



Letter to the editor

Food and chemical toxicology

Dear Editor

I have carefully read the paper entitled "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize". I am very familiar with historical publications on this topic.

A number of criticisms of this paper have appeared in the media. They appeared shockingly quickly which caused me concern because I find it takes more time to properly and thoroughly read a scientific paper of this complexity. Most criticisms were of a general nature and without substance worthy of entering the scientific debate. Some criticisms were specific, referring to the type of rat used, the kind of statistical analysis, and the interpretation of the response to increasing concentrations of the agrichemicals, Roundup, or genetically modified plant ingredient.

I performed a quick review of papers on rat feeding studies using genetically modified feed components also published in this same journal. In addition to the paper by Seralini et al., I found seven studies between 2004 and now all published in Food and Chemical Toxicology in which Sprague–Dawley rats were fed diets supplemented with material from GM plants. All of these papers were published by those companies who developed the GM plant used in the study. One paper was from Monsanto, and the others from DuPont/Pioneer. None of the papers extended beyond ~90 days.

These studies used approximately the same number of rats as the study by Seralini et al. All of them used the same kind of rat as the Seralini et al. study. The 2004 study by Hammond used marginally more rats in the relevant control group, but was in my opinion less powerful statistically because of the inclusion of 'reference' control lines that were not fed on the near-isogenic non-GM diet. The power gained by the additional rats (20/sex vs. 10/sex) was offset by the noise introduced by irrelevant variables.

The statistics used in these other studies passed anonymous peer-review. Aside from that, there is no other peer-reviewed evidence that these statistical approaches are either uniquely appropriate or validated for their use in this kind of study. On those fronts, I find Seralini et al.'s statistical analysis equally valid. I would encourage both the scientific community and the regulatory community to engage in an exercise of validation of statistical analyses if this remains an issue of contention.

Where the Seralini et al. study has no peer in this group of papers is in its duration. No number of 90 day feeding studies

can refute the findings of a long term study when the effects are largely those that appear after 90 days.

Some critics have attempted to disparage the most recent findings by drawing doubt on the nature of the response, pointing out that the severity of the effect did not uniformly increase with dosage. I am aware of a number of toxicological studies that report similar phenomena. For example, Welshons et al. (2003) said in their article in Health Perspectives: "Furthermore, receptor-mediated responses can first increase and then decrease as dose increases, contradicting the assumption that dose–response relationships are monotonic." The effect fits perfectly well with receptor-mediated or saturated effects and within the hypotheses presented by Seralini et al. While there is always room for more science on any topic, in my opinion the Seralini et al. study stands shoulder to shoulder with the best of those published by others on this same issue. Importantly, it explores hypotheses that industry-based authors largely did not and therefore these earlier studies are in no way evidence against the most recent findings. The proper pathway forward is for any uncertainty in the findings to be put to rest through: the establishment of a consensus protocol developed through a transparent and openly peer-reviewed methodology; definitive study using this protocol to be conducted by industry-independent scientists of appropriate qualifications, such as Seralini et al., with reasonable access for observation by those nominated by the industry and regulatory communities.

In the meantime, it is my view that the recent study is a valuable contribution to the scientific literature, debate and process of evaluating technologies. I trust your journal to publish quality science and you have vindicated my trust.

Reference

- Welshons, W.V., Thayer, K.A., Judy, B.M., Taylor, J.A., Curran, E.M., vom Saal, F.S., 2003. Large effects from small exposures. I. Mechanisms for endocrine-disrupting chemicals with estrogenic activity. *Environ. Health Perspect.* 111, 994–1006.

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