	SACHS, ERIC S	Redacted	
Sent:	9/28/2012 2:29:29 PM		
То:	'Peter Raven' Redacted STEINER, JERRY Redacted		
CC:	STEINER, JERRY	Redacted	; DINICOLA, NATALIE
	Redacted		
Subject:	Seralini Paper - Letter to the Editor o	f JFCT from 25 Scientists in 14 Countries	
Peter			
	tter sent to Wally Haves Editor in Ch	ief if the Journal of Food & Chemical Toxic	rology
Eric Sachs			
Regulatory	Policy & Scientific Affairs		
Re	dacted		
	33333		
	l Message		
From: Val (Giddings Redacted		
Sent: Frida	y, September 28, 2012 08:13 AM Cen	ntral Standard Time	
	hatter Redacted		
To: AgBioC	·	to Parill	
	natter: what we sent to Hayes & cc'ed	I to rei iii	
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Editor-in-Chief, Food and Chemical Toxicology

Redacted

Harvard School of Public Health

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), https://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)

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) Former Science and Technology Adviser to the Secretary of State & Evan Pugh Professor, Huck Institutes of the Life Sciences, Penn State University L. Val Giddings, Ph.D., President & CEO

Statement on Data and Databases), if practicable, and should in any event be prepared to retain such data for a

PrometheusAB, Inc.

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