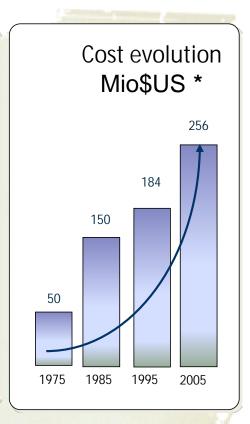
Considerations for the future

- Current options are pretty good
- New products must be even better
- Current standards leave room for improvement
 - Higher level of activity
 - Wider application window

Success rates in the past and today...

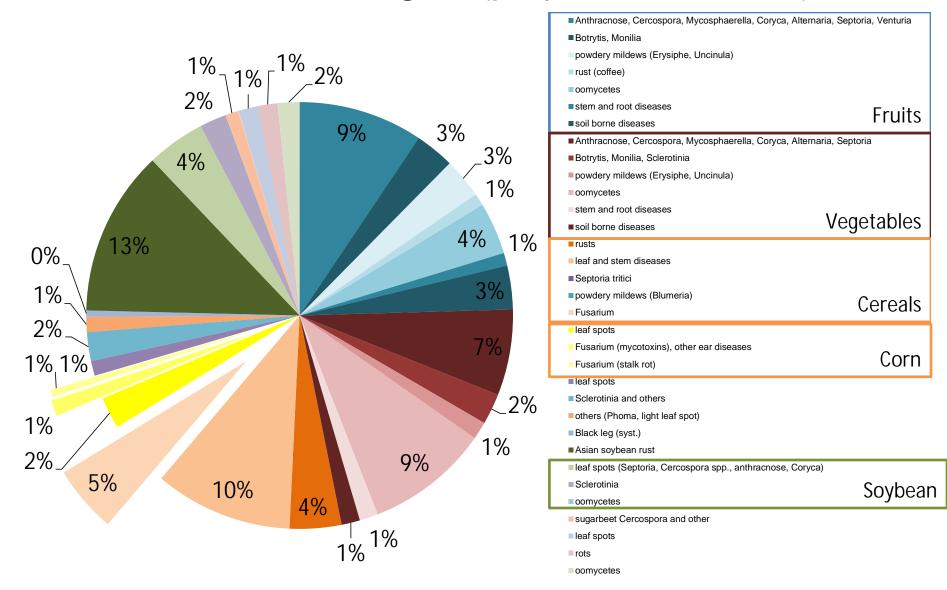




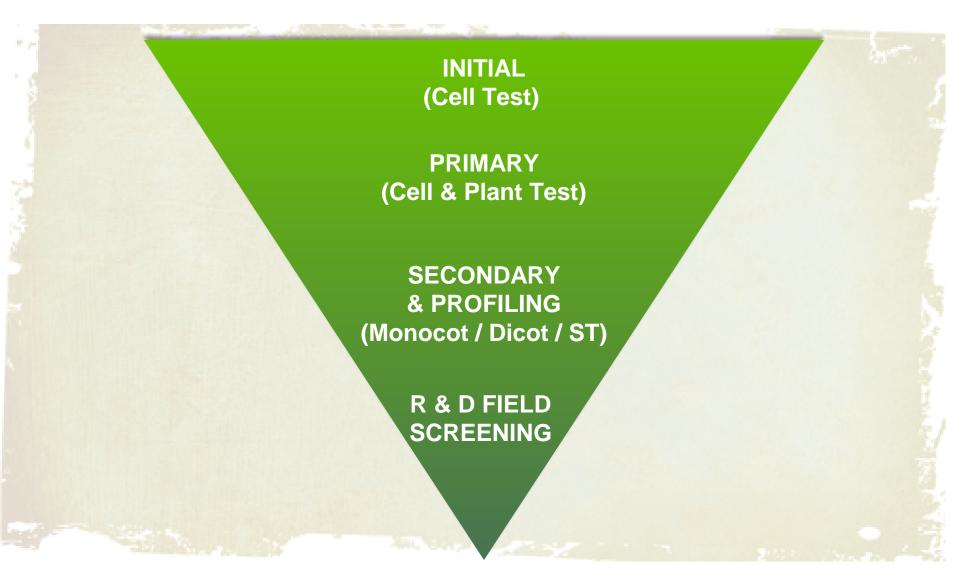


- Finding a new crop protection compound is an expensive numbers game.
- Automation and miniaturization are virtually manditory.

