

Message

From: STEINER, JERRY [Redacted]
Sent: 10/1/2012 1:00:23 PM
To: SACHS, ERIC S [Redacted]
Subject: RE: Seralini Paper - Letter to the Editor of JFCT from 25 Scientists in 14 Countries

Have you talked to raven or Hjelle or Carrington? I would welcome those views also as to how to handle this

From: SACHS, ERIC S [Redacted]
Sent: Sunday, September 30, 2012 10:18 PM
To: STEINER, JERRY [Redacted]; QUARLES, LEE [Redacted]; HELSCHER, THOMAS M [Redacted]; GAO, YONG [Redacted]; MILLER, PHILIP W [Redacted]
Cc: DINICOLA, NATALIE L [Redacted]
Subject: RE: Seralini Paper - Letter to the Editor of JFCT from 25 Scientists in 14 Countries

Jerry and all,

Several in Chatter are asking for the letter signed by 25 scientists to be shared publicly and leveraged. The most recent suggestion is to translate to French and try to get in published in Le Monde. I also learned that BIO asked if they could circulate the letter, and that Val and Bruce C agreed.

I am on the fence. If distributing the letter widely would compromise it being included in the journal then it would be better to hold back. If on the other hand publicizing the letter would lead Hayes and Elsevier to retract then it should be done immediately. What are your thoughts? I asked Val to urge BIO not to take any action until I gathered inputs. It is important to get this right.

There is a small cohort in Chatter that wants to "punish Hayes" but this is short-sighted. There may be a time when this is justified but not before the fate of the paper is known. In reality, if Hayes was not an accomplice in the review process debacle then he is already under fire for allowing it to happen on his watch. Would you want to be in Hayes shoes while your colleagues are clamoring for you to take action - action that may be outside your authority? The situation is complicated by Elsevier and by likely pressure/threats from Seralini back on Elsevier and Hayes.

I believe that Hayes needs to take responsibility for the review process failure or be held accountable for the consequences of his failure to guarantee expert peer review. If he does not resolve this matter by raining condemnation down on the Seralini study and removing those involved in the peer review then and only then should Hayes be held accountable.

I am urging the Chatter group to be patient.
Eric

From: SACHS, ERIC S [Redacted]
Sent: Sunday, September 30, 2012 12:20 PM
To: STEINER, JERRY [Redacted]; QUARLES, LEE [Redacted]; HELSCHER, THOMAS M [Redacted]
Cc: DINICOLA, NATALIE L [Redacted]
Subject: RE: Seralini Paper - Letter to the Editor of JFCT from 25 Scientists in 14 Countries

Jerry
The letter will be made public in due course but for now only has been shared among AgBioChatter and with Wally

Hayes the journal editor. We should not share more broadly. There is much more happening and we don't want to jeopardize retraction. I can explain over the phone.

If you want to talk, I am in India all week. Just let me know and will call you.

Your logic below is essentially correct. We have run the stats on mortality and there are no differences among the groups of rats, including the controls.

Eric Sachs

Regulatory Policy & Scientific Affairs

Redacted

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

From: STEINER, JERRY [Redacted]

Sent: Sunday, September 30, 2012 09:40 AM Central Standard Time

To: SACHS, ERIC S [Redacted]; QUARLES, LEE [Redacted]; HELSCHER, THOMAS M [Redacted]

Cc: DINICOLA, NATALIE L [Redacted]

Subject: RE: Seralini Paper - Letter to the Editor of JFCT from 25 Scientists in 14 Countries

Eric. This is a great letter. Does he plan to open this letter up if he does not get a response quickly? Can the letter be shared with other experts?

Is the following a way of describing the statistics of the small sample size of the control?

A simple way to describe the statistical impact of one small sample group, and nine treatments groups is to imagine each group is completely random. This is not an unrealistic assumption because these rats are known to spontaneously generate tumors as they age anyway, especially on unlimited diets.

If you have one control, and roll a dice 10 times, how many times will we get a 6? Let's say you get 1 six.

Then you repeat this 9 more times for the treated groups. What is the chance that one or two of these groups get more than one six? Statistically pretty high.

But it may not be the highest does as you'd predict—it would just be random. And that is exactly what he got. Any scientists would know the most important group is the control group. It is why you need large numbers so you eliminate this random effect. Its why I feel comfortable saying this well known anti GM scientists designed the experiment knowing he had a very good RANDOM chance of creating the exact result he wanted.

Jerry

9:29 AM

To: 'Peter Raven'

Cc: STEINER, JERRY [Redacted] DINICOLA, NATALIE L [Redacted]

Subject: Seralini Paper - Letter to the Editor of JFCT from 25 Scientists in 14 Countries

Peter

Here is a letter sent to Wally Hayes, Editor in Chief if the Journal of Food & Chemical Toxicology.

