



Message

From: Teixeira Filipe BRSP [/O=ECSM-R0012/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FILPE.TEIXEIRA]
Sent: 9/26/2017 5:21:05 PM
To: Felipe Antonio BRSP [/O=ECSM-R0012/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Antonio.felippe]
Subject: FW: PQ Brazil Update Sep 25th.

From: Zangirolami Rinaldo BRSP
Sent: Tuesday, September 26, 2017 2:09 PM
To: Casabianca Pablo BRSP <pablo.casabianca@syngenta.com>
Cc: Teixeira Filipe BRSP <filipe.teixeira@syngenta.com>
Subject: RE: PQ Brazil Update Sep 25th.

Pablo, por favor, inclua o Filipe no tema. Obrigado.
Rinaldo

From: Casabianca Pablo BRSP
Sent: terça-feira, 26 de setembro de 2017 14:06
To: Parr Jon CHBS <jon.parr@syngenta.com>; Fischer Valdemar Luis BRSP <Valdemar.Fischer@syngenta.com>
Cc: French Dave CHBS <dave.french@syngenta.com>; West Steve CHBS <steve.west@syngenta.com>; Duan James CHBS <james.duan@syngenta.com>; Neill Rob CHBS <rob.neill@syngenta.com>; Cook Andy GBJH <Andy.Cook@SYNGENTA.COM>; Giampani Laercio BRSP <laercio.giampani@syngenta.com>; Zangirolami Rinaldo BRSP <rinaldo.zangirolami@syngenta.com>; Pinheiro Laila BRSP <laila.pinheiro@syngenta.com>; Brunner Valter BRSP <valter.brunner@syngenta.com>
Subject: RE: PQ Brazil Update Sep 25th.

Gentlemen
The Resolution translation attached
Best regards
Pablo

From: Casabianca Pablo BRSP
Sent: segunda-feira, 25 de setembro de 2017 19:16
To: Parr Jon CHBS <jon.parr@syngenta.com>; Fischer Valdemar Luis BRSP <Valdemar.Fischer@syngenta.com>
Cc: French Dave CHBS <dave.french@syngenta.com>; West Steve CHBS <steve.west@syngenta.com>; Duan James CHBS <james.duan@syngenta.com>; Neill Rob CHBS <rob.neill@syngenta.com>; Cook Andy GBJH <Andy.Cook@SYNGENTA.COM>; Giampani Laercio BRSP <laercio.giampani@syngenta.com>; Zangirolami Rinaldo BRSP <rinaldo.zangirolami@syngenta.com>; Pinheiro Laila BRSP <laila.pinheiro@syngenta.com>; Brunner Valter BRSP <valter.brunner@syngenta.com>
Subject: RE: PQ Brazil Update Sep 25th.

UPDATE Sep. 25th.

1. REGULATORY/ ANVISA:
 - a. Meeting with Anvisa president Mr. Jarbas Barbosa on Sep 25th with PQT Task Force
 - The meeting was held in a constructive environment and had the participation of Mr. Jarbas, his assistant and the PQT Task Force
 - TF expressed the lack of clarity and agreement on some terms of the Resolution published on Friday 22nd

