Dicamba Diary

Part II: Regulatory Milestones
1960-2017

1960s:

- 1967: First Government Action
- 1968: Toxicology Review

First Regulatory Actions

Developed for the Children's Environmental Health Network Healthy Kids Project.


Contact Info: charlesbenbrook@gmail.com
1967: First Government Action

1967: First known government action, temporary tolerance petition for grain sorghum, at 2.0 parts per million (ppm).

1968: First toxicology review of dicamba.

1990s:

Dicamba Tolerances Documented

- 1996: Soybean Tolerances 0.05-1.0 ppm
- 1996: Food Quality Protection Act Passed
- 1998: EPA Chimes in on Health Risks
- 1999: Dramatic Increase in Tolerances
- 1999: EPA Applies 10-X Safety Factor

1996:
Soybean Tolerances 0.05-1.0 ppm

- Soybean grain tolerance 0.05 ppm
- Soybean hay and forage at 1.0 ppm

Source: EPA’s comprehensive listing of tolerances issued as part of Food Quality Protection Act (FQPA) implementation (EPA, 1999b).

1996: Food Quality Protection Act Passes

The Food Quality Protection Act (FQPA) was signed into law by Bill Clinton on August 3, 1996.

This seminal legislation was designed to more fully protect pregnant women, infants, and children from the reproductive and developmental effects of pesticides.

1996, Subtopic: The "Risk Cup"

EPA introduces the concept of the “risk cup” in implementing the FQPA. The volume, or size, of the “risk cup” is set by the pesticide’s maximum, acceptable daily exposure aka the pesticide’s chronic Reference Dose (cRfD).

The more toxic the pesticide, the smaller the allowed “risk cup.”

EPA also requires EPA to apply an additional 10-fold safety factor when setting cRFDs and evaluating tolerances, to more assuredly protect vulnerable populations (i.e. pregnant women, infants and children). The EPA Administrator can reduce or drop this added safety factor if developmental risks are well characterized, and the agency has solid data to estimate exposures.

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**1998: EPA Chimes in on Health Risks**

EPA determines dicamba cancer risk is "not classifiable" because the maximum tolerable dose was not achieved in required cancer studies.

Plus, EPA acknowledges it lacks data to quantify drinking water exposures -- usually the most significant source of herbicide exposure in the diet.

**1999: Dramatic Increase in Tolerances**

January 6, 1999: Final rule establishes, revokes, and revises various dicamba tolerances.
- Increases soybean tolerance to 10 ppm, from 0.05 ppm, a 200-fold increase!

Animal Feed Tolerances:
- Increase soybean forage and hay tolerances to 125 ppm and 200 ppm respectively, more than a 10,000-fold increase.
- Establishes new tolerance in aspirated grain fractions at 5,100 ppm.
1999: EPA Applies FQPA 10-X

Dicamba cRfD based on a NOAEL (No Observable Adverse Effect Level) of 45 mg/kg/day in a multi-generation rat reproduction study. (EPA, 1999a)

Key Action: EPA applies the added, FQPA 10-X safety factor, lowering the dicamba cRfD from 0.45 mg/kg/day, to 0.045 mg/kg/day.

(cRfD = chronic Reference Dose, the maximum amount of daily, dietary exposure deemed acceptable by EPA).

1999, Subtopic: Trouble on the Horizon

71.1% of this new, lower dicamba cRfD/cPAD* is taken up by existing uses/dietary exposure for non-nursing infants <1 year old, and 54.8% for children 6 years old.

71% of the cPAD taken up ten years BEFORE the huge increase in dicamba use that began around 2010 – trouble on the horizon.

*When an added safety factor called for by the FQPA is applied, a cRfD becomes a cPAD = chronic Population Adjusted Dose.

2000s:

New Tolerances and Reregistration

2000

Up to 200-fold Increase in Tolerances

2006

EPA Releases
Dicamba RED

mg/kg/day
2000: Up to 200-fold Increase in Tolerances

EPA reissues all 60 dicamba tolerances:

- Corn grain and forage tolerance = 0.5 ppm
- Barley grain 6 ppm, barley straw 15 ppm
- Soybean hulls tolerance set at 13 ppm
- Aspirated grain fractions remains at 5,100 ppm!! (EPA, 2000)

(5,100 ppm = 5.1 parts per 1,000 = 0.51 part per 100, or ½ of 1%!!)

2006: EPA Releases Dicamba RED

EPA issues dicamba Reregistration Eligibility Document (RED).

