
From: Botham Phil GBJH
Sent: 26 May 2016 20:46
To: Hertl Peter CHBS; French Dave CHBS
Subject: FW: PARAQUAT : BRAZIL

More from Helena/Andy

Phil

From: Sassaki Helena BRSP
Sent: 26 May 2016 14:37
To: Cook Andy GBJH; Lewis Dick GBJH; Botham Phil GBJH; Pires Karla BRSP; Rodrigues Rose BRSP
Subject: RE: PARAQUAT : BRAZIL

Dear Andy and colleagues,

According to ANVISA director, Renato Porto, they have sent the remaining questioning to other agencies, right after the Expert Panel (02/03/2016), and they intend to conclude their Technical Assessment in June.

The current ANVISA GGTOX team is more science based than it used to be in previous team (they had a significant change on GGTOX managers between 2012-2015). The difference of the 1st Technical Assessment of Paraquat and the 2nd is the prove of this. They made the Expert Panel to hear the positioning of scientists indicated by the industry and by themselves. But the current team don't want to have any interference of the industry in their decisions, they hear all stakeholders, but they are building very robust and independent assessment to allow them change (or not) their proposal of ban published in the Public Consultation. The positioning of international agencies would give them a good support in this case. In this meeting on 17th May, we gave them 2 assessment of notorious jurists with juridical base to keep Paraquat in the market, discussing precautionary principle, proportionality and reasonability of decision. Wearing their shoes, they have to be very well prepared for the pressure of anti-Paraquat or anti-pesticide people and ONGs to change their positioning.

The perception of the TF members, including the SINDIVEG lawyer, is that Renato Porto was very interested in our mitigation plan, especially in the chain control and the toxicovigilance that can influence in their decision. Due to this, the Sub-TF Stewardship is working hard to improve this. There is another product, Acephate that the revaluation decision established some years with some chain control that is not working, so they may be sceptics. We need to prove them, that our mitigation plan is reliable and it will work.

Regards,

Helena Mami Sassaki
Gerente de Registro – Fungicidas CP



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From: Cook Andy GBJH
Sent: quinta-feira, 26 de maio de 2016 08:31
To: Lewis Dick GBJH; Botham Phil GBJH
Cc: Pires Karla BRSP; Sassaki Helena BRSP; Rodrigues Rose BRSP
Subject: RE: PARAQUAT : BRAZIL

Dear all,

ANVISA do not have further technical questions for industry. As I already stated ANVISA is looking for independent regulator inputs to justify whatever their final regulatory position may be. There is no clear insight into the specific questions or the regulatory agencies which have been contacted (my expectation is Canada, USA, EU/EFSA, Australia, possibly China). ANVISA made reference to 'prohibitive characteristics' by which we assume they refer to the Brazilian cut-off criteria from 1989 which would therefore logically include the following:

- Mutagenicity
- No antidote or effective medical treatment
- Substances shown to be more toxic to man than demonstrated by the animal regulatory studies (ANVISA referred to PD in this context)

Depending on the precise nature of the questions I doubt all agencies contacted will respond. The only useful contribution on the first point would be the APVMA since no other agencies have recently (i.e. since the JMPR evaluation) reviewed the totality of the data, including the published studies on which ANVISA is focused. Similarly only the APVMA (other than ANVISA themselves) have recently looked at the totality of the information on PD.

I still see this move by ANVISA as potentially positive since they could otherwise simply have reverted to their own original negative assessment. Nevertheless any potential response from Canadian PMRA could unhelpfully refer to their recent 'dilution' decision and similarly US EPA would be likely to refer to their proposed decision on prohibition of backpack/knapsack uses plus closed transfer systems for remaining uses (all of this information is already in the public domain).

Regards.

Andy Cook

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From: Lewis Dick GBJH
Sent: 26 May 2016 12:08
To: Botham Phil GBJH
Cc: Pires Karla BRSP; Cook Andy GBJH
Subject: RE: PARAQUAT : BRAZIL

And tomorrow too... but I'll try him anyway

Dick

From: Botham Phil GBJH
Sent: 26 May 2016 12:06
To: Lewis Dick GBJH
Cc: Pires Karla BRSP; Cook Andy GBJH
Subject: RE: PARAQUAT : BRAZIL

Yes I believe it is a holiday (Corpus Christi?)

From: Lewis Dick GBJH
Sent: 26 May 2016 12:06
To: Botham Phil GBJH
Cc: Pires Karla BRSP; Cook Andy GBJH
Subject: RE: PARAQUAT : BRAZIL

I will give him a call and get back to you (although it may be a public holiday today?)

