Message

From: [redacted]@fcs-feinchemie.com]
Sent: 7/19/2012 10:18:12 AM
To: [redacted]@gtaduran.com]; [redacted]@arystalifescience.com; [redacted]@cheminova.com]; [redacted]@dow.com; [redacted]@at.nufarm.com; [redacted]@syngenta.com; [redacted]@afrasa.es; [redacted]@agria.bg; [redacted]@Laronkarn.co.uk]; [redacted]@agrotrade.de; [redacted]@etracoms.com; [redacted]@agrichem.nl; [redacted]@barclay.ie; [redacted]@bros.pl]; [redacted]@excelcropcare.com; [redacted]@helmag.com; [redacted]@pinus-[redacted]@rotam.com; [redacted]@sabero.com]; [redacted]@sfp-rd.com; [redacted]@uk.exponent.com; [redacted]@agro.sapec.pt; [redacted]@uniphos.com; [redacted]@wynca.com
CC: [redacted]@live.co.uk]; [redacted]HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=230737]; SALTMIRAS, DAVID A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=DASALT]; [redacted]
Subject: AW: Genotox Review: your approval requested!

Dear [redacted]

FCS agrees to the additional costs as well.

Best regards,

[redacted]

Von: [redacted]@monsanto.com]
Gesendet: Mittwoch, 18. Juli 2012 19:12
An: [redacted]@arystalifescience.com; [redacted]@dow.com; [redacted]@at.nufarm.com; [redacted]@syngenta.com; [redacted]@afrasa.es; [redacted]@agria.bg; [redacted]@agrotrade.de; [redacted]@etracoms.com; [redacted]@agrichem.nl; [redacted]@barclay.ie; [redacted]@excelcropcare.com; [redacted]@helmag.com; [redacted]@pinus-tki.si; [redacted]@rotam.com; [redacted]@sfp-rd.com; [redacted]@uk.exponent.com; [redacted]@agro.sapec.pt; [redacted]@uniphos.com; [redacted]@wynca.com
Cc: [redacted]HEYDENS, WILLIAM F (AG/1000); SALTMIRAS, DAVID A (AG/1000); [redacted]
Betreff: Genotox Review: your approval requested!
Wichtigkeit: Hoch

Plaintiff Exhibit
0445

URGENT REQUEST

Dear RWG,

As part of the GTF literature review the RWG and Board agreed to ask Larry Kier (former Monsanto expert and now independent consultant) to write a genetox review paper on technical glyphosate and glyphosate based Plant Protection Products. This paper would pool data from confidential Taskforce Member studies which was the reason why David Saltmiras (MON), chair to the tox-TWG, stepped down as a co-author for this paper. In addition when trying to combine both reviews (on technical glyphosate and PPPs) the manuscript turned into such a large mess of studies reporting genetoxic 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 David Saltmiras, Larry Kier and Bill Heydens consulted by other Monsanto tox experts thought there was a need to re-group & redesign the approach to the manuscript.

The suggested approach was to split-up the reviews in 2 papers (one on tech glyphosate and one on PPPs). In addition it was suggested that one way to help enhance credibility is to have an additional author on the papers who is a renowned specialist in the area of genotoxicity. Larry Kier did a search for possible co-authors and came up with 5. After internal discussion and some checking by David Saltmiras with fellow TWG tox folks (see extracts from TWG-meeting minutes below), [redacted] was identified as the best candidate.

[redacted] is an independent consultant with a history at Covance Laboratories. He is an expert in 'COMET'-assays on PPPs and is member of the editorial board for 'Mutagen Research' and member of the Environmental Mutagen Society in the UK. [redacted] would most definitely add substantial expertise and credibility to this critical paper.

The initial cost estimate for this manuscript was 9k$ (approved by the board).

Adding [redacted] as a co-author to both review papers would add £14,000 (pounds Stirling) to the project, which split by 25 seems a fair investment.

Please let me know as soon as possible if we have your support to proceed with [redacted] as a co-author. We need a decision soon since [redacted] only has the month of August to work on the papers.

David, Bill, please let me know if I missed or misinterpreted something.

Best regards,

[redacted]

From: SALTMIRAS, DAVID A [AG/1000]
Sent: Wednesday, July 18, 2012 4:54 PM
To: [redacted]
Subject: RE: Genotox Review

[redacted]

Below are extracts from recent meeting minutes this month. [redacted] was discussed as a strong candidate to coauthor on July 2nd and ToxTWG endorsed him on July 16th and plans to engage him were put in motion.

- **From July 2nd**

a. Genotoxicity review manuscript.

i. Discussed approaches for literature and data reviews

ii. Consensus gained for two companion papers on active ingredient and formulated product genotoxicity data (GTF member company data and peer reviewed publications

iii. **Co-authors with Larry Kier were discussed.** [redacted] **was proposed as strong candidate for this role.** Syngenta proposed [redacted] expressing possible bias towards COMET assay data by [redacted] will inquire within the Syngenta genotox group on suitability of [redacted] to provide an objective scientific review including weight of evidence for the full data set (GTF member study reports and peer reviewed publications).

- **NOTE**: Larry had contacted [redacted] yesterday to discuss the paper and Larry contacted David Saltmiras today (Tuesday July 3rd) to debrief.

- Larry is convinced that [redacted] will provide a strong technical skill set to evaluate the breadth of data including the COMET data (weighing convenience of

COMET assays with credible data interpretability) and believes [redacted] would be an excellent choice to co-author the manuscript.

- [redacted] is available to work on this project in August/Sept and submit to the journal by the end of September.

iv. Still targeting *Critical Reviews in Toxicology*, based on the length of these papers.

