

Dicamba Tolerance System Agreement Joint Working Group Updates October 1, 2014





Company Confidential

Working Group Meetings

Participants met in Raleigh, September 22-23, 2014

	BASF	Monsanto
CWG	Dan Steltz, Ron Repage, Bryan Perry, Nathan	Jay Butka, Melinda McCann
RWG	Jeff Birk, Rodrigo Fiorati, Danny O'Byrne	Susan Martino-Catt, Tina Bhakta
DWG	Steve Bowe, Walter Thomas, John Frihauf, Chad Brommer	Joe Sandbrink, Jeff Travers



Commercial Working Group



Stakeholder Outreach

- Regulatory Advocacy
- Independent efforts to coordinate input during comment period
- Joint awareness necessary on all active topics
- BASF/Monsanto bi-weekly dialogue continues
- Industry Affairs, Government Affairs, Communications teams



CWG Follow-up Topics

- Recommendation by CWG to refocus participation in bi-weekly joint regulatory advocacy calls
- Identify opportunities for aligned messaging to the market
- Recommendation by CWG for adoption/ maintenance of state/ federal regulatory advocacy events calendar
- Joint awareness needed
- Coordination when appropriate
- Considerations for development of common messaging
- Recommendation by CWG to revive/ update some efforts from the past
- Joint FAQs
- System benefits
- Application requirements
- Technical bulletins
- CWG work plan updated by next AMT



Regulatory Working Group



U.S. Regulatory Status

- USDA published dEIS for DT crops early August
- Comment period scheduled to end September 25th
- 15 day extension of comment period until October 10th
- EPA registration for OTT use of M1691 expected by end 2014 USDA maintains position - end 2014 for deregulation of DT crops
- MON is in active negotiation with EPA regarding:
- Weed Resistance management
- Stewardship
- Threatened and Endangered species (limited state approval)
- Remaining global trait import and chemistry MRL approvals necessary to keep launch on track



Brazil Submission Strategy

Important Change for Line Swapping in Brazil

- companies to use line swapping strategy Recent indication by ANVISA that they will no longer allow
- Agency released statement related to "equivalent" submissions
- submissions (label extensions, etc.) Informal follow up confirmed agency would not accept for any
- submission of a Dicamax clone (conventional + OTT) Q4 2014 BASF and MON aligned for MON to make new registration
- MON agrees to submit a clone for BASF at the same time
- of Dicamax and Atectra Soy Currently reassessing strategy for the label extension for OTT use
- Teleconference planned for week of October 6th to make final decision



South America Update

Argentina

- Trait, DGA, BAPMA OTT chemistry approval expected by mid 2016
- Commercialization possible for 2016/2017 season

Paraguay

- Trait approved, DGA OTT chemistry approval expected by mid 2016
- Commercialization possible for 2016/2017 season

Uruguay

- Trait approved, DGA OTT chemistry approval expected by mid 2016
- Commercialization possible for 2016/2017 season



U.S. Sensitive Crop Tolerances

- Tolerances for first crop groups are likely to be in place Q1
- BASF to make first submission in November 2014
- berries, grape, brassica veg., cucurbit veg., root & tuber veg., tree nut
- MON to make second submission in December 2014
- fruiting veg., leafy veg., legume veg. peanut





Enlist Update

- Trait deregulated by USDA September 2014
- Joint RWG estimated timelines:
- EPA to finalize Enlist Duo label Q4 2014
- China trait import process approval estimated mid 2016
- Projected trait import approvals for remaining countries estimated early 2015



RWG Follow-up Topics

- Finalization of sensitive crop program agreement
- Reimbursement by MON for sensitive crop study costs
- RWG work plan updated by next AMT



Development Working Group



2014 Field Program Update

Efficacy

- Good performance across geographies and cropping systems
- Dicamba increases consistency of tankmix partners
- Key focus areas weed size, use of residuals, early season weed control

Crop Tolerance

- Soybean slightly higher level of necrosis in 2014 (ca avg 3; max -5
- Cotton similar / slightly lower than 2013; higher than soy (ca avg 10; max - 20)
- Proactively position necrosis potential with growers



2014 Field Program Update

Application Training / Validation

Communication objectives:

- Formulation Selection
- Nozzle Selection
- Wind Speed / Direction
- Boom Height
- Ground Speed
- Equipment Cleaning

- Awareness of Sensitive Plants
- Additive Restrictions (ie, AMS)
- Impact of Weed Size
- Weed Resistance Management
- System Approach: use of appropriate rate, inclusion of residuals, multiple SOAs
- New Application Technologies

Opportunities

 Pulse Width Modulation, AirAssist, Hooded, PatternMaster, new nozzle technology



Label Development

- BASF + MON Aligned
- Adjuvants
- No AMS; acceptable water conditioning alternatives TBD
- Adjuvants NIS, HSOC (MSO, COC allowable w/ dicamba alone)
- Recommend use of deposition agent (DRA)
- Action: Test worst-case commercial tank mixtures
- Nozzles XC to UC spray quality
- Crop Response
- Necrosis observed
- Additional Discussion Required
- POST BASF 0.375 to 0.5 lb/ac depending weed spectrum; MON
- 0.5 lb/ac
- Necrosis potential in soy and cotton