- He showed openness for the continuous dialogue and committed to answering every point in a timely manner
 - There should be a memo of today's meeting
 - He expressed that the presentation of studies on mutagenesis should either maintain current decision to ban or to review it
- b. Key points on way forward to challenge Anvisa's Resolution:
- There is a procedure to review any Resolution: has to be through a written communication; and ANVISA is obligated to respond every point
 - After their answer Anvisa can (per Mr Jarbas' explanation):
 - Modify the Resolution to bring more clarity and minor changes; in this case, it has to be voted at DICOL (bi weekly Directors' meeting)
 - Or in case of substantial change where there is NEW evidence, it is needed a new DICOL meeting presenting the new arguments. Then, it is necessary to appoint a new rapporteur to manage the process, including a public consultation and a recommendation to a DICOL meeting for them to vote on a new Resolution to close the process. It is NOT a re-evaluation process again
- c. Actions (Based on current Resolution):
- Aligned priorities on the specifics of the Mutagenesis studies, the terms of reference and evaluation methodology
 - Get a written document from ANVISA on the criteria to be used on the evaluation of the mutagenesis studies; so we leave very little room for interpretation from their technical area
 - Get a written response from ANVISA on what is the process after the evaluation of the mutagenesis studies and the mechanism to have a new Resolution
 - Obtain an answer on what they refer to "other studies"
 - Evaluation from Legal on the potential liability of the label warning on Parkinson and mutagenesis
- d. STAKEHOLDERS (Aprosoja / Abramilho / Abrapa- farmers associations, FPA - Agriculture leadership on Congress)
- We are engaging them to explain our concerns on the actual Resolution
 - Continue the political engagement we have been having for the past 2 years until a new Resolution comes
 - MOA is critical since they are accountable for the registration of any CP product, especially on the label changes
2. INDUSTRY
- a. There will be a meeting on Sep 26 to start discussing with TF the way forward and aligning industry reaction and Anvisa communications
- b. After we decide our priorities, it is required that we align all 12 companies on the task force
- c. Some companies from TF may be misaligned with our strategic approach on the required studies and can decide to move ahead isolated
- d. Continue leading the Task Force – there is a real risk of some companies to move apart on their own
3. COMMERCIAL:
- a. Reactive statement, key messages and Q&A communicated with sales force, marketing, distributors, retailers, etc.
- b. Brazil TLT being updated regularly
- c. Daily review in case of need
4. MEDIA :
- a. Reactive stand-by statement made and approved with Basel and Legal
- b. Constant monitoring shows the coverage is very low traffic in the subject, mostly in trade media
- c. There is a tier 1 example attached published in Valor Economico website where the possibility to revert the decision is mentioned
5. NEXT STEPS FROM SYNGENTA

- a. Decide on way forward on the required studies: will we move ahead or not?
- b. Dissection: are we together with the TF and will challenge the immediate ban decision and request 180 for implementation?
- c. Terms/Folder: what wording do we feel legally comfortable and will use to challenge ANVISA's proposal?

From: Brunner Valter BRSP

Sent: sábado, 23 de setembro de 2017 18:50

To: Fischer Valdemar Luis BRSP <Valdemar.Fischer@syngenta.com>

Cc: Parr Jon CHBS <jon.parr@syngenta.com>; French Dave CHBS <dave.french@syngenta.com>; West Steve CHBS <steve.west@syngenta.com>; Duan James CHBS <james.duan@syngenta.com>; Neill Rob CHBS <rob.neill@syngenta.com>; Cook Andy GBJH <Andy.Cook@SYNGENTA.COM>; Giampani Laercio BRSP <laercio.giampani@syngenta.com>; Zangirolami Rinaldo BRSP <rinaldo.zangirolami@syngenta.com>; Pinheiro Laila BRSP <laila.pinheiro@syngenta.com>; Casabianca Pablo BRSP <pablo.casabianca@syngenta.com>

Subject: RE: PQ Brazil

Valdemar

Yes, agree. Our position always was and is that we would only carry out additional studies if there were a clear and formal commitment from them that this specific study would enable us to revert the three years phase out. We changed our decision and offered to do it under this condition. And this is one of the points to be explored on the Monday meeting with Anvisa's president. Let's see the outcome of Monday's meeting.

Thanks

Valter

From: Fischer Valdemar Luis BRSP

Sent: sábado, 23 de setembro de 2017 18:40

To: Brunner Valter BRSP <valter.brunner@syngenta.com>

Cc: Parr Jon CHBS <jon.parr@syngenta.com>; French Dave CHBS <dave.french@syngenta.com>; West Steve CHBS <steve.west@syngenta.com>; Duan James CHBS <james.duan@syngenta.com>; Neill Rob CHBS <rob.neill@syngenta.com>; Cook Andy GBJH <Andy.Cook@SYNGENTA.COM>; Giampani Laercio BRSP <laercio.giampani@syngenta.com>; Zangirolami Rinaldo BRSP <rinaldo.zangirolami@syngenta.com>; Pinheiro Laila BRSP <laila.pinheiro@syngenta.com>; Casabianca Pablo BRSP <pablo.casabianca@syngenta.com>

