

Cc: GARNETT, RICHARD P [AG/5040]; HEYDENS, WILLIAM F [AG/1000]

Subject: RE: Genotox Review

Will do!!

From: SALTMIRAS, DAVID A [AG/1000]

Sent: Wednesday, July 18, 2012 3:47 PM

To: GUSTIN, CHRISTOPHE [AG/5040]

Cc: GARNETT, RICHARD P [AG/5040]; HEYDENS, WILLIAM F [AG/1000]

Subject: FW: Genotox Review

Importance: High

Christophe,

Will you please take this to the RWG ASAP? At this point we have an open Monsanto contract with David Kirkland, CDA's with individual member companies are being initiated and Larry Kier plans to get a draft manuscript to him by the end of the month (i.e. in less than 2 weeks). Kirkland is only available to work in this project in August and approval of his involvement is strongly recommended by the ToxTWG. If our time lines slip on this we will probably not have a genotoxicity review manuscript available for our submission window in January.

Is there a way to get this through the RWG in a week?

Thanks,

David Saltmiras, Ph.D., D.A.B.T.

Toxicology Manager

Regulatory Product Safety Center

Monsanto

ph (314) 694-8856

From: GRAHAM, WILLIAM [AG/5432]

Sent: Wednesday, July 18, 2012 8:24 AM

To: HEYDENS, WILLIAM F [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; GUSTIN, CHRISTOPHE [AG/5040]; GARNETT, RICHARD P [AG/5040]

Cc: LEMKE, SHAWNA LIN [AG/1000]; KRONENBERG, JOEL M [AG/1000]

Subject: RE: Genotox Review

I think it has to go through the normal process- TWG to RWG to Board, with documented agreement at each stage. Once the RWG has agreed we can do the Board by email.

I think Bill H's summary could be a good basis for getting RWG alignment.

BillG

From: HEYDENS, WILLIAM F [AG/1000]

Sent: Tuesday, July 17, 2012 5:54 PM

To: GRAHAM, WILLIAM [AG/5432]; SALTMIRAS, DAVID A [AG/1000]; GUSTIN, CHRISTOPHE [AG/5040]; GARNETT, RICHARD P [AG/5040]

Cc: LEMKE, SHAWNA LIN [AG/1000]; KRONENBERG, JOEL M [AG/1000]

Subject: RE: Genotox Review

Bill,

David & I were just touching base on a couple things, and we were wondering what your thinking is on how to progress this with the Board – let us know – thanks.

Bill

From: HEYDENS, WILLIAM F [AG/1000]

Sent: Friday, July 13, 2012 1:09 PM

To: HEYDENS, WILLIAM F [AG/1000]; GRAHAM, WILLIAM [AG/5432]; SALTMIRAS, DAVID A [AG/1000]; GUSTIN, CHRISTOPHE [AG/5040]; GARNETT, RICHARD P [AG/5040]

Cc: LEMKE, SHAWNA LIN [AG/1000]; KRONENBERG, JOEL M [AG/1000]

Subject: RE: Genotox Review

Bill,

Here is my further perspective on top of David's...

As David notes, we are still essentially talking about lines 12 & 13 on the Excel spreadsheet you sent. David embarked on the Genotox publication work with Larry Kier as agreed by the Board.

But here is what transpired after that. After they got all the studies amassed into a draft manuscript, it unfortunately turned into such a large mess of studies reporting genotoxic effects, that the story as written stretched the limits of credibility among less sophisticated audiences. For most 'stories', the approach would have been fine. But even though we feel confident that glyphosate is not genotoxic, this became a very difficult story to tell given all the complicated 'noise' out there. So we (David, Larry, Bill H, Joel & Shawna) thought we needed to re-group & redesign the approach to the manuscript. As part of that re-tooling approach, it was suggested that one way to help enhance credibility is to have an additional author on the paper who is a heavy-hitter in the area of genotoxicity. Larry did a search for possible co-authors and came up with 5. After internal discussion and some checking by David with fellow TWG tox folks, we landed on Kirkland as the best candidate. That has led to the request you have before you.

So if you think there needs to be a discussion with the Board rather than trying to gain approval via e-mail, then we could take that approach, but this obviously slows down the process. Is there a Board phone conference scheduled anytime soon?

Bill

From: HEYDENS, WILLIAM F [AG/1000]

Sent: Friday, July 13, 2012 11:20 AM

To: GRAHAM, WILLIAM [AG/5432]; SALTIRAS, DAVID A [AG/1000]; GUSTIN, CHRISTOPHE [AG/5040]; GARNETT, RICHARD P [AG/5040]

Subject: RE: Genotox Review

Bill, I have to run to a meeting, but I will give you my perspective later today when you are drinking G&Ts.

From: GRAHAM, WILLIAM [AG/5432]

Sent: Friday, July 13, 2012 11:17 AM

To: SALTMIRAS, DAVID A [AG/1000]; GUSTIN, CHRISTOPHE [AG/5040]; HEYDENS, WILLIAM F [AG/1000]; GARNETT, RICHARD P [AG/5040]

Subject: RE: Genotox Review

There is a lot of information here which the Board has not seen (to my knowledge) . The discussion of published summaries took place at the 13th Meeting (March 2012) and I attach the information which was presented and agreed (according to the Minutes). I think you will agree that the current situation needs to go to the Board for a second discussion and updated Agreement.

If Richard or Bill H have any additional information about the Board discussions on this subject then I will gladly change my opinion.