2015 Joint Testing Objectives

- 2015 seed (cotton and soy) for BASF R&D trials
- Commercial mixtures (including adjuvants) on crop tolerance
- Evaluate new application technologies (ie, AirAssist, PWM, etc)
- Continue application and herbicide stewardship training



DWG Follow-up Topics

- 2015 seed (cotton and soy) for BASF R&D trials
- Decision on public release of sensitive crop rankings to dicamba
- DWG discussion continues on:
- Resistance mitigation, endangered/sensitive crop setbacks, On-target deposition experience (large and small scale)
- Add Latin America / ROW DWG status by next AMT
- DWG work plan updated by next AMT



RWG BACK UP SLIDES



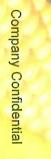
Regulatory Status - North America

USA DT Soy/Cotton Deregulation (USDA) DGA in DT Crops (Soy/Cotton) (EPA) BAPMA Conventional and DT Soy/Cotton (EPA) MON DGA Premix in DT Soy/Cotton (EPA) MON DGA Premix in DT Soy/Cotton (EPA) MON 4Q	(
DT Soy/Cotton Deregulation (USDA) DGA in DT Crops (Soy/Cotton) (EPA) BAPMA Conventional and DT Soy/Cotton (EPA) MON DGA Premix in DT Soy/Cotton (EPA) MON			Submitter	Submit/Approve
A Conventional and DT Soy/Cotton BASF/MON DGA Premix in DT Soy/Cotton (EPA) MON			MON	Jul 2010 – 4Q 2014
A Conventional and DT Soy/Cotton BASF/MON DGA Premix in DT Soy/Cotton (EPA) MON	D	GA in DT Crops (Soy/Cotton) (EPA)	MON	Apr 2010 – 4Q 2014
	Œ B	APMA Conventional and DT Soy/Cotton :PA)	BASF/MON	May 2012 – 4Q 2014
	<	ON DGA Premix in DT Soy/Cotton (EPA)	MON	4Q 2014 – 2Q 2015









Regulatory Status - North America

Country Submission		Submitter	Submit/Approve
Canada* DT Soy Trait Approval		MON	Nov 2010 - Oct 2012
DGA in DT Soy		MON	Apr 2010 – Dec 2013
BAPMA in DT Soy	ТЅоу	BASF/MON	Mar 2014 – April 2016

* Canadian launch delayed until US launch



Regulatory Status - Brazil:

			by Uctober 2014)	extension strategy to be aligned	Brazil (Label	Country	(
DGA in DT Cotton (dependent on trait approval)	BAPMA in DT Soy (dependent on trait approval)	DGA in DT Soy (dependent on trait approval)	DGA Conventional Crops	New registration (Dicamax Clone + OTT use) and Clone for BASF	DT Soy Trait Approval	Submission	
BASF or MON	BASF	BASF	BASF	MON	MON	Submitter	
2Q 2015 – 1Q 2019	3Q 2015 – 3Q 2019	3Q 2015 – 3Q 2018	Dec 2011 – 2Q 2015	4Q 2014 – TBD	3Q 2014 – 3Q 2016	Submit/Approve	









Regulatory Status - South America

		Uruguay			Paraguay				Argentina	Country
BAPMA in DT Soy	DGA in DT Soy*	DGA EUP DT Soy for MON	BAPMA in DT Soy	DGA in DT Soy* (submission timeline considering efficacy trials delivered by MON on time)	DGA EUP for MON	BAPMA in DT Soy**	DGA in DT Soy*	DGA Conventional Crops	DT Soy Trait Approval	Submission
BASF	BASF or MON	BASF	BASF	BASF	BASF	BASF	BASF	BASF	MON	Submitter
TBD***	2Q 2015 – 4Q 2015	Done (EUP approved)	<i>TBD***</i>	2Q 2015 – 2Q 2016	Done (EUP approved)	1Q 2015 – 1Q 2016	1Q 2015 – 1Q 2016	2QCY13 - 4QCY14	4Q 2013 – 2Q 2016	Submit/Approve

^{*} MON registration is an extension of BASF registration. Requires BASF to submit MON OTT data

Company Confidential

^{**} Registration assumes no need for in-country trials due to same dose rate/GAP to DGA
*** No regulatory work has been done to date

Dicamba Import Tolerance/MRL Actions

Japan

Korea

Taiwan

CODEX

- Soybean
- A process of inquiry in MHLW has been completed & MAFF is now in the final legal check & approval process for amendment of the Ministerial ordinance on Dicamba before going to gazette publication process in the Printing Bureau. Expectation: December 2014
- Soybean, corn
- BASF/MON coordinated submissions after KFDA consultation
- October 2012 2Q 2014 (1x rate residues data submitted)
- Approval timeline: 2Q 2015
- Soybean, corn
- TFDA published the MRLs in Dec. 31 2013.
- Soybean
- 2013 JMPR session recommended a Dicamba MRL of 10 ppm.
- August 2014: Dicamba MRL of 10 ppm final approval, valid to support
- DT Soybean
- EFSA proposed a separate MRL for DCSA in DT soy while leaving intact current MRL for Dicamba in conventional soybean.
- Standing Committee on the Food Chain and Animal Health to discuss approach with different residue definitions for GMs/conventional crops
- MRL expected approval: 1Q 2015

