

GM Corn Leads to Organ Failure!? Not So Fast

<http://blogs.discovermagazine.com/80beats/2010/01/13/gm-corn-leads-to-organ-failure-not-so-fast/>

Few things bring out the hyperbole like genetically modified organisms (GMOs), and that was true again with a study making the rounds yesterday and today.

In the International Journal of Biological Studies, a team examined three genetically modified corn varieties created by Monsanto. The study's authors say they see evidence of possible toxicity to the kidney and liver, "possibly due to the new pesticides specific to each GM corn." However, the findings became over-hyped headlines like the Huffington Post's "Monsanto GMO Corn Linked to Organ Failure, Study Reveals."

That's a pretty big leap from the not entirely convincing finding of a potentially questionable study. What actually happened is that the research team, led by Gilles-Eric S  ralini, re-analyzed data from tests that Monsanto scientists themselves conducted on rats eating these three varieties of corn-data that, to be fair, the team had to scratch and claw and sue to get their hands on. In their statistical analysis, S  ralini's team says that Monsanto interpreted its own data incorrectly, and that its new analysis shows potential for toxicity.

But the scientists themselves give significant caveats that make such bold headlines a bit of a reach: "Clearly, the statistically significant effects observed here for all three GM maize varieties investigated are signs of toxicity rather than proofs of toxicity"-that is, the evidence isn't rock solid, and not enough to warrant a bunch of alarmist headlines. The researchers argue that more research is necessary to settle the question either way: "In conclusion, our data presented here strongly recommend that additional long-term (up to 2 years) animal feeding studies be performed in at least three species, preferably also multi-generational, to provide true scientifically valid data on the acute and chronic toxic effects of GM crops, feed and foods."

In addition, there are a couple issues that make the study itself seem a little fishy:

1. Funding. "Greenpeace contributed to the start of the investigations by funding first statistical analyses in 2006, the results were then processed further and evaluated independently by the authors," the scientists write. Certainly one can't oppose a huge corporation like Monsanto without funding, but drawing those funds from a political lightning rod like Greenpeace can paint conclusions in a bad light, University of California, Davis, plant genomics expert Pamela Ronald tells DISCOVER. "That does not mean that it is incorrect," she says, "but makes me a little skeptical."
2. The journal: The International Journal of Biological Sciences is somewhat obscure, with an "unofficial"-that is, self-assigned-impact factor of 3.24. "In other words, it has not been assessed for impact or quality," Ronald says. Again, that doesn't mean S  ralini's team is wrong, but it suggests that jumping to conclusions would be unwise.

The actual data analysis of the paper has started an in-depth back-and-forth on the the statistical analysis. We'll continue following this story to see how the analysis shakes out.

GM Corn & Organ Failure: Lots of Sensationalism, Few Facts

<http://blogs.discovermagazine.com/80beats/2010/01/15/gm-corn-organ-failure-lots-of-sensationalism-few-facts/>

On Wednesday, we covered the overreaction by a few important online sources to an International Journal of Biological Sciences article claiming to find "signs of toxicity" in three varieties of genetically modified (GM) corn produced by Monsanto. We posted some caveats that made us uneasy about the study, such as the funding sources, the unknown quality of the journal, and the fact that the toxicity claims rely on reinterpreting statistical data that Gilles-Eric S  ralini and his coauthors themselves note is not as robust as it needs to be.

Karl Haro von Mogel, a University of Wisconsin Ph.D. student who works with Pamela Ronald (the GM expert we quoted in our last post), responded with some other problems he has on this study. He has a blog post of his own (in which he gets hopping mad at coverage that attributed organ damage, organ failure, or even cancer to the rats in the study). But here are the major issues he points out to DISCOVER:

