

Message

From: Scott Herndon [sherndon@americansugarbeet.org]
Sent: 5/12/2017 11:18:49 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
CC: Bennett, Tate [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fa92542f7ca4d01973b18b2f11b9141-Bennett, El]; Palich, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=330ad62e158d43af93fcbbece930d21a-Palich, Chr]; Cassie Bladow [Cassie.Bladow@beetsugar.org]; Graham, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=26722dfde5b34925b0ad9a8dd4aff308-Graham, Amy]
Subject: Re: Section 18
Flag: Flag for follow up

Nancy,

This is incredibly helpful information and it is evident that you all are devoting a LOT of resources to help our industry! Thank you! Thank you! Thank you!

I'll bring our folks up to speed!

Have a great weekend!

Scott

Sent from my iPhone

On May 12, 2017, at 6:35 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Scott,

Below is the latest. Long story short, we are currently working with state and Extension Service experts to explore and identify possible alternatives as we evaluate the request. We have had similar situations like this and have been able to work cooperatively to find alternative approaches in emergency situations. Our staff is meeting internally with extension experts and trying to schedule a meeting with the sugar beet states for next week.

Regarding the data needs, below is what I've learned. However, I would encourage you to keep in mind that the work noted above to identify possible alternative approaches with the states is what will likely be most helpful to your group because it does take time to run through the full risk evaluation process.

Summary:

North Dakota and Minnesota submitted to the agency emergency exemption requests for the subject uses in late March and early April, 2017, respectively, but chlorothalonil has outstanding data requirements most of which concern the need for a subchronic inhalation study, which precludes the agency from being able to make the required aggregate risk safety finding.

More specifically, the Chlorothalonil Scoping Document of March, 2012, developed to support the opening of the docket for registration review, indicates that in our most recent risk assessment (2010),

- MOEs for short and intermediate-term occupational handler inhalation exposures exceed HED's LOC (MOE ≤1000). For mixing/loading liquids for aerial, chemigation, and groundboom applications, MOEs range from 42 to 180.

- MOEs for short-term residential handler exposure exceeded HED's LOC (MOE=1000). For mixing/loading/applying liquids with a brush or sprayer MOEs range from 52 to 220.

Because there is no inhalation study of appropriate length available to assess short- and intermediate-term exposures, HED relied upon an acute study (in which no NOAEL was achieved) to assess short- and intermediate-term exposure. Additional UFs were applied for both the lack of an NOAEL and the lack of a subchronic inhalation study.

In response to this risk assessment, the registrant withdrew the new use applications that triggered the need for this risk assessment.

In March 2013, after OMB review, we issued the Registration Review data call-in. Nearly 25 studies were identified as being needed to support the registration review. Most pertinent to this situation is the need for a 90-day subchronic inhalation study, but we identified a number of other missing studies across human exposure, animal tox, environmental fate, and ecological effects. Sipcam Agro, the registrant for the requested product under section 18, was a recipient of the DCI and a copy of the DCI has been posted in the registration review public docket since July 2013.

We have been working with the consortium of chlorothalonil registrants to build a record for an upcoming FIFRA SAP peer review meeting on the use of in vitro studies and CFD/MMAD models for deriving points of departure and uncertainty factors. This would be the first time that EPA derived a point of departure from an in vitro study. We are targeting late 2017 or early 2018 for that SAP meeting.

So as you can see this process takes time. Given all that and the need for the emergency use, as I noted above, we are reaching out to the states and to the land grant universities to explore other control options for this fungal pest that we might be able to make available under section 18. The point Rick was trying to make in his testimony is that the earlier engagement we have with the states on potential control tools, the less likely that we will find ourselves in a situation mere days before the use needs to occur of having to scramble to find an alternative. This is an approach that we use with IR-4 ([Interregional Risk Project 4](#)); they don't conduct research on chemicals where we don't think we'll be able to make the FFDCA safety finding. That way, their packages move rather quickly through the review process.

Please let me know if you have any questions.