Subject: Re: PQ Brazil

Valter, I had the chance to read the entire communication from Anvisa today and was wondering if we should not review the position to carry out the additional testing. The way it is written, it will be very difficult to get a review of the ban. Lets talk Monday about it. Cheers, Valdemar

Sent from my iPad

On Sep 23, 2017, at 6:08 PM, Brunner Valter BRSP <valter.brunner@syngenta.com> wrote:

Dear

Just to share with everybody some key points of the strategy and plan which we have in place in Brazil and some actions already prepared and to be delivered / happen on Monday;

a) Meeting of PQT TF with Anvisa's president. In this meeting we have three different targets and approach :

- make clear the points which are not aligned with previous commitment, mainly regarding the ban wording versus the clear commitment of a review of the phase out if mutagenic study will be presented in the three years window. Ask for "corrections" on the communication. There will be delivered a written position on this points to assure it is on the records.
- specific review on some time limits for some restrictions implementation (i.e. dissection);

- clarification alignment on some points (i.e. warnings etc.)
 - In addition of PQT TF we already have confirmed growers representatives (APROSOJA) for this meeting
 - b) Review the approved media strategy. I believe that there is an opportunity to have a more proactive and assertive position on trade media (i.e. Agrow). The "after Anvisa meeting" on Monday can be a good opportunity for a press release or at least a new statement. The team will work on it (Global, Region and Territory). For mass media we still on reactive mode once it was not covered there yet (no tier one media so far). Anyway, it needs to be evaluated.
 - c) Specific commercial communication already started to be delivered in Brazil for customers, clients , growers leaders etc.
 - d) Update on Q&A to address current trade media media approach , formal TF position informed to ANVISA on Monday meeting and the lack of clarity of some points published.
 - e) Regional evaluation: So far no impact om other Latam countries and been monitored closely . Important to remark that all Comms materials, letters etc. are revised by Legal which is involved in all process.
- This is a process which still under developments .
- Thanks
- Valter

From: Fischer Valdemar Luis BRSP

Sent: sábado, 23 de setembro de 2017 05:27

To: Parr Jon CHBS <jon.parr@syngenta.com>

Cc: French Dave CHBS <dave.french@syngenta.com>; West Steve CHBS <steve.west@syngenta.com>; Duan James CHBS <james.duan@syngenta.com>; Neill Rob CHBS <rob.neill@syngenta.com>; Cook Andy GBJH <Andy.Cook@SYNGENTA.COM>; Brunner Valter BRSP <valter.brunner@syngenta.com>; Giampani Laercio BRSP <laercio.giampani@syngenta.com>

Subject: Re: PQ Brazil

Jon, we are not sure yet about the degree of damaging of the ruling, but it is a political play from Anvisa and they will explore it in the media. I agree we need to move into crisis mode now, especially because of potential impact in other countries and the fact that they are banning some uses immediately, which will harm our customers (soya dissipation).

As you say, we need to rally farmer groups, other government agencies and industry groups to help us to shed more light on the ruling and the potential impacts for agriculture in Brazil.

At the same time, we need to review our overall product strategy for NSH, including diquat and the potential impact for volumes around the world. We already have a generic registration from Sharda in Brazil for a formulated product and a couple for the active ingredient (Nufarm and Adama).

We can discuss details on the phone call on Monday and pick this topic up again at the MBR on Tuesday.

Cheers,
Valdemar

Sent from my iPad

On Sep 23, 2017, at 4:59 AM, Parr Jon CHBS <jon.parr@syngenta.com> wrote:

Dave, Team

Thanks for the update, transparency and speed are important.

This is an infuriating development. We need to think about getting some farmer groups wound up about this to make life uncomfortable for the Anvisa bureaucrats who have done this. Again we seem to be surprised by the turn of events. The problem is this will fuel the next PIC listing meeting in 2019 which in turn will influence the Brazilian decision in 3 years, in 2020. Plus we have a ticking clock to a ban which we have to stop, which is vastly more difficult than working with the threat of a ban.