Dick

From: Botham Phil GBJH
Sent: 26 May 2016 11:56
To: Lewis Dick GBJH
Cc: Pires Karla BRSP
Subject: FW: PARAQUAT : BRAZIL

Dick

Is there anything more we can find out via Manuel on the specific concerns regarding tox and mutagenicity that ANVISA is now discussing with other reg authorities

Phil

From: Sullivan Jonathan Dale CHBS
Sent: 26 May 2016 09:02
To: Duan James CHBS; Hertl Peter CHBS; Hull Sarah USWS; Malarkey Trish CHBS; Mewes Kersten CHBS; Parr Jon CHBS
Cc: Botham Phil GBJH; French Dave CHBS; Cook Andy GBJH
Subject: PARAQUAT : BRAZIL

All,

I have now received from Peter Hertl and Phil Botham a set of notes of the May 17 meeting with ANVISA, produced by Helena Sassaki, a Syngenta Brazil regulatory manager who attended the meeting, which are reproduced below . The notes are significantly more detailed than the summary report which I circulated on May 23, and the comments

stated in the notes to have been made by Renato Porto, the ANVISA Board member and Rapporteur for the Paraquat Evaluation who was present at the May 17 meeting, appear to raise a number of concerns :

- (1) Reference is made to the issue of the intrinsic toxicity of paraquat, which together with alleged mutagenicity is the subject of ongoing enquiries being made by ANVISA of other regulatory authorities, as being capable of leading to a ban of paraquat in Brazil
- (2) The concept seems to be raised more than once of a process of control over the entire value chain from import to end user, and that this could be precedent-setting for other products. Less clearly, it is indicated that this "control" would be exercised by GGTOX (ANVISA)
- (3) There is a suggestion that the paraquat registration could be subject to annual re-approval based on data-gathering apparently to measure the effectiveness of the mitigation plan .

I will seek to schedule a further call of the PILT Paraquat Brazil Task Team with a view to obtaining better clarity on these points and (whether or not there is any opportunity for further engagement by the task force with ANVISA) the potential implications for the outcome of the evaluation .

Jonathan .

Date : 17/05/2016 - 16:30-18:00 at Renato Porto office at ANVISA (Brasília)

Attendants:

- ANVISA – Renato Porto (member of ANVISA board – reporter of PQT revaluation) and Daniela Bravo (his advisor)
- Farmer Associations – Fabricio Rosa (Aprosoja - Soybean), Marcio Portocarrero, Edivandro Seron (Abrapa – Cotton) and Gustavo Carneiro (Abramilho – Corn)
- PQT-TF members – Elaine Silva (Leisor – vice-coordinator of TF), Lidia Santos (SINDIVEG lawyer), Luiz Dinnouti and Helena Sasaki (Syngenta)

Fabricio Rosa (Aprosoja director) opened the meeting, welcomed the opportunity, praising the ANVISA's role in making the technical panel considering the importance of the product to Brazilian agriculture and the risks to human health. He reported that the mitigation plan was presented to them and they support it, to be in line with correct use programs they promote in their associations. They filed a letter of adhesion to the mitigation plan in ANVISA (attached).

Elaine Silva presented the mitigation plan (attached). Basically the same plan presented during the expert panel on 02.03.2016 with some refinements, suggested in this event.

Lidia Santos said that because of legal questions raised during the panel, the TF discussed aspects of the precautionary principle and reasonableness with two reputable lawyers who produced legal opinions that have been filed at ANVISA.

Renato Porto comments :

- Some questions related to intrinsic toxicity of paraquat which may lead to ban in Brazil that still remained between the revaluation team even after the panel of experts were sent to some international regulatory agencies and they are waiting these positioning. They plan to complete the evaluation in June.
- If they decide to keep the registration, certainly they will establish use restrictions and measures of traceability, because they consider the product especially very toxic and should be very controlled.
- He liked the idea of having the control of the entire chain, from import, sale to the final consumer, the use to compare with the data of poisoning incidents, he thinks that it can be a "case of success" a benchmark for the world. He made a parallel with medicines, these, after being approved to be launched in the market, regulators collect the information of all incidents related to the product that may be prohibited, depending on the results, as occurred with Vioxx. Thus, periodically (e.g., every year) would evaluate the incidence of data to maintain or not Paraquat in the market. It can be a way to meet the "precautionary principle". He questioned how it would be the access of ANVISA to such data. He said that GGTOX has structure and experience to manage this control because its managers come from the regulatory department of pharmaceuticals of ANVISA.
- He highlighted that to work, the data must be reliable.

- They would involve the Public Prosecutor to make a conduct adjustment agreement to all who import and sell the product until the return of empty packaging, in order to "control risk" very strictly. It would be a way to change the bad image of the pesticide industry today as "industry against society".
- The objective of the mitigation plan is "zero harm" to workers and without accidents. For this, it would be possible to measure it, have reliable data to prove that the population is safe.
- Who uses PQT to commit suicide can use knife, revolver. He does not believe in the efficacy of the box with 2 locks to storage PQT packaging.
- He agrees that the exclusion of 1L packaging can increase the fractioning and increase the risk of poisoning. But he consider important to prioritize the control of this package specifically .
- Their biggest concern is the workers without training. They consider the product technically very dangerous, very harmful. We should focus on the effectiveness of the safe use training
- He was very interested in the possibility of improving the toxicovigilance with Agrotoline and have 100% control of the entire chain of Paraquat products. He has never seen anything like it in the world and if successful, can be a model for all pesticides.