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273

Ex. 6

beck.nancy@epa.gov

From: Scott Herndon [<mailto:sherndon@americansugarbeet.org>]

Sent: Friday, May 12, 2017 4:10 PM

To: Beck, Nancy <Beck.Nancy@epa.gov>

Cc: Bennett, Tate <Bennett.Tate@epa.gov>; Palich, Christian <palich.christian@epa.gov>; Cassie Bladow <Cassie.Bladow@beetsugar.org>; Graham, Amy <graham.amy@epa.gov>

Subject: Re: Section 18

Thanks so much!

Scott

Sent from my iPhone

On May 11, 2017, at 6:30 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Scott,
I will work with my staff to get you some answers.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273

Ex. 6

beck.nancy@epa.gov

From: Scott Herndon [<mailto:sherndon@americansugarbeet.org>]
Sent: Thursday, May 11, 2017 12:38 PM
To: Bennett, Tate <Bennett.Tate@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Palich, Christian <palich.christian@epa.gov>; Cassie Bladow <Cassie.Bladow@beetsugar.org>; Graham, Amy <graham.amy@epa.gov>
Subject: RE: Section 18

Christian and Amy, it was nice meeting you!

I have listened to the hearing about 20 times now so that I could transcribe the Section 18 comments verbatim for our growers. I've pasted them below for you as well. When you are able, do you mind telling me what data is missing, if any? I've heard that it is the vapor data that is missing but have alternatively heard that it is the residue data that is missing. I want to make sure that our folks have or can provide all necessary data. I've also attached the relevant contacts for this issue.

Thanks so much again!

My transcript of Section 18 comments from today's hearing below:

Senator Stabenow:

"Thank you Mr. Chairman and thank you to both of our witnesses. Mr. Keigwin, I first want to thank you personally for your engagement with Michigan State University and our Michigan hop growers that created the gift that we just gave to the Chairman to facilitate Section 18 exemptions under FIFRA. Most recently I've heard from Michigan sugar beet growers about emergency use needs under Section 18 as well. What steps can be taken by growers, states, manufacturers and the EPA to make this Section 18 process more efficient so that growers facing unexpected risk can get needed crop insurance tools in a timely manner?"

Mr. Rick Keigwin, Acting Director, Office of Pesticide Programs, EPA

“Thank you, Senator, and I’ve had the great fortune of meeting with Michigan growers on a number of occasions. Your growers sponsor an annual tour to help educate EPA employees about Michigan agriculture and what farmers do to help grow our crops so thank you for that. In terms of Section 18s, we have a pretty solid record of completing our decision making for most Section 18 emergency exemptions in less than 50 days but there are times and I think this situation with the sugar beet ones, the growers, that came to your attention highlights the need for early engagement between EPA, the Michigan Department of Agriculture and the grower community and the land-grant universities. Knowing early on what tools a grower might need to address an emerging pest situation. It is hard when at the end of the process, or right when they need to apply the product, for EPA to say, ‘wait, hold on, we might have a problem’ so one process efficiency would probably be for us to have earlier engagement, maybe even before the state submits their Section 18 request to see if there might be any issues with that particular chemical and to the extent to which there are we could work collaboratively with cooperative extension and with the state to maybe find some alternatives that we could move through the process more quickly to address the emerging pest management.”

Scott Herndon

Director of Biotechnology and Regulatory Affairs

American Sugarbeet Growers Association

1155 15th Street NW #1100

Washington, DC 20005

202-595-0786

From: Bennett, Tate [<mailto:Bennett.Tate@epa.gov>]

Sent: Wednesday, May 10, 2017 10:21 PM

To: Beck, Nancy <Beck.Nancy@epa.gov>

Cc: Palich, Christian <palich.christian@epa.gov>; Scott Herndon

<sherndon@americansugarbeet.org>; Cassie Bladow <Cassie.Bladow@beetsugar.org>;

Graham, Amy <graham.amy@epa.gov>

Subject: Re: Section 18

Scott- Christian and Amy will be at the hearing tomorrow with Rick. Were you planning to be there?

On May 10, 2017, at 10:05 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

This is bizarre. On our call when we discussed reaching out to Stabenow, Rick clearly stated that he would state that believed his staff spoke prematurely and that they were looking at all the options.