We urgently need that full evaluation of the implications. The explanation to me has migrated in the last week from something not good to something very bad. DO we yet understand the full implications of this?

We certainly need to group on Monday

Regards

Jon

From: French Dave CHBS

Sent: 22 September 2017 18:13

To: Parr Jon CHBS <jon.parr@syngenta.com>; West Steve CHBS

<steve.west@syngenta.com>; Duan James CHBS <james.duan@syngenta.com>

Subject: PQ Brazil

Importance: High

Jon, James,

It seems that ANVISA have today unexpectedly published a document outlining the rationale behind their decision; we were hoping to have further opportunity to discuss exact wording but that is now not the case.

The decision has already been picked up by the media and reported as a ban so we are now in damage limitation mode. Internal comms are aware and regulatory teams around the world have already been alerted and have stand by/Q&A available.

Andy Cook has an english version of the ANVISA document and is working to evaluate the full implications of what has been released. My understanding is that the details reflect what was discussed in the Task Force meeting but the language used may be unhelpful in explaining the situation with regard to PD and mutagenicity.

I'm in Denmark without my laptop this weekend so suggest you call me if you need more info. I will look for an opportunity for us to discuss f2f on Monday.

Sorry for this late on Friday but wanted to make sure you were aware. Dave

Sent from my Samsung Galaxy smartphone.

----- Original message -----

From: Cook Andy GBJH <Andy.Cook@SYNGENTA.COM>

Date: 22/09/2017 15:46 (GMT+01:00)

To: French Dave CHBS <dave.french@syngenta.com>

Cc: Dieterle Roland Mario CHBS <roland_mario.dieterle@syngenta.com>, Rado Schumann Luciana CHBS <luciana.rado_schumann@syngenta.com>
Subject: FW: AGROW REPORT OF TODAY - THE OFFICIAL ANVISA NOTICE WAS PUBLISHED IN THE OFFICIAL GAZETTE FIRST THING THIS MORNING

Dave,

FYI to my surprise the AGROW article you forwarded below includes a link ('ordered') to the full text of the complete 22 page document (you already have the full English translation) which is apparently already accessible via the ANVISA website. I thought it may point to today's notice in the official gazette but it is the complete document Porto used for the Board meeting on 19th.

Regards.

Brazil bans paraquat

- 22 Sep 2017
- NEWS
- <image001.jpg>

Robert Birkett robert.birkett@informa.com

The Brazilian national health surveillance agency, the Anvisa, has ordered a three-year phase-out of the herbicide, paraquat.
<image002.jpg>

The Brazilian national health surveillance agency, the Anvisa, has ordered a three-year phase-out of the herbicide, paraquat. The agency's decision came this week after an assessment started in 2008 as part of a 14 pesticide active ingredient reassessment programme. Paraquat is approved as a non-selective herbicide and desiccant on various crops including cotton, maize and soybeans.

The action is being taken due to concerns over risks to human health. It is important to note that the mutagenicity and Parkinson's disease risks arising from the use of the product are restricted to workers handling the product, and not food safety for consumers, the Anvisa says. There is no evidence that the use of paraquat leaves residues in food, it adds.

Immediate restrictive measures for worker safety have also been imposed. Only application by closed cabin tractors will be allowed. Its use on various crops, and as a desiccant is prohibited, as is the sale in containers of less than 5 litres. New rules on user training and labelling will also be enacted.

New scientific evidence that might exclude mutagenic potential in germ cells, and biomonitoring studies that would ensure negligible exposure

may lead to a review of the ban within the period of the phase-out. The agency notes that the impact of the phase-out could be reduced by the adoption of zero tillage practices. It highlights the herbicide's high efficacy, low cost, and lack of resistance concerns, as well as its environmental advantages and allowing the adoption of the system of zero tillage.

The Anvisa called for public comments for a recommended ban on the herbicide in 2015. Last year, it initiated a panel including the Ministry of Agriculture and the environmental agency representatives to expedite the re-evaluation of paraquat.

Andy Cook

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