The agency drops the added, 10-X FQPA safety factor, raising the crfD back to 0.45 mg/kg/day

**Why did EPA drop the 10-X safety factor?**

*Impact of dropping the FQPA 10-X?*


2006, First Subtopic (Question Mark), Stacked Slide (1/2): Justification for Dropping Dicamba’s 10-X Safety Factor

EPA states in the 2006 RED:

“The FQPA Safety Factor has not been retained for dicamba because acceptable developmental and reproduction studies have been submitted and reviewed, there is a low concern and no residual uncertainties for pre- and postnatal toxicity, and the dietary and the residential assessments are not expected to underestimate exposure.” (EPA, 2006)
2006, First Subtopic, Next Slide (2/2):

This important action received little attention at the time.

A strong case can be made for restoring the FQPA 10-X safety factor based on uncertainty in EPA’s exposure estimates, recent dicamba drift and volatilization episodes, and peer-reviewed studies linking dicamba exposure to human reproductive problems and birth defects.

See the Children’s Environmental Health Network’s Herbicide Use and Birth Outcomes in the Midwest project website for more: http://cehn-healthykids.org/

2006, Second Subtopic (Domino): Impact of Dropping the 10-X Safety Factor?

Adding the 10-X would lead to a cPAD of 0.045 mg/kg/day -- leaving little room for growth in dicamba uses and exposure.

Without this 2006 EPA action, Monsanto would not have invested billions in development of Xtend, dicamba-resistant crop technology, nor in the new chemical plants needed to manufacture dicamba herbicide.

A coincidence?? – In 2005, Monsanto completed the deal with the University of Nebraska, gaining exclusive, global rights to apply the University’s dicamba-resistant technology to crops.

2006, Third Subtopic (Baby): EPA’s 2006 Dietary Risk Assessment

Children aged <1 are the most heavily exposed group.

Current, 2006 uses and tolerances, and water account for 11% of the cRfD of 0.45 mg/kg/day.

For children aged 1-2, current uses and water account for 7.6%.

If the FQPA 10-X had been retained, some children would have been overexposed – 10 years before the first acre is planted to a dicamba-resistant soybean or cotton crop!
2010s:

Dicamba is very prone to volatilization and drift and can cause extensive damage to sensitive crops including soybeans and specialty crops like tomatoes and grapes.

As Monsanto pursues EPA approval of dicamba-resistant crops, farmers, scientists, and public interest groups warn that increased use of dicamba will result in extensive damage to non-target crops.

2010-2013, First Subtopic (Farmers): Farmers Raise Concerns

In 2010, Steve Smith, the Director of Agriculture at Red Gold, the largest canned tomato processor in the U.S., testifies before Congress on the approval of dicamba-resistant soybeans.

He reports that the use of dicamba will seriously impact non-herbicide-resistant crops. He calls this "the single most serious threat to the future of the specialty crop industry," valued at $254 million in his home state of Indiana alone (Smith, 2010).

"The widespread use of dicamba is incompatible with Midwestern agriculture." — Steve Smith, Red Gold
2010-2013, Second Subtopic (Scientists): Scientists Raise Concerns

In a 2012 paper in the journal *BioScience*, David Mortensen et al point out the high volatility of dicamba and warn of "frequent incidents of significant injury or yield loss to susceptible crops."

"Agronomic drivers suggest that once an initial number of growers in a region adopt the resistant traits, the remaining growers may be compelled to follow suit in order to reduce the risk of crop injury and yield loss." (Mortensen et al., 2012)

2010-2013, Third Subtopic (Public Interest Groups): Public Interest Groups Raise Concerns

NGOs also submit comments to EPA about the pending approval of dicamba-resistant soybeans:

The Center for Food Safety warns of a "huge increase in the use of dicamba herbicide in American agriculture," resulting in rapid development of resistant weeds, expanded risk of human and environmental exposure, and "much increased crop damage" from drift. (Center for Food Safety, 2012)

Zooms to:

The Save Our Crops Coalition, a grassroots collection of farmers and farm interests set up to prevent injury on non-target crops from dicamba and 2,4-D based herbicides, also submit formal comments. SOCC stresses that:

- Dicamba "has proven to be one of America's most dangerous herbicides for drift damage" (Smith, 2012).
- Data from farmer surveys backs this up - although dicamba is not one of the top 15 most used herbicides in the country, it was one of the most cited for drift complaints, appearing on 70% of top-5 lists in 10 Midwestern states (AAPCO, 2005).
- In many specialty crops, no established tolerance exists for dicamba so any residues will "render crops unmarketable" (Smith, 2013).
Citing damage to non-target crops from dicamba drift (see photo), The Save Our Crops Coalition (SOCC) petitions EPA to conduct a review of dicamba herbicides, calling for use restrictions (Smith, 2016a).

Dicamba amounts as low as 1/300th of the soybean application rate cause significant loss in tomatoes (Smith, 2016a).

