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**From:** SALTMIRAS, DAVID A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=DASALT]  
**Sent:** 10/10/2012 10:07:05 PM  
**To:** LEMKE, SHAWNA LIN [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=649549]; VICINI, JOHN L [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=56908]; HAMMOND, BRUCE G [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=91757]  
**Subject:** RE: Seralini- Key points from Americas/Europe and Asia Teleconfereces yesterday

Shawna, John and Bruce,

Yong wants Tox team input. The views I express below may not reflect those of the team.

Alternatively, one may that consider that inevitably a third party may procure funding to verify Seralini's claims, either through a government agency or the anti-GMO/anti-pesticide financiers (note that Auchan and perhaps the Carrefour Group paid for the Seralini research).

Who do we want conducting such research? Do we place ourselves at risk by not undertaking a well executed chronic study? Either way, Seralini has generated sufficient momentum to claim a "small" victory, despite his scientific credibility being even more widely and indelibly soiled.

David Saltmiras, Ph.D., D.A.B.T.  
Toxicology Manager  
Regulatory Product Safety Center  
Monsanto  
ph [REDACTED]

**From:** GAO, YONG [AG/1000]  
**Sent:** Wednesday, October 10, 2012 4:51 PM  
**To:** HAMMOND, BRUCE G [AG/1000]; VICINI, JOHN L [AG/1000]; HEYDENS, WILLIAM F [AG/1000]; LEMKE, SHAWNA LIN [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; GOLDSTEIN, DANIEL A [AG/1000]; SACHS, ERIC S [AG/1000]; SWARTHOUT, JOHN T [AG/1000]  
**Cc:** CHEIKH, NORDINE [AG/1000]; GLENN, KEVIN C [AG/1000]  
**Subject:** RE: Seralini- Key points from Americas/Europe and Asia Teleconfereces yesterday

As to the studies listed in Dan's notes below, I would like to hear our tox team's opinion. A natural reaction of defense is to do more studies to disprove the anti's claims. For some issues that may be the right action, but in general it might not be the right strategy as it will never end. We may fall into the traps of the anti's. One can imagine that Seralini is already plotting for the next big "study".

We may hear similar requests or wishes on doing such studies from regulatory affairs managers of other companies. How do we manage it at the industry level? Is the tox project team/panel of CLI (or ILSI) the right platform to align tox experts position?

Thanks

Yong

**From:** GOLDSTEIN, DANIEL A [AG/1000]

**Sent:** Tuesday, October 09, 2012 9:48 AM

**To:** GAO, YONG [AG/1000]; NAIR, RASHMI S [AG/1000]; SACHS, ERIC S [AG/1000]; DOBERT, RAYMOND C [AG/1000]; KURTYKA, LUCYNA K [AG/1920]; REDING, H KEITH [AG/1000]; HOOD, AIMEE [AG/1000]; SOTERES, JOHN K [AG/1000]; SWARTHOUT, JOHN T [AG/1000]; PRADO, JOSE RAFAEL [AG/1000]; RUBINSTEIN, CLARA P [AG/5000]; SALAMINI, ALESSANDRA [AG/6042]; TINLAND, BRUNO [AG/5040]; MODENA, NATALIA [AG/5000]; DE LA FUENTE, JUAN M [AG/7879]; OLIVEIRA, IGOR C [AG/5050]; BOOKOUT, JEFFREY T [AG/1000]; JENKINS, DANIEL J [AG/1920]; EPPARD, PHILIP J [AG/1000]; TREACY, BRIAN K [AG/8070]; PEREZ PICO, EDUARDO [AG/7879]; HEREDIA, OSCAR [AG/7879]; ALVAREZ ARANCEDO, MIGUEL [AG/5000]; BERGER, GERALDO U [AG/5050]; PLEYSIER, ANNICK [AG/5040]; CAMPOS, HUGO [AG/5130]; CARCOVA, JORGELINA [AG/5000]; NEGRI ARANGUREN, IGNACIO [AG/6230]; JACOBS, ERIK [AG/1000]; WATERS, STEPHEN P [AG/5040]; BRANTS, IVO O [AG/5040]; GARNETT, RICHARD P [AG/5040]; WESSELS, WILLIE [AG/5360]; SELCUK, FEYZA [AG/5040]; RAMAMOCHAN, G [AG/8036]; TINLAND, BRUNO [AG/5040]; MODENA, NATALIA [AG/5000]; YAMANE, SEIICHIRO [AG/5270]; NAIR, RASHMI S [AG/1000]; GLICK, HARVEY L [AG/5340]; LI, YUE J [AG/6000]; EKE, KEVIN H [AG/5340]; PANT, DHIRAJ [AG/6020]; GUO, BEI HAI [AG/6000]; KIM, DONGYEON [AG/5340]; SRIVATANAKUL, METINEE [AG/5340]; NAKAI, SHUICHI [AG/5270]; RHO, MIN JEONG [AG/2660]; CHEN, KELLY [AG/5400]; ASIM, MUHAMMAD [AG/8089]; SURESH, P J [AG/6020]; KALIA, SANJEEV [AG/8036]; ROMERO, GABRIEL ORTEGA [AG/5330]; NGUYEN, HA THUY [AG/5283]; NATHWONG, BOONYANATH [AG/5410]; LEADER, MICHAEL [AG/5020]; KURNIAWAN, REDI FAJAR [AG/5235]