Rick seems like such a straight shooter this just isn't adding up. Are we sure that Rick was the only one that spoke w Stabenows office and there wasn't some other call with his staffer?

I can check w Sven as he would have been on the call.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

On May 10, 2017, at 9:27 PM, Palich, Christian
<palich.christian@epa.gov> wrote:

I sat in on that call for a minute but was pulled away to another meeting, ill follow up with career staff in the morning to see a status.

I'll defer to Nancy on how to handle this more technical response.

Thanks so much for the heads up Scott.

Christian R. Palich
Deputy Associate Administrator
Congressional & Intergovernmental Relations
202.306.4656

Sent from my iPhone

On May 10, 2017, at 9:15 PM, Bennett, Tate
<Bennett.Tate@epa.gov> wrote:

Thank you for the heads up. Looping in Nancy as it relates to the imminent hearing tomorrow. We probably need to give some messaging instructions on this so he doesn't tie our hands "on the record." Thoughts?

On May 10, 2017, at 9:10 PM, Scott Herndon
<sherndon@americansugarbeet.org>
wrote:

Tate,

I wanted to give you a heads up that Senator Stabenow's Ag. Committee staff spoke with EPA career staff this afternoon. The EPA staff don't believe that they have any room on this issue and still believe there is a data gap. From what Stabenow's staff relayed to me, EPA staff

characterized the Section 18 component as relatively straightforward under FIFRA but the Food Drug and Cosmetic Act (FDCA) requirements for residues and granting tolerances are very strict. Under Section 18, the cost benefit analysis can weigh the economic harm, etc. I asked them to triple check with EPA that they were looking at the data SipCam submitted on Friday and they said they would (attached).

Also, they may bring this up at the Senate Agriculture hearing tomorrow with the Director of Pesticide Programs. We did not ask them to do this but I also don't think that I can ask them not to do it. I just wanted to give you a heads up so you all wouldn't be caught off guard. Hearing info here:

<https://www.agriculture.senate.gov/hearings/pesticide-registration-under-the-federal-insecticide-fungicide-and-rodenticide-act-providing-stakeholders-with-certainty-through-the-pesticide-registration-improvement-act>

Thanks again!

Scott

Scott Herndon

*Director of
Biotechnology and
Regulatory Affairs
American Sugarbeet
Growers Association
202-595-0786*

From: Cassie Bladow
[mailto:Cassie.Bladow@beetsugar.org]
Sent: Tuesday, May 09, 2017 4:43 PM
To: Bennett, Tate
<Bennett.Tate@epa.gov>; Scott Herndon
<sherndon@americansugarbeet.org>
Subject: RE: Section 18

Thank you, Tate! Really appreciate your help!

From: Bennett, Tate
[mailto:Bennett.Tate@epa.gov]
Sent: Tuesday, May 9, 2017 4:37 PM
To: Scott Herndon
<sherndon@americansugarbeet.org>
Cc: Cassie Bladow
<Cassie.Bladow@beetsugar.org>
Subject: RE: Section 18

FYI we are on it.

Interesting. I'm not confident her management is aware of these conversations. Will find out.

—
Nancy B. Beck, Ph.D.,
DABT
Deputy Assistant
Administrator, OCSPP
P: 202-564-1273
Ex. 6
Beck.Nancy@epa.gov

From: Scott Herndon
[mailto:sherndon@americansugarbeet.org]
Sent: Tuesday, May 9, 2017 4:09 PM
To: Bennett, Tate
<Bennett.Tate@epa.gov>
Cc: Cassie Bladow
<Cassie.Bladow@beetsugar.org>
Subject: RE: Section 18

Tate,

I've looped Cassie back in and wanted to give you both an update. Dr. Mohamed Khan with NDSU had a conversation with Andrea Conrath at EPA (her contact information is below) this morning about the new data that was supplied by SipCam. Dr. Khan prepared the Section 18 applications that were requested by the ND and MN Departments of Agriculture. He also prepared the application that we expect the Michigan Department of Agriculture to file soon.