In an open letter to Monsanto, SOCC urges the company to address drift and crop damage problems, highlighting:

"That unscrupulous applicators will apply non-labeled generic forms of dicamba that are prone to off-target movement if such generic forms cost less, and, That dicamba application later and later in the growing season is especially hazardous given dicamba’s propensity to volatilize and drift as temperatures rise" (Smith, 2016b).

The first dicamba-resistant soybeans are planted in 2016, despite no label allowing post-emergent use of dicamba.

Tens of thousands of soybean acres are damaged by dicamba drift from illegal applications on Xtend-brand, dicamba-resistant soybeans.
Fall 2016-Today: Dicamba Watch

See “Dicamba Watch” for more on drift and damage cases in 2016-2017, responses by state and federal regulators, and responses by farmers and ag industry leaders.

Access at:
http://cehn-healthykids.org/herbicide-use/herbicide-timelines/

December 2016: Dicamba cRfD Reduced to 0.04 mg/kg/day-

December 8, 2016

EPA completes “Dicamba and Dicamba BAPMA Salt: Human Health Risk Assessment for Proposed Section 3 New Uses on Dicamba-tolerant Cotton and Soybean.”

Establishes a new dicamba cRfD at 0.04 mg/kg/day. (EPA, 2016c)

December 2016, First Subtopic (Rat): Why a Third Change in Dicamba cRfD Since 1999?

- New rat reproduction study on DCSA metabolite of dicamba (MRID #47899517) submitted to EPA.
- NOAEL of 4.0 mg/kg/day based on reduced rat pup weight.
- EPA drops the added 10-X FQPA safety factor.
- EPA estimates that residues in food and water from current uses utilize 42% of the cRfD for children 1-2 years old, but...
December 2016, Second Subtopic ("Science"): Old Data and Flawed Assumptions Mask Rising Risks

...EPA does not include exposure from the newly approved use on dicamba-resistant soybeans!! Plus...

...EPA assumes only 10% of corn treated with dicamba, while USDA data shows 15% corn acres treated in 2016 (and likely higher in 2017).

Winter 2016: Monsanto Granted Tolerance Increase

December 8, 2016

Final rule establishes new and increases some existing dicamba tolerances, in response to 2010 and 2012 tolerance petitions from Monsanto to cover higher residues in Xtend crops.

- Petition requests soybean forage tolerance of 45 ppm and soybean hay at 70 ppm. (EPA, 2016c)

Winter 2016, Subtopic: Boxed In By Developments

December 2016: With some 4 million acres of Xtend soybeans harvested over the last few months, and under enormous political pressure post-election, EPA approves tolerances at 60 ppm for soybean forage and 100 ppm in soybean hay (EPA, 2016c).

- EPA increases Monsanto-proposed tolerance based on results from the OECD (Organization for Economic Co-Operation and Development) Maximum Residue Level calculation procedure, in accord with current EPA policy (OECD O.K.; International Agency for Research on Cancer (IARC) not so much?).
- Using the OECD procedure is part of EPA harmonization efforts.

(EPA, 2016c)
Using the OECD procedure is part of EPA harmonization efforts.

**Winter 2016: Low-Balling Rising Risks**

EPA’s late-2016 dietary exposure assessment underestimates use in corn, soybeans, and cotton, *and hence* also exposure and risk.

Uncertainty in exposure estimates is *one of two major reasons* in the FQPA for imposing the added, 10-X FQPA safety factor.

**Low-Balling Risks, Subtopic: Compliance With the FQPA Will Curtail, If Not End Xtend Technology**

The added, FQPA 10-X safety factor would lower dicamba’s cPAD to 0.004 mg/kg/day. The strongest statutory reason to do so is major uncertainty in EPA’s dietary exposure estimates.

Updated exposure data reflecting rapidly rising use on corn, soybeans and cotton would likely put estimated exposures in children – and for pregnant women -- over EPA’s “level of concern,” even after EPA “refines” its estimates of exposure.

*But...?*

In crop year 2018, up to 40 million acres will be planted to Xtend soybeans, around one-half the U.S. soybean crop.

Will the Trump Administration’s EPA pull the plug in 2018 on one-half of the nation’s soybean crop?

But...?
July 2017: Drift Damages Lawsuit Filed

Following extensive damage from dicamba drift in 2016, seven farmers from Arkansas file a class action lawsuit against Monsanto, BASF, DuPont and Pioneer in federal court in St. Louis, MO.

The farmer-plaintiffs claim that the companies privately assured farmers in 2016 they could apply existing dicamba products on the new dicamba-resistant soybeans. (Gray, 2017a)

July 2017, Subtopic:

“This was Monsanto’s real plan: publicly appear as if it were complying, while allowing its seed representatives to tell farmers the opposite in person,” the suit alleges. “Their sales pitch: assure purchasers that off-label and illegal uses of dicamba would be just fine.” (Gray, 2017)