**Cc:** HAMMOND, BRUCE G [AG/1000]; VICINI, JOHN L [AG/1000]; HEYDENS, WILLIAM F [AG/1000]; LEMKE, SHAWNA LIN [AG/1000]; SALTMIRAS, DAVID A [AG/1000]

**Subject:** Seralini- Key points from Americas/Europe and Asia Teleconfernces yesterday

I wanted to capture a number of key points from the Asia/Pacific and Americas/Europe/Africa Seralini phone conferences yesterday. **A list of pending actions in St. Louis is provided below.**

I have combined the two groups for this purpose as I think it is important to see the differences in perceived needs and issues. Special thanks to John Swarthout and Jose Prado for assembling the slide set while I was on the road!

Please feel free to elaborate or correct any points, and to add any critical information.

**KEY POINTS:**

- 1) **Retraction-** Both Dan Jenkins (US Government affairs) and Harvey Glick made a strong case for withdrawal of the paper if at all possible, both on the same basis- that publication will elevate the status of the paper, bring other papers in the journal into question, and allow Seralini much more freedom to operate. The co-publication idea (in which rebuttals would be published with the paper) will probably have a letter of explanation/editorial from the journal editor which could help to address these issues- but this is seen as less than ideal. All of us are aware that the ultimate decision is up to the editor and the journal management, and that we may not have an opportunity for withdrawal in any event, but I felt it was worth reinforcing this request.
  
- 2) **Study needs moving forward-** unfortunately, all three potential issues regarding long term studies have now come up and will need some consideration and probably a white paper of some type (either internal or external). These are:
  - a. 2 year rat / long term cancer (and possibly repro) on GM crops. As discussed in the EU call yesterday, this needs to be a key point in our rebuttal documents. We have added this in as a point in our letter to the editor (which will also go to Korean regulators and probably other agencies as well), indicating that this study found nothing other than the usual variation in SD rats, and as such there is no reason to question the recent EFSA guidance that such studies were not needed for substantially equivalent crops. We did NOT do a review of literature and marshal the full set of arguments as we do not have sufficient time to do so. We will look into options for a separate white paper/op-ed or publication (Internal, academic, or organization like ILSI/HESI or IFBiC, etc.)
  
  - b. 2 year/chronic studies on pesticide formulations. This question is already being asked in Asia and of course was noted in the BfR response. The key point is the same- the paper actually finds nothing- so there is no need to draw any conclusions from it- but the

theoretical issue has been placed on the table. We need to be prepared with a well considered response.

- c. And finally- the one you have all been waiting for: 2 year rat/chronic studies of pesticide formulations on crop. This has come up in discussions in Korea. This approach would suggest that the same issue arises for conventional crops and that every individual formulation would need a chronic study over every crop (at a minimum) and probably every variety of crop (since we know they have more genetic variation than GM vs conventional congener) and raises the possibility of an almost limitless number of tests. We also need a coherent argument for this issue.

I would note that the pesticide formulation issue is a variant of the “mixture” issue which has been addressed in the literature and in recent EU regulations as to mixture testing, although I concede that there is hardly what anyone could call a “consensus” around the issue. The formulation X Crop/variety question is in fact simply a more complex variant of the same problem in the sense there is a potential for (and often a known) interaction between pesticide components and plants (metabolism, etc). We will need to identify a focused team to work on these issues (not necessarily do the work- but look at options, guide process, and write it if that is the ultimate decision) moving forward- with the first item (2 year study on GM) being the most pressing of the three.

- 3) **Need for additional information** regarding study funding, role of French supermarket chains, whether the labs were in fact GLP, whether the OECD was met even for the 90 day study, etc. This would be helpful but must be verifiable and correct information before we can share it externally.

#### **ACTIONS IN ST LOUIS:**

- 1) Detailed analysis of paper needed for Korea by COB today and also for use as letter to the editor of FCT (I am pushing this through final review along with Bruce).
- 2) Update to Monsanto response with 3<sup>rd</sup> party quotes at the beginning to improve impact and addition of newer links to scientific and media commentary. This will be done with a minimum of change to the existing document- an added paragraph at the beginning and new links at the

end- so that existing translations can still be used (there is nothing incorrect in earlier versions) and updated translation can be done quickly and with minimal effort.

- 3) Update to teamsite.
- 4) Follow-up on items 2a thru 2c above- mechanics and timelines to be determined.
- 5) Information gathering about the study is going on in many locations by various scientists and organizations. We will continue to monitor media as well as engaging industry colleagues in Europe and the efforts of the regulatory agencies to gain more information, and pass this information along when we have sufficient confidence that it can be relied on.

My thanks to everyone who participated in the teleconferences!!

Dan

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Lead, Medical Sciences and Outreach

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