Bill

From: SALTMIRAS, DAVID A [AG/1000]

Sent: Friday, July 13, 2012 3:48 PM

To: GRAHAM, WILLIAM [AG/5432]; GUSTIN, CHRISTOPHE [AG/5040]; HEYDENS, WILLIAM F [AG/1000]; GARNETT, RICHARD P [AG/5040]

Subject: RE: Genotox Review

Bill,

Two different projects have been merged, the first of which was well underway before the PAG was instituted. The initial project was a review manuscript of the glyphosate genotoxicity literature authored by Larry Kier and me (authorized Feb 22, 2011 for \$9,000). The second (initiated by the PAG and supported by the RWG and Board, cost estimate of \$13,195) was a review manuscript involving all glyphosate genotoxicity studies owned by GTF member companies on both active ingredient and formulated products, authored by Larry; the review of GTF members' proprietary study reports prohibit my coauthorship.

This first became a very long and tedious manuscript, which would have been difficult to publish. Following on from this first draft manuscript review, discussions with Bill H., Joel, me and Larry Kier resulted in a merging of the two projects (also discussed at the ToxTWG) with a view to publish two companion manuscripts on glyphosate genotoxicity for the active ingredient (paper 1) and formulated products (paper 2). Thus Larry was

the sole author and given his geography and industry alignment, other highly credible genotoxicologists coauthors from European were sought. David Kirkland was the first choice of the GTF ToxTWG.

David Kirkland's expertise comes at a premium. I believe Larry Kier significantly under charges for his services, but his combined cost estimate for project 1 and project 2 is \$22,195. David Kirkland believes his efforts will be less than 10 days at £1,400/day (equivalent to \$21,780 with the current exchange rate), so we are effectively doubling the cost of the combined projects, but reaping significant value/credibility from David Kirkland's involvement. Given the growing number of questionable genotoxicity publications, in my mind this is worth the addition cost.

I have subsequently coordinated an open master contract between Monsanto and David Kirkland (we may need his services in the future) and on the next ToxTWG call (Monday) will request all member companies get confidentiality agreements in place with him ASAP (the same CDAs as previously signed with Larry Kier, enabling him to see their study reports).

David Saltmiras, Ph.D., D.A.B.T.

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From: GRAHAM, WILLIAM [AG/5432]

Sent: Friday, July 13, 2012 9:01 AM

To: GUSTIN, CHRISTOPHE [AG/5040]; HEYDENS, WILLIAM F [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; GARNETT, RICHARD P [AG/5040]

Subject: Genotox Review

The project was initiated by the PAG and supported by the RWG and Board. The cost was \$9k and I thought the job had been completed. The name "David Kirkland" has never come to my attention before and I would suggest that the RWG needs to explain to the Board why, at this point, it believes that trebling the expenditure to include a second author is a justifiable expense.

I wonder if this is a true PAG project where those companies who want to see this work carried out pay for it.

I have received questions about future expenditure and I cannot see it on Richard's list which went to the Board for approval/discussion last month.

Bill

From: GUSTIN, CHRISTOPHE [AG/5040]
Sent: Friday, July 13, 2012 2:04 PM
To: HEYDENS, WILLIAM F [AG/1000]; SALTMIRAS, DAVID A [AG/1000]
Cc: GRAHAM, WILLIAM [AG/5432]; GARNETT, RICHARD P [AG/5040]
Subject: RE: A FedEx shipment [793774060139] was created.

Hi Bill,

The proposal sounds very reasonable and having David Kirkland co-authoring this paper can only strengthen the case. Since the board has approved the project I agree it makes sense to ask the board directly to approve the extra funding. It I don't seem to remember this (adding Kirkland) being discussed at RWG level but could be wrong. If not I'll send out an update message to make sure everyone is on the same page.

Regards,

C.

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Thursday, July 12, 2012 10:52 PM
To: SALTMIRAS, DAVID A [AG/1000]; GUSTIN, CHRISTOPHE [AG/5040]
Cc: GRAHAM, WILLIAM [AG/5432]; GARNETT, RICHARD P [AG/5040]
Subject: RE: A FedEx shipment [793774060139] was created.

Christophe,

We (David, Joel, Kier, me) think we should proceed with pursuing Kirkland as a co-author for the glyphosate genotox publication. David also got some other toxicologist feedback from within the Tox TWG and that was favorable as well.

So how should we proceed? For expediency, since this project is already supported by the Board, could we have Bill go directly to the Board by sending out a note asking them to approve contracting with Kirkland for an estimated maximum amount of £14,000?

Thanks.

Bill

From: SALTMIRAS, DAVID A [AG/1000]
Sent: Thursday, July 12, 2012 11:03 AM
To: HEYDENS, WILLIAM F [AG/1000]; GUSTIN, CHRISTOPHE [AG/5040]
Subject: FW: A FedEx shipment [793774060139] was created.

Bill & Christophe,

We (Monsanto) have a signed master contract with David Kirkland. This will enable him to coauthor the genotoxicity review paper with Larry Kier, as well as engaging him on any other projects which may come up... it may be necessary to have an EU based expert in genotoxicity on hand if issues arise during the regulatory review.

Please note David's estimated cost, below, which will need GTF board approval....he thinks likely less than 10 days work (at £1,400/day).

David Saltmiras, Ph.D., D.A.B.T.
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From: David Kirkland [<mailto:root@genetoxconsulting.co.uk>]
Sent: Thursday, July 12, 2012 10:49 AM
To: SALTMIRAS, DAVID A [AG/1000]
Subject: RE: A FedEx shipment [793774060139] was created.

David,

Daily rate is equivalent to 8 hours, namely GBP1400 per day.

I estimate a maximum of 10 days (i.e. GBP14,000) but unless I have to delve very deeply into a lot of the reports and papers that Larry includes, it should be less than this.

Kind regards,

David.

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