In his email to me he stated "I spoke to Andrea today at EPA. Unfortunately, she does not believe the new tolerance data submitted will help. Seems they are looking for some data for some other studies." I have been unable to determine what additional data they

need and have asked
Dr. Khan if that was
relayed to him but have
not yet heard back.

<image001.jpg>

Thanks!

Scott Herndon
Director of
Biotechnology and
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Growers Association
1155 15th Street NW
#1100
Washington, DC 20005
202-595-0786

-----Original Message-----

-

From: Scott Herndon
Sent: Monday, May 8,
2017 5:43 PM
To: 'Bennett, Tate'
<Bennett.Tate@epa.gov
>
Subject: RE: Section 18

SipCam has state
registrations for Cercos
(brand name) in
Michigan, North
Dakota, Minnesota.

North Dakota expires in
12/31/2017
Michigan expires in
6/30/2017
Minnesota expires
12/31/2017
SipCam will renew all of
them

Scott Herndon
Director of
Biotechnology and
Regulatory Affairs

American Sugarbeet
Growers Association
1155 15th Street NW
#1100
Washington, DC 20005
202-595-0786

-----Original Message-----

-

From: Bennett, Tate
[mailto:Bennett.Tate@
epa.gov]
Sent: Monday, May 8,
2017 5:33 PM
To: Scott Herndon
<sherndon@americans
ugarbeet.org>
Subject: Re: Section 18

Do these states
currently have permits?
What is the exact date
of expiration?

> On May 8, 2017, at
5:20 PM, Scott Herndon
<sherndon@americans
ugarbeet.org> wrote:

>

> Tate,

>

> Apologies for the
delay! I am now back
at my computer and
have put together a
short backgrounder as
well as relevant
industry contacts.

>

> I have also attached
the correspondence
from EPA to the ND and
MN Departments of
Agriculture asking them
to withdraw their
request.

>

> In addition, I have
attached a cover letter
that SipCam submitted
to EPA on Friday, May
5th with additional
data.

>
> Thanks so much for
your help and please
don't hesitate to email
or call if you have any
questions.
>
> Have a great evening!
>
> Scott
>
> Scott Herndon
> Director of
Biotechnology and
Regulatory Affairs
American Sugarbeet
> Growers Association
> 1155 15th Street NW
#1100
> Washington, DC
20005
> 202-595-0786

Ex. 6

> -----Original Message-----
> From: Bennett, Tate
[mailto:Bennett.Tate@
epa.gov]
> Sent: Monday, May 8,
2017 3:34 PM
> To: Scott Herndon
<sherndon@americans
ugarbeet.org>
> Cc: Cassie Bladow
<Cassie.Bladow@beets
ugar.org>
> Subject: Re: Section
18
>
> Thanks!
>
>> On May 8, 2017, at
3:32 PM, Scott Herndon
<sherndon@americans
ugarbeet.org> wrote:
>>
>> Tate,
>>
>> I have all of the
information in my office
but am on the Hill right
now. I'll send

everything to you this evening.

>>

>> Thanks so much!

>>

>> Scott

>>

>> Sent from my iPhone

>>

>>> On May 8, 2017, at 3:13 PM, Bennett, Tate <Bennett.Tate@epa.gov> wrote:

>>>

>>> Hey Scott- do you have any summaries/background papers?

>>>

>>>> On May 8, 2017, at 2:47 PM, Cassie Bladow <Cassie.Bladow@beetsugar.org> wrote:

>>>>

>>>> Tate,

>>>>

>>>> Thank you for taking the time to chat this morning. As we discussed, I am looping Scott Herndon who works for the American Sugarbeet Growers Association into the conversation since he has done a lot of work on this issue and will be able to provide you with background and answer any questions you have.

>>>>

>>>> We really appreciate your guidance helping us move this along, especially given our tight timeline.

>>>>

>>>> Thanks again!

>>>> Cassie

>>>>

> <Section 18 for
Chlorothalonil
Contacts.docx>
<Chlorothalonil
> Background.docx>
> <2017-05-05
Chlorothalonil Tech-
Echo 500 Sugarbeet Tol
Pet-Label
> Amend-C....pdf> <EPA
email to ND and MN
Departments of
> Agriculture.docx>
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