Eric Sachs

Regulatory Policy & Scientific Affairs

Redacted

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

From: Val Giddings [Redacted]

Sent: Friday, September 28, 2012 08:13 AM Central Standard Time

To: AgBioChatter [Redacted]

Subject: Chatter: what we sent to Hayes & cc'ed to Perill

Wallace Hayes, PhD, DABT, FATS, FIBiol, FACFE, ERT

Harvard School of Public Health

Editor-in-Chief, Food and Chemical Toxicology

Redacted

Dear Dr. Hayes:

We write to you, as Editor in Chief, to request a serious reconsideration of the recent paper by Seralini et al. alleging tumorigenesis in rats resulting from consumption of corn derived from crops improved through biotechnology (Séralini, G.-E., et al. Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Food Chem. Toxicol. (2012), <http://www.sciencedirect.com/science/article/pii/S0278691512005637>).

As you are undoubtedly aware, the use of molecular methods to improve crop plants, now known as GMOs, continues to be a highly controversial subject globally despite the absence of evidence, to date, of human, animal or environment harm. The paper by Seralini et al. makes claims that contradict a large body of literature on the subject, reviewed recently in your journal by Snell et al. (2012) under the title "Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review." Food Chem. Toxicol. 50:1134. This review, analyses by serious scientific bodies, including the U. S. National Academy of Sciences and the Royal Society, as well as the European Union's recent overview of 25 years of biosafety research on GMOs, all conclude that there are no negative health impacts specifically attributable to the use of molecular methods of crop improvement. Moreover, the

herbicide glyphosate, which affects an enzyme present in plants, but not animals, has a short residence time in the environment and a long history of safe use, as does the bacterium *Bacillus thuringiensis*, from which the so-called “Bt” gene was transferred to a number of crops to render them resistant to certain kinds of insect pests.

Seralini et al. make the extraordinary claim that rats fed GM corn, with or without added glyphosate, develop tumors earlier in life and die prematurely compared with controls, attributing enhanced morbidity and mortality to consumption of the GM corn and herbicide. Such extraordinary claims must be based on sound and extensive evidence, as they are guaranteed to cause – and indeed, have caused – widespread alarm. As detailed below, this study does not provide sound evidence to support its claims. Indeed, the flaws in the study are so obvious that the paper should never have passed review. This appears to be a case of blatant misrepresentation and misinterpretation of data to advance an anti-GMO agenda by an investigator with a clear vested interest. We find it appalling that a journal with the substantial reputation of FCT published such “junk” science so clearly intended to alarm and mislead.

In view of the importance of the ability to use modern molecular methods of crop improvement to increase the global food and feed supply and decrease the deleterious environmental impacts of conventional agriculture, we appeal to you to subject the paper to rigorous re-review by appropriate experts and promptly retract it if it fails to meet widely held scientific standards of design and analysis, as we believe it fails to do.

We make this request for you to reconsider the paper because it falls short of the customary scientific and ethical standards in several specific regards:

-  The experimental design is flawed, using far fewer animals per treatment (10) than dictated by the OECD guidelines mentioned (but not cited) in the paper (N = 50; see <http://www.oecd.org/science/biosafety-biotrack/42470554.pdf>);
-  The reader is not informed that the rats used in the study, Sprague-Dawley rats, fed *ad libitum* diets, would be expected to develop tumors in patterns fully consistent with what the paper reports, vitiating the authors attempt to link the observed tumors with any specific dietary components. There is an abundant literature on these rats, and their responses to ad lib/restricted diets, which the authors cite in an incomplete and entirely misleading way;
-  The experiment lacks appropriate controls (i.e., at least 50 individuals, fed a measured diet of confirmed identity differing from tested diets only by absence of inserted DNA; a robust experiment would also include a random, unrelated diet, e.g., one derived from organic maize);
-  Inappropriate and non standard statistical tests were used, rendering meaningless any interpretations of the results reported – robust statistical tests of raw data to determine whether or not differences are statistically significant must be used, not mere reporting of percentages or irrelevant and exotic tests of no value (e.g., OPLS-DA);
-  Critical details on how much food was consumed by each rat are absent, making it impossible to establish any dose/response relationship;
-  The identity of the “control” diet (i.e., “non GM” was not confirmed, and details on food preparation methodology were not provided);
-  The animals were not euthanized in a timely manner to eliminate unnecessary pain and suffering, as stipulated by both European and U.S. animal research guidelines;
-  The underlying and complete data are being withheld, not shared with other scientists, as is required by Elsevier’s published policies (“Authors may be asked to provide the raw data in connection with a paper for editorial review, and should be prepared to provide public access to such data (consistent with the ALPSP-STM Statement on Data and Databases), if practicable, and should in any event be prepared to retain such data for a reasonable time after publication...” - http://publicationethics.org/files/u2/New_Code.pdf).

Thank you in advance for your consideration.

Sincerely,

Robert Wager

Vancouver Island University

Canada

Alda Lerayer, Ph.D.

Senior Researcher

Institute of Food Technology

Campinas, São Paulo

Brasil

Dr. Nina Fedoroff

Distinguished Professor, King Abdullah University of Science and Technology (KAUST)

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Cornell University

Lúcia de Souza, Ph.D.

Vice-president

ANBio - Brazilian Biosafety Association

Cc: Elizabeth Perill **Redacted**

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