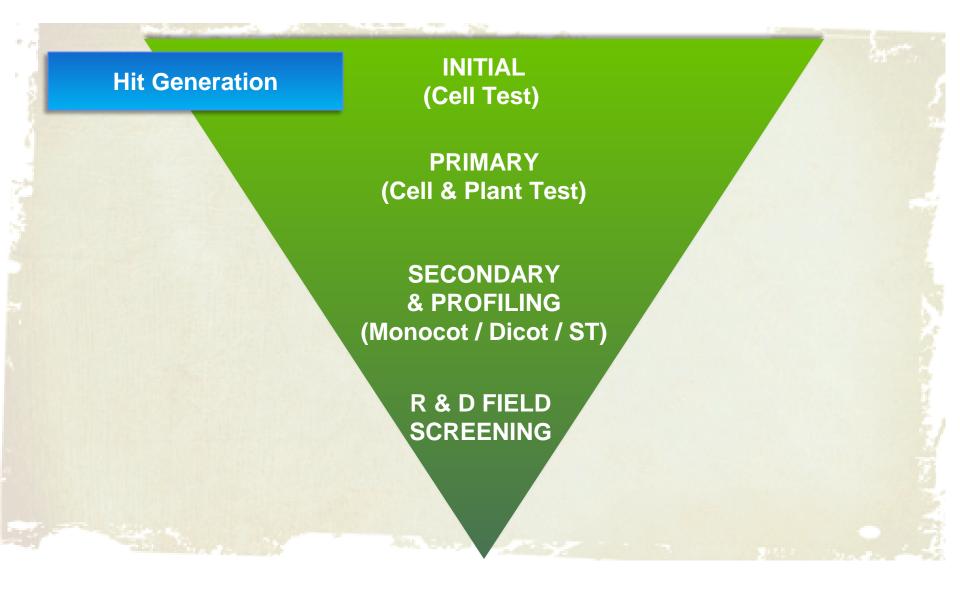
Estimated/expected size of fungicide segments as evaluated for R&D targets (projection for 2025)



Screening Cascade



Screening Cascade

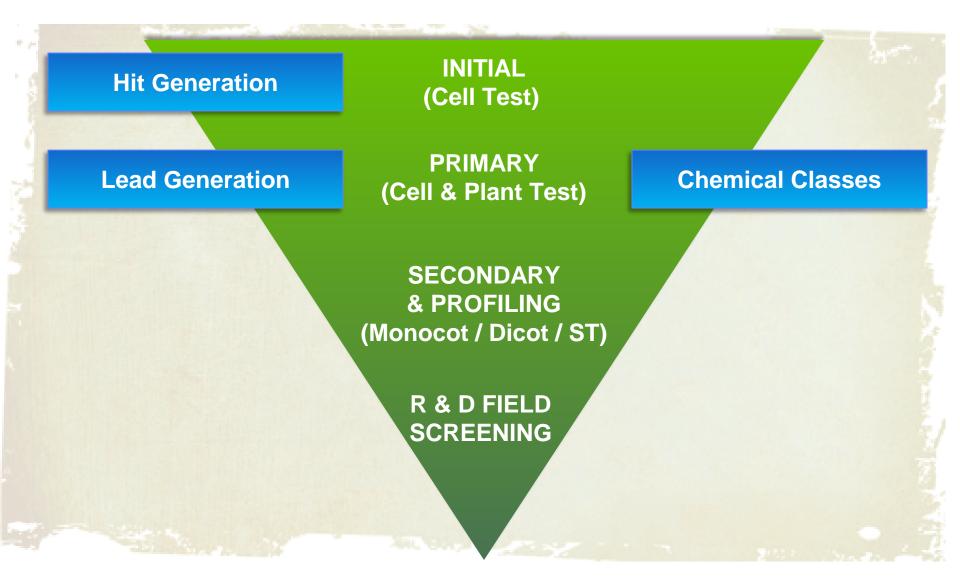


Cell Testing



Extensive use of robotics and scanners.

