Message

From: GOLDSTEIN, DANIEL A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=[redacted]

Sent: 9/22/2012 11:21:14 PM

To: SACHS, ERIC S [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=[redacted]; Henry Miller [redacted]@stanford.edu]

CC: SALTMIRAS, DAVID A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=[redacted]; LEMKE, SHAWNA LIN [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=[redacted]; HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=[redacted]; HAMMOND, BRUCE G [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=[redacted]

Subject: RE: Seralini

Henry and Eric-

Two additional comments- I have copied in Toxicology as I think we need their input on the second item.

1) I agree with Eric's concerns about some of the more insulting language- which may just be inflammatory rather than helpful. How far to push is a tough call.

2) It is true that he used 10 controls (per sex) and 10 rats in each of 3 dose groups. In my experience (TOX- please chime in!- I do not know OECD guidelines) most protocols actually do have an equal number of animals per test group- either control of one of the test doses (3 in this case). Statistically, I realize there actually are sometimes design reasons to employ unequal numbers- but this has limitations or at least raises issues as to what variance estimate to apply in significance testing.

In this design, he had 100 rats divided into 10 groups- control, 3 doses of GMO, 3 doses of GMO plus RU and 3 doses of RU. This does indeed end up with 90 test and 10 control animals per sex- but this simply reflects the large number of test groups employed. Virtually all industry studies – even if they only have control and 2 doses- have "twice as many test as control" … and we are usually admonished to use 3 doses so that we can see if we are in a linear range.

I am not sure that it is appropriate to criticize this as a fundamental design defect- he just has a lot more test groups than we usually see. This of course greatly increases the likelihood of a peculiar or unusual event occurring in one of the collected test animals- but this is why one does statistics- which he failed to do.

In short- I believe his error is one of interpretation and not a fundamental error in experimental design. There is no recommendation I am aware of that the number of control animals should equal the total number of animals in all test groups combined. It is not surprising to see 9-times as much weirdness in the 90 test animals as in the 10 controls- the good scientist takes this into account in the analysis.

Dan

From: SACHS, ERIC S [AG/1000]
Sent: Saturday, September 22, 2012 10:26 AM
To: Henry Miller
Cc: GOLDSTEIN, DANIEL A [AG/1000]
Subject: Re: Seralini

Henry – I made a few suggestions. Where possible I think it is helpful to provide an explanation of how Seralini's methods either contribute to or directly lead to misleading outcomes. This supports your premise that Seralini is abusing the scientific method to support his ideological opposition to GM crops and glyphosate. In some cases the consequences of the faulty study design may not be clear or understandable to some readers.

Eric

From: Henry Miller [mailto:[redacted]@stanford.edu]
Sent: Friday, September 21, 2012 10:54 PM
To: SACHS, ERIC S [AG/1000]
Cc: GOLDSTEIN, DANIEL A [AG/1000]
Subject: Re: Seralini

I cleaned up the text a bit and made a few additions.

H

From: "ERIC S SACHS (AG/1000)" <[redacted]@monsanto.com>
To: "Henry Miller" <[redacted]@stanford.edu>, "DANIEL A GOLDSTEIN (AG/1000)" <[redacted]@monsanto.com>
Sent: Friday, September 21, 2012 8:01:10 PM
Subject: RE: Seralini

Henry
I will look at it tomorrow.

Eric Sachs
Regulatory Policy & Scientific Affairs
Desk: [redacted]
Mobile: [redacted]
[redacted]@monsanto.com

-----Original Message-----
From: Henry Miller [redacted]@stanford.edu]
Sent: Friday, September 21, 2012 08:21 PM Central Standard Time
To: SACHS, ERIC S [AG/1000]; GOLDSTEIN, DANIEL A [AG/1000]
Subject: Seralini

Eric and Dan,

Attached is my humble effort on the Seralini paper. I'd welcome any suggestions, large or small, but most especially, correction of any inaccuracies.

There's not a terrific hurry, but the sooner you get it back to me, the sooner I can get it into Forbes.

Thanks!

Henry

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