1. Cherry-picking. "They were picking out about 20-30 significant measurements out of about 500 for one of the sets of data they analyzed," Haro von Mogel tells DISCOVER. "At the 95% significance level, you would expect that 5% of the observations would show a significant difference due to chance alone, which is what happened." In other words, one would expect to get some alarming results in approximately 25 out of the 500 of the measurements, which is indeed what they found. "Picking apart what seems to be normal background variability seems to me to be data dredging."
2. "False Discovery Rate." The battle over these corn varieties has been cooking for years; S  ralini and others published a paper in 2007 on the same issues, and after statistical criticisms like the ones just mentioned the authors came around with this new edition. One of the main shots scientists took at the previous paper, Haro von Mogel says, was that the team didn't employ a "false discovery rate"-a stringent statistical method that controls for false positives. This time they did, but for at least two of the three varieties-MON 810 and MON 863-the researchers themselves note p-values that are not significant. (A p-value is a measure of the likelihood that any particular finding was due to chance alone rather than a real effect. By convention, science calls anything that has a greater than 5 percent chance of being a random effect "insignificant.")
3. "Insignificant" results. As you can see in the study's chart, there a significant effect shown in "Lar uni cell" (large unnucleated cell count) for female rats fed the GM corn as 11 percent of their diet. But for female rats fed three times as much GM corn, it's not there. "Are they highlighting random variation or finding genuine effects? These are the kinds of questions that scientists need to address before concluding that they have found 'signs of toxicity,'"Haro von Mogel asks. (S  ralini et al. have argued that more attention needs to be paid to nonlinear toxic effects, where greater doses would cause less harm.)
4. Lack of corroboration or explanation. The government organization Food Standards for Australia and New Zealand (which disputed S  ralini's 2007 paper [Microsoft Word file]), also disputes the recent study, in part because there is no other science corroborating the statistical data-data that was challenged in the previous points. Their response concludes by saying, "The authors do not offer any plausible scientific explanations for their hypothesis, nor do they consider the lack of concordance of the statistics with other investigative processes used in the studies such as pathology, histopathology and histochemistry - Reliance solely on statistics to determine treatment related effects in such studies is not indicative of a robust toxicological analysis. There is no corroborating evidence that would lead independently to the conclusion that there were effects of

toxicological significance. FSANZ remains confident that the changes reported in these studies are neither sex- nor dose-related and are primarily due to chance alone."

We emailed Séralini to ask if he would respond to these particular criticisms, and have not yet heard a response. But the study is currently available to read for free, and you can see a YouTube clip of him discussing this paper, his methods, and his criticisms of Monsanto.

In light of these concerns regarding the study, it would be an enormous stretch to say the study proves that these corn varieties cause organ damage in mammals. But none of this puts Monsanto's GM corn totally in the clear, either. As commenters on our earlier post pointed out, Monsanto was simply following the rather laissez-faire rules for government approval, doing the 90-day trials themselves. But Séralini's team calls for long-term studies, upwards of two years, to get reliable data.

With the dearth of available data, which Monsanto was loath to give up to the researchers in the first place, strong conclusions are tough to come by. As Per Pinstrup-Andersen, a Cornell food expert not associated with Haro von Mogel's team, sums up this study: "It is very convoluted but the authors imply that the results are not scientifically valid by recommending a study "to provide true scientifically valid data," he tells DISCOVER.

But, as Séralini notes in his YouTube clip, that scientifically valid study would cost a fortune. And considering that these biotech crops have already been approved, Monsanto has little incentive to continue testing them.

=====

Study Says Monsanto's Genetically Modified Corn Is Toxic. But Is It?

- Dan Mitchell, Slate - The Big Money, January 14, 2010

<http://www.thebigmoney.com/blogs/daily-bread/2010/01/14/study-says-monsantos-genetically-modified-corn-toxic-it?page=full>

A study published by the International Journal of Biological Sciences concludes that three types of Monsanto's genetically modified corn cause organ damage in rats. Monsanto has disputed the findings, saying the methodology was all wrong.

The corn that was tested? You've eaten it.

But hold on a minute. The science journalists over at Discover, always on the case, put the findings into a context that was ignored by the Huffington Post and any number of other sites that tend to latch on to any tidbit that lets them say "Monsanto Bad." "Few things bring out the hyperbole like genetically modified organisms (GMOs), and that was true again with a study making the rounds yesterday and today," say the writers of Discover's 80Beats blog.

