press releases

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Expert reaction to GM maize causing tumours in rats

A toxicology study in Food and Chemical Toxicology into the health impact of a GM tolerant maize crop and the herbicide Roundup suggested lab rats developed mammary tumours and were more likely to die prematurely.

Prof Maurice Moloney, Institute Director and Chief Executive , Rothamsted Research, said:

"Although this paper has been published in a peer–reviewed journal with an IF of about 3, there are anomalies throughout the paper that normally should have been corrected or resolved through the peer-review process. For a paper with such potentially important findings, it would have been more satisfying to have seen something with a more conventional statistical analysis. A comparison of each measured parameter, which took into account the variance throughout the experiment, which would have been revealed using a multiple range test, would have provided better evidence for the concluding remarks and the abstract. Figure 1 does not provide any data from the controls and their variance is unreported here. Table 2 reports different numbers of individuals used for the controls than the treatments. In all cases the controls have used less individuals than used in the treatments. The data in Table 2 do not show confidence intervals or provide evidence of significant differences between all the treatments and the controls. The lack of a dose response effect is argued by the authors to be indicative of a “threshold” effect. This is an extrapolation of their findings and could only be determined by intermediate dosing. The photographs are very graphic, but do not include a control. Sprague-Dawley rats frequently develop mammary tumours in well-fed controls. Are we to conclude from this that no controls developed tumours? Numerically, we cannot tell, because they are absent also from Figure 2. We are performing a more detailed analysis of the statistics in relation to the conclusions, but for the present it is fair to point out that normally a referee would insist on showing the control data and its variance in such a study."

Prof David Spiegelhalter, Winton Professor of the Public Understanding Of Risk, University of Cambridge, said:

"In my opinion, the methods, stats and reporting of results are all well below the standard I would expect in a rigorous study – to be honest I am surprised it was accepted for publication.

“All the comparisons are made with the ‘untreated’ control group, which only comprised 10 rats of each sex, the majority of which also developed tumours. Superficially they appear to have performed better than most of the treated groups (although the highest dose GMO and Roundup male groups also fared well), but there is no proper statistical analysis, and the numbers are so low they do not amount to substantial evidence. I would be unwilling to accept these results unless they were replicated properly."

Dr Wendy Harwood, senior scientist, John Innes Centre, said:

"The full data set has not been made available, but the findings do not contradict previous findings that genetic modification itself is a neutral technology, with no inherent health or environmental risks.

"We have to ask whether a diet with this level of maize is normal for rats. Another control with an alternative diet should have been included.

"Ten rats per group is a small number. For example, is the death of three out of ten controls compared to five out of ten males in the treated group statistically significant?

"The data from the control group fed non-GM maize is not included in the main figures making it very difficult to interpret the results.

"Without access to the full data, we can only say that these results cannot be interpreted as showing that GM technology itself is dangerous. However they do indicate possible concerns over long-term exposure to Roundup that require further study."

Further comments from other scientists:

"Other issues that have come up:

• 'All data cannot be shown in one report and the most relevant are described here' – this is a quote from the paper.
• Small sample size
• Maize was minimum 11% of the diet – not balanced
• No non-maize control?
• No results given for non-gm maize
• For nearly 20 years, billions of animals in the EU have been fed soy products produced from genetically modified soybean, mainly from Latin America. No problems have been reported by the hundreds of thousands of farmers, officials, vets and so on.
• The same journal publishes a paper showing no adverse health effects in rats of consuming gm maize (though this is a shorter 90-day study)
• Statistical significance vs relative frequencies.
• We also have to ask why the rats were kept alive for so long – for humane reasons this study would not have been given approval in the UK.
• In Fig.2, I assume the bars with a zero is for the non-maize control. Those bars don't looks significantly different from the bars indicating 11, 22, and 33% of GM maize in the diet? Have the authors done stats on their data?"

Prof Anthony Trewavas, Professor of Cell Biology, University of Edinburgh, said:

"The control group is inadequate to make any deduction. Only 10 rodents so far as I can see and some of these develop tumours. Until you know the degree of variation in 90 or 180 (divided into groups of ten) control rodents these results are of no value.

"These figures for normal appearance of tumours in these rodent lines are surely available and using a line which is very susceptible to tumours can easily bias any result. To be frank it looks like random variation to me in a rodent line likely to develop tumours anyway."

Prof Ottoline Leyser, Associate Director of the Sainsbury Laboratory, University of Cambridge, said:

"Like most of the GM debate, this work has very little to do with GM. The authors of the paper do not suggest that the effects are caused by genetic modification. They describe effects of the roundup herbicide itself and effects that they attribute to the activity of the enzyme introduced into the roundup resistant maize. There is good evidence that introducing genes in to crops using GM techniques results in fewer changes to the crops than introducing them using conventional breeding.

"This is unfortunately rather a subtle point and is somewhat tangential to the immediate issue."

Prof Tom Sanders, Head of the Nutritional Sciences Research Division, King's College London, said:

"Most toxicology studies are terminated at normal lifespan i.e. 2 years. Immortality is not an alternative.

"No food intake data is provided or growth data. This strain of rat is very prone to mammary tumours particularly when food intake is not restricted.

"There is a lack of information on the composition of the diet. One concern is whether there were mycotoxins in the maize meal because of improper storage. Zearalanone is a well know phytoestrogen produced by filamentous fungi that grow on maize.

"The statistical methods are unconventional, there is no clearly defined data analysis plan and probabilities are not adjusted for multiple comparisons."

Prof Mark Tester, Research Professor, Australian Centre for Plant Functional Genomics, University of Adelaide, said:

"The first thing that leaps to my mind is why has nothing emerged from epidemiological studies in the countries where so much GM has been in the food chain for so long? If the effects are as big as purported, and if the work really is relevant to humans, why aren't the North Americans dropping like flies?! GM has been in the food chain for over a decade over there – and longevity continues to increase inexorably!

"And if the effects are as big as claimed, why have none of the previous 100+ plus studies by reputable scientists, in refereed journals, noticed anything at all?

"Finally, of course, this was a study of one event with one gene. To then extrapolate to all genetically modified crops is absurd. Even if it eventuates that there is an issue with this one event, or even this one gene, there is no reason at all for other genes introduced using GM to carry the same burden of risk. GM is an adaptation of a natural process that occurs all the time all over the planet – it is "only" a technology, a technique. It is how it is used that is more important. Generalisations about the risk of the technology per se are absurd."

Prof Alan Boobis, Professor of Biochemical Pharmacology, Imperial College London, said:

"Some of the effects are presented in a way that makes it difficult to evaluate their significance. For example, there does not appear to be a statistical analysis of the mammary tumours. These occur quite often in untreated animals. One would usually also take into account the historical controls in the testing lab, in reaching a conclusion. The pesticide itself has been subject to long term studies in rodents by others."

'Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize' by Seralini *et al.*, published in *Food and Chemical Toxicology* on Wednesday 19th September.

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