Screening Cascade



Plant Testing

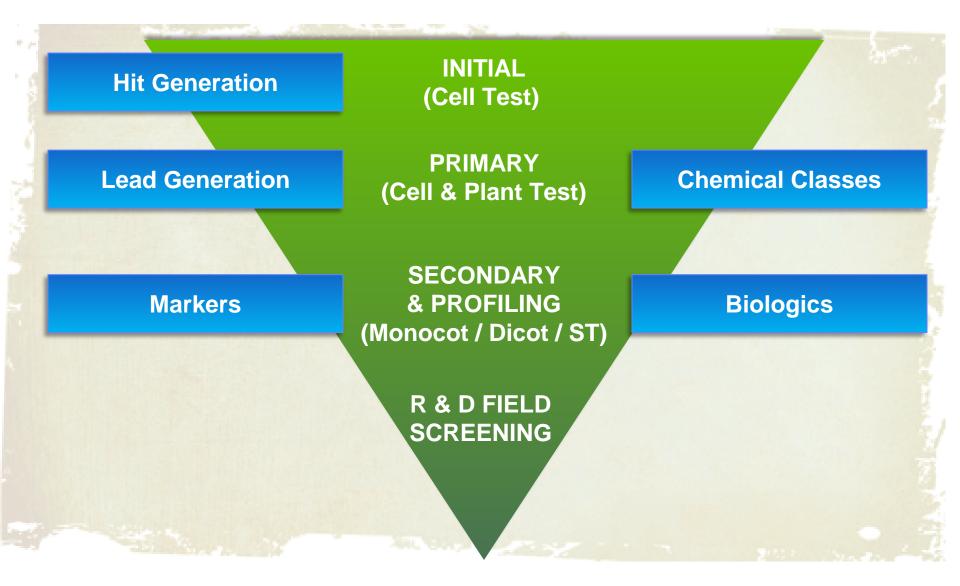


Each pot has a QR code for tracking.

Spray Cabinets



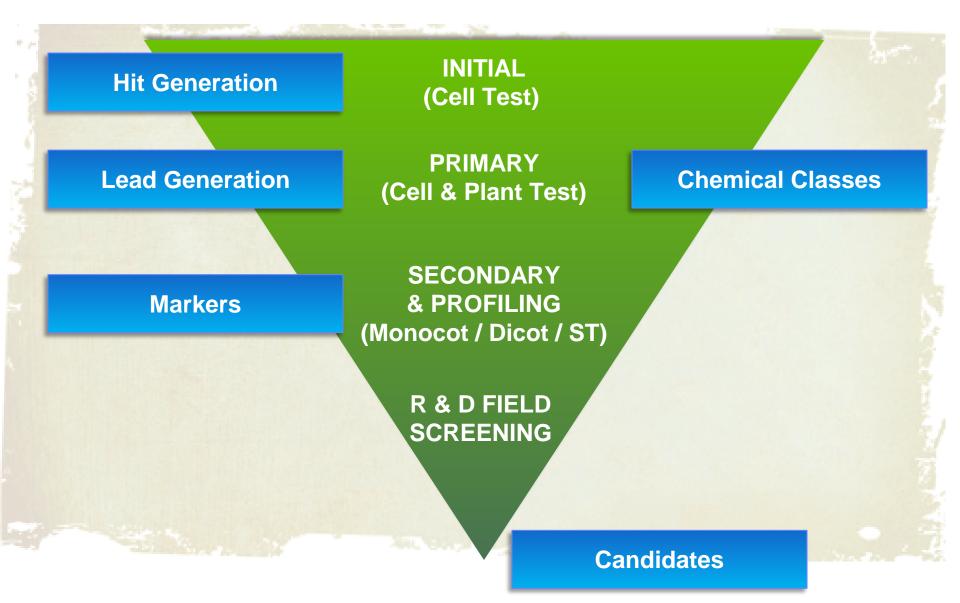
Screening Cascade



Micoplot Testing



Screening Cascade



Characterization Testing

- Formulation development
- Rainfastness
- Effect of adjuvants
- Handling features



Registerability

Assessments conducted to support registration include:

- Human health dietary risk (acute, chronic, and/or carcinogenic as applicable)
- Aggregate risks (drinking water, non-occupational)
- Cumulative risks (common mechanism of toxicity)
- Occupational Exposure (mixers, loaders, applicators, scouts, harvesters, etc.)
- Environmental exposure and risks (ecotoxicology)

New tools will be coming for FHB

- This is an area of interest.
- It takes time.
- It demands significant resources.
- The process requires cooperation.



Thanks for the opportunity to speak with you.

Any questions I might answer?