- Larry has briefly discussed with the chief editor of *Critical Reviews in Toxicology* (Roger McClellen), who expressed concern that the GTF member study reports are not public (weighing in on negative genotox results) vs the publication record (weighing in on positive genotox results). This will present itself as an issue with any credible journal. To have credibility, rather than make all study reports public, the GTF may consider submitting all the genotoxicity study Tier II Summaries from the dossier (which may well fall into the public domain) as supplementary data to the journal.

- **Please email David Saltmiras regarding this approach of submitting the TIIS for genotox studies as supplementary data if your company owns genotoxicity data.**

- **From July 16th**

2. Genotoxicity review manuscript

a. David Saltmiras will circulate contact information for [redacted] for individual companies to arrange CDAs (Arysta LifeScience, Cheminova, Excel Crop Care, Feinchemie Schwebda, Helm, Nufarm, Syngenta).

b. Data for manuscript

i. General agreement was reached to provide member company study methodology and data summaries as supplementary information in support of publications on (i) active substance and (ii) formulated products.

ii. Study summaries and citations should be sanitized to exclude

- Study director names

- Data owner/company name

iii. Study summaries and citations may include

- Study/report number
- Study/report title
- Year of study/report
- Performing laboratory (not necessary, sometimes deleted/sanitized for public information like DARs)
- Test substance purity (for active substance)
- Formulation type (for formulated product)
- Note of whether GLP or non-GLP
- Test Guideline(s) followed (OECD/US EPA, JMAFF, etc.)
- Brief description of methodology
- Summarized data tables

iv. Transfer of study information between coauthors

- Larry Kier needs to email a rider/CDA amendment for each company to grant him permission to share data with [redacted]
- Larry Kier and [redacted] should sign a CDA with eachother.

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center
Monsanto
ph (314) [redacted]

From: [redacted]
Sent: Wednesday, July 18, 2012 9:40 AM
To: SALTMIRAS, DAVID A [AG/1000]

Cc: [redacted] 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: [redacted]
Cc: [redacted] HEYDENS, WILLIAM F [AG/1000]
Subject: FW: Genotox Review
Importance: High

[redacted]

Will you please take this to the RWG ASAP? At this point we have an open Monsanto contract with [redacted] 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). [redacted] 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) [redacted]

From: [redacted]
Sent: Wednesday, July 18, 2012 8:24 AM

To: HEYDENS, WILLIAM F [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; [redacted]
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: [redacted]; SALTMIRAS, DAVID A [AG/1000]; [redacted]
Cc: LEMKE, SHAWNA LIN [AG/1000]; KRONENBERG, JOEL M [AG/1000]
Subject: RE: Genotox Review

[redacted]

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]; [redacted] SALTMIRAS, DAVID A [AG/1000]; [redacted]
Cc: LEMKE, SHAWNA LIN [AG/1000]; KRONENBERG, JOEL M [AG/1000]
Subject: RE: Genotox Review

[redacted]

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 Genetox 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 genetoxic 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 [redacted] 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: [redacted] SALTMIRAS, DAVID A [AG/1000]; [redacted]
Subject: RE: Genotox Review

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

From: [redacted]
Sent: Friday, July 13, 2012 11:17 AM
To: SALTMIRAS, DAVID A [AG/1000]; [redacted] HEYDENS, WILLIAM F [AG/1000]; [redacted]
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 [redacted]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: [redacted] HEYDENS, WILLIAM F [AG/1000]; [redacted]
Subject: RE: Genotox Review

[redacted]

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 coauthorhip.

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. [redacted] was the first choice of the GTF ToxTWG.

[redacted] 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. [redacted] 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 [redacted] 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 [redacted] (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.
Toxicology Manager
Regulatory Product Safety Center
Monsanto
ph (314)[redacted]

From: [redacted]
Sent: Friday, July 13, 2012 9:01 AM
To: [redacted] HEYDENS, WILLIAM F [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; [redacted]
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 [redacted] 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 [redacted] list which went to the Board for approval/discussion last month.

[redacted]

From: [redacted]
Sent: Friday, July 13, 2012 2:04 PM
To: HEYDENS, WILLIAM F [AG/1000]; SALTMIRAS, DAVID A [AG/1000]
Cc: [redacted]
Subject: RE: A FedEx shipment [793774060139] was created.

Hi [redacted]

The proposal sounds very reasonable and having [redacted] 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 [redacted] 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,

[redacted]

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Thursday, July 12, 2012 10:52 PM
To: SALTMIRAS, DAVID A [AG/1000]; [redacted]
Cc: [redacted]
Subject: RE: A FedEx shipment [793774060139] was created.

[redacted]

We (David, Joel, Kier, me) think we should proceed with pursuing [redacted] as a co-author for the glyphosate genetox 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 [redacted] go directly to the Board by sending out a note asking them to approve contracting with [redacted] 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]; [redacted]
Subject: FW: A FedEx shipment [793774060139] was created.

Bill & [redacted],

We (Monsanto) have a signed master contract with [redacted] 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 [redacted] 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.
Toxicology Manager
Regulatory Product Safety Center

Monsanto
ph (314) [redacted]

From: [redacted]@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,

[redacted]

States, potentially
including but not limited to the Export Administration Regulations (EAR) and sanctions regulations issued by the U.S. Department of
Treasury, Office of Foreign Asset Controls (OFAC). As a recipient of this information you are obligated to comply with all
applicable U.S. export laws and regulations.

Feinchemie Schwebda GmbH
Edmund-Rumpler-Str. 6
51149 Koeln

Geschaeftsfuehrer: [redacted]
Amtsgericht Koeln HRB 66957