The team-written blog notes that the study was a reanalysis of the data Monsanto itself had earlier collected (and then held onto like grim death, forcing the researchers to sue the company for it). The researchers concluded that Monsanto interpreted its data incorrectly and that the new analysis shows that the GMO corn could be toxic. "But the scientists themselves give significant caveats that make such bold headlines a bit of a reach," says the Discover blog, which noted that the researchers found, in their own words, "signs of toxicity rather than proofs of toxicity."

That, Discover says, is "not enough to warrant a bunch of alarmist headlines." The researchers say their findings show a need for further, more long-term study. Discover also found some details surrounding the study to be "fishy," including the fact that the environmental group Greenpeace contributed to the early part of the study and the fact that the International Journal of Biological Sciences is "somewhat obscure" and hasn't been officially assessed for quality.

The news of the study is being widely cited with a link to a writeup in Twilight Earth, which says it is "dedicated to saving the Environment through shared News, Discussion, Advocacy and Activism." That site's Adam Shake summarized the results of the study with an anti-GMO spin, ending with a link reading "Click here to sign a petition to halt the sale of Monsanto GMO Corn!"

Immediately after that link, he later provided this update, copied here verbatim: I received an Email from Monsanto shortly after publication of this article with a rebuttal. In deference to journalistic fairness, because we consider ourselves unbiased in our reporting and because Monsanto has a history of litigation and heavy handedness---

Dan Mitchell has written for The New York Times, The Chicago Tribune, The Minneapolis Star-Tribune and Wired.

=====

Monsanto Corn Causes Organ Damage? Not So

- Dan Goldstein (aka Dr. Dan) January 12, 2010

<http://blog.monsantoblog.com/2010/01/12/monsanto-addresses-study/>

Recently, a paper was released claiming three Monsanto corn varieties cause organ damage in mammals. This simply isn't true.

In the current paper (de Vendomois et al., 2009) as with the prior publication (Seralini et al, 2007), Seralini and his colleagues use non-traditional statistical methods to reassess toxicology data from studies conducted with MON 863, MON 810 and NK603 corn varieties, and reach unsubstantiated conclusions.

It is important to note that several groups of scientists have gone over the study, and refute the claims.

* The French High Council on Biotechnology (HCB) has considered both the de Vendomois (2009) and Seralini (2007) papers and has found that these papers make no useful contribution to the safety assessment.

* The Food Standards Australia New Zealand (FSANZ) have also dismissed this study, stating, "Séralini and colleagues have distorted the toxicological significance of their results by placing undue emphasis on the statistical treatment of data, and failing to take other relevant factors into account."

Statistical fluctuations occur commonly in any large study with many endpoints, and statistical significance alone does not determine when an observation can be translated into evidence of risk. Making this determination requires consideration of:

* dose-related trends (higher dose should produce greater effect)

- * reproducibility
- * relationship to other findings such as abnormal organ appearance on pathology examinations
- * the magnitude of the differences and the relationship of the findings to the normal range of values
- * occurrence of a particular finding in both sexes (adjusting for known gender related differences in some tests)

When considered using proper statistical analysis in conjunction with these other criteria, the toxicology studies cited demonstrate no adverse effects of these products.

A more complete discussion of the issues related to this publication, as well as references to pertinent publications, is available on the Monsanto website: Monsanto Response: de Vendomois et al. 2009

http://www.monsanto.com/products/techandsafety/fortherecord_science/2010/monsanto_response_de_vendomois.asp

Dan is the Director of Medical Sciences and Outreach at Monsanto. He is a pediatrician, medical toxicologist, and clinical pharmacologist by training, and for the past 10 years his role at Monsanto has been devoted on human safety and health; Prior to Monsanto, Dan spent 10 years in private practice in Denver, Colorado, providing consultation in the area of Clinical, Occupational, Environmental and Forensic Toxicology. He joined Monsanto's Medical Department in 1998, was appointed a Senior Science Fellow in 2002, and currently serves as Director of Medical Sciences and Outreach within Regulatory Affairs.

=====