Dicamba Project Update

Significant changes since the January 21, 2015 update are highlighted

Introduction

This document was prepared at the request of Juergen Oldeweme, for BASF internal use only. This project is a collaboration between Monsanto and BASF. Both companies intend to obtain registrations for the use of dicamba on Dicamba Tolerant Crops (DTC). Monsanto has proprietary rights to the trait and serves as the technical lead associated with development of dicamba use on the DTCs (corn, cotton, soybean). BASF owns dicamba and provides associated technical and regulatory support.

Countries included in Phase one of the project scope are: Argentina, Canada, Brazil and the United States. Several additional Latin American countries are included in Phase two of the project scope.

Canada is the most advanced regarding regulatory approvals. They have deregulated the trait in soybean and approved the use of dicamba on dicamba tolerant soybean. The authorities granted these approvals with minimal opposition from NGOs. Approval for DT corn is expected in the future.

Regulatory approvals in Argentina, Brazil and Phase two countries have not begun or are in the early stages with minimal public opposition from NGOs so far.

Authorities in the US are currently evaluating dossiers supporting approval of the DT trait and associated use of dicamba on soybean, cotton and corn. NGOs have expressed opposition to these proposed uses and for a separate project to develop 2,4-D (Enlist[1]) tolerant corn and soybean. The basis for the opposition is similar for both projects: 1) the potential for off-target movement causing damage to non-target crops and endangered plant and animal species and 2) development of herbicide resistant weeds. Following is a summary of the actions being taken by the authorities, BASF and Monsanto.

BRAZIL Regulatory Information

- Registrations (based on a Dicamba Technical Letter of Access from Syngenta) of Atectra® Soy and Dicamax (Monsanto brand name) for conventional uses are expected for 2Q 2015.
- Label extension for Over the Top use (OTT) / Early Post emergence will be done in parallel by BASF and MON. Letter of Access to be provided / exchanged between both companies.
- Monsanto will submit a new registration of a Dicamax clone + OTT use in December 2014. A Letter of Access from Syngenta (Dicamba Technical registrant) will be necessary. BASF Globally (Regulatory and Marketing) will manage the request of this Letter of Access to provide to Monsanto. MON is going to submit a clone for BASF at the same time.
- Dicamba soybean tolerant deregulation is expected by 3Q 2016.

ARGENTINA Regulatory Information

- Registration (based on a Dicamba Technical Letter of Access from Syngenta) of Clarity® (conventional uses) was granted in November 2014.
- BASF Dicamba Technical registration is expected for 4Q 2014.
- After BASF Clarity® registration, Monsanto will receive a Letter of Access from BASF to support their registration for conventional uses.
- Monsanto will provide BASF their Over the Top (OTT) data (efficacy and residues) to be submitted by BASF in the label extension process.
- After receiving the label extension (OTT use) approval, BASF will authorize MON to include the OTT use in their own registration / label.
- Dicamba soybean tolerant deregulation is expected by 2Q 2016.

USDA: Environmental Impact Statement (EIS) for DT Trait Deregulation

The USDA public comment period for the final dicamba EIS closed on January 12, 2015. The USDA deregulated the DT traits for soybean and cotton on January 20, 2015. Monsanto will sell DGT cotton in 2015, but only glyphosate and glufosinate are labeled for use. Dicamba will not be labeled for use and there is concern about growers being tempted to use dicamba illegally.

US EPA: Pending Product Registrations

The EPA has not negotiated new PRIA dates for Engenia or Monsanto's M1691. Monsanto has informed EPA that they will not negotiate a new PRIA date until EPA opens the public comment period for the proposed registration of M1691. Once EPA completes their review of M 1691, they are expected to propose approval for dicamba use in DT crops and open the docket for a 60 day public comment period. With a 60 day public comment period and the administrative time needed to complete these actions the dicamba (M 1691) DT crop use approval will be no sooner than May 2015, with Engenia® approval to follow.

In December, EPA indicated to both BASF and Monsanto that they had renewed concerns about the off target movement potential of dicamba, based on off target crop injury reports from several states in 2015. This renewed concern has caused EPA to investigate these reports and possibly need to reevaluate their risk assessment for nontarget plant injury. EPA indicated that a significant delay in a registration decision for M1691 and Engenia could be expected, suggesting that final approval may not be possible before 4Q15.

Endangered Species Risk Assessment

EPA is still working through the endangered species risk assessment for the propose DT crop uses for dicamba. As mentioned above state reports of significant dicamba drift has caused EPA to investigate those reports and possibly revise their endangered species risk assessment. EPA has told Monsanto that 16 states have been determined to have no endangered species concerns and will be approved for use. This is similar to what we have already seen with Enlist[1] and the initial approval for corn and soybean use in six states with another 10 states pending approval.

Off Target Movement Concerns

On May 20, 2014, Monsanto received an addendum to the dicamba EFED risk assessment from EPA. The addendum specifically addresses the existing information on dicamba spray drift and EFED's assessment of that data for the determination of spray buffer requirements to protect nontarget organisms. EPA determined that the Monsanto field trial drift data (soybean height and yield) should be interpreted with caution because of the inherent variability in field studies and study design issues. EPA referenced other available spray drift information from a number of resources including the Spray Drift Task Force, AgDrift modeling, the BASF DRT field study and Crop Life America data. Communication between Monsanto and EPA suggest that EPA is considering the use of 70 and 140 foot spray buffers for the 0.5 and 1.0 lb/A rates of dicamba respectively.

Spray Droplet Testing Requirements for Dicamba Spray Mixtures

As EPA has announced with the approval of Dow's Enlist Duo Herbicide, EPA will require wind tunnel testing to determine the impact of all approved spray mixtures on the spray droplet size spectrum to insure that spray droplet size is not reduced by the spray mixture components (adjuvants, other pesticides, water conditioner), increasing spray drift potential. The required wind tunnel testing must be specific for the spray mixture components, by brand name, spray nozzle size and type, spray volume and spray pressure. A prioritized list of over 300 spray mixtures for cotton use has been developed and wind tunnel testing will be performed in January. A second list of spray mixtures is being developed for use in soybeans and wind tunnel testing will be performed in March.

Dicamba Crop Residue Studies

The analytical phase of the sensitive crop residue program is in full progress and the first study reports should be available in October with the majority of the other crop reports to be available between January and March. The first EPA submissions for the new uses are expected by February 2015.

Additional Toxicology Studies Required by USEPA

The three toxicology studies requested by the EPA for Engenia® were submitted to EPA on August 18 and the 28-day inhalation study with dicamba acid was submitted on September 3. All study submission requirements for Engenia have been completed. There has been no response from EPA other than to inform BASF that the PRIA date will need to be renegotiated.

Global Import Tolerances and DT Trait Deregulation

Dicamba Import Tolerances - Soybean

CODEX: A document was issued in October 2013 as a result of the annual Joint FAO/WHO Meeting on Pesticide Residues (JMPR) proposing 10 ppm as a maximum residue level for dicamba (soybean dry). This MRL is based on data submitted by BASF from pre-plant and pre-harvest applications in non-DT soybean. BASF agrees with this MRL.
MRLs established / approved by CODEX Commission in August 2014.

EU: In 4Q 2013 EFSA issued a Reasoned Opinion (RO) for a soybean MRL of 0.4 ppm for DCSA (3,6-dichloro-salicyclic acid) + its conjugates. This MRL is based on data submitted by

Monsanto from post-emergent applications in DT soybean. Monsanto and BASF agree with this RO. Additionally, BASF and Monsanto expect that EFSA will accept CODEX MRLs for Dicamba in soybean based on the non-DT residue data. There is some chance that the EU will struggle with how to promulgate both MRLs. MRLs/ITs expected by 4Q 2014 / 1Q 2015.
Japan: MHLW on September 24 the PF subcommittee proposed MRLs for Dicamba at 10 ppm for soybean were reviewed & recoghized.
Process of inquiry in MHLW has been completed & MAFF is now the final legal check & approval process for amendment of the ministerial ordinance on Dicamba before going to gazette publication process in the Printing Bureau.
Korea: Soybean and Corn MRLs establishment expected for 2Q 2015.
Taiwan: TFDA Proposed Dicamba MRLs for soybean (3 ppm) and corn (0.1 ppm) on Sep,19.

DT Trait Deregulation - Soybean

To allow for the import of commodities containing the DT trait, Monsanto is seeking DT trait approval in the following countries for both the single and dicamba + glyphosate stacked trait.

Country	Stack Approval Date	Single Approval Date
EU (EFSA)	3Q-14-1Q-15	1-3Q 2014
Korea (KFDA)	November 2013	October 2013
Korea (KRDA)	2Q-14	December 2012
Japan (MHLW/FSC)	February 2014	October 2013
Japan (MAFF-Feed)	October 2013	October 2013
Japan (MAFF/MOE)	February 2014	October 2013
Taiwan (TFDA)	4Q-14 (still in review)	April 2013
China (MOA/GMO)	--------	1Q-2Q 2015 (single approval only)

Dicamba Import Tolerances - Cotton
Monsanto is in the lead for generating residue data and applying for IT MRLs. BASF has requested information from Monsanto regarding their intentions for IT MRLs. Cotton seed can be an animal feed item and cotton seed oil can be used for cooking. BASF believes that export of these commodities is minimal.

DT Trait Deregulation – Cotton

To allow for the import of commodities containing the DT trait, Monsanto is seeking DT trait approval in the following countries for both the single and dicamba + glyphosate stacked trait.

Country	Stack Approval Date	Single Approval Date
EU (EFSA)	4Q-16	2Q 2015
Korea (KFDA / KRDA)	2Q-15	4Q 2014
Japan (MAFF/MOE) (MHLW/FSC) (MAFF-Feed)	1Q-15	4Q 2014
Mexico (Health Ministry)	July 2014	January 2014
Canada (Health Canada)	September 2014	June 2014
China (MOA/GMO)	------	2Q 2017 (single approval only)

Dicamba Supply

The EPA submission to register the Yangnong (China) dicamba technical has been made and has an EPA PRIA date of March 23, 2015. The new Rudong (China) production location recently received an EPA Establishment Number, and the Rudong location has been successfully added to the proposed dicamba registration action.

Preparations are being made to import unregistered Yangnong dicamba technical for production scale up and eventual use in Clarity herbicide production in April 2015.

The Tagros dicamba technical source was submitted to EPA in December. No PRIA date has been set for EPA approval, but 4Q15 is expected.

[1] Enlist is a registered trademark of Dow Agro Science
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