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Letter to the editor

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Dear Dr. Hayes,

I have serious concerns related to a recent online publication in one of the Elsevier Journals, Food and Chemical Toxicology: Séralini et al. Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Food Chem. Toxicol. (2012).

This paper has some relevant flaws from the experimental design, through the statistical analysis and the way the data is presented. In addition, it lacks of some crucial information for the proper understanding and full assessment of the work.

First the choice of the rat breed, Sprague–Dawley, the duration and the uncontrolled feeding used in the study. These animals were maintained for 24 months and fed ad-lib. This specific breed of rats is well known to be prone to develop cancer with age and especially when there is no dietary restriction. For example, Prejean et al. (1973) noted a spontaneous tumour incidence of 45% in 360 Sprague–Dawley rats (179 males and 181 females) in an 18-month series of carcinogenesis experiments. The percentage of female rats with tumours was almost double that of males. Durbin et al. (1966) reported a mean incidence of 71%, the peak incidence in normally aging rats were age-related with abrupt increases in the rate of development of mammary tumour, one occurring at about the 500th and the other at about the 660th day of life, with the median age at 671 ± 41 days. Harlan, the company that marketed the animals, describes the high incidence of 76% of mammary gland tumours (predominantly fibroademonas) in females on Life-span and Spontaneous Disease of Sprague-Dawley. Keenan et al. (1995) describes spontaneous tumours in up to 87% of females and up to 71% of males fed ad lib. Dietary restriction significantly reduced the incidence of tumours. Uncontrolled ad libitum feeding significantly contributes to a high variability and poor reproducibility of a study limiting its usefulness in risk assessment (in Keenan et al. (1999)). The number of rats in Séralini et al. (2012) developing tumours fall within the history of reported spontaneous tumour rate in this breed of rat. Séralini et al. even mention that control animals survived on average less than 24 months but it is not explained about their death in sufficient detail.

Second the way the data is presented and analysed. Scientists have to be careful and take measures to avoid being trapped by own bias, but the authors seem to consider the bits that supported their own beliefs and forgot to question their own contradicting results. An example of that, it is the missing discussion; for instance, on why male rats appear protected to cancer when eating high quantities of GM maize (see Fig. 1). In females, all treated groups died 2–3 times more than controls, and more rapidly. This difference was visible in 3 male groups fed GMOs. The comparison is unusual with important statistical analysis elements missing. The very small control group is not sufficiently described. Actually, due to the high incidence of spontaneous cancer under the conditions of the study, any conclusion based on such a small group is basically impossible. According to OECD guidelines, at least 50 per sex and group would be needed, but this study only used 10 animals. It is very limited for the reader to make own judgments and conclusions on the meaning of the study.

Discussion is important in science, but this publication stirred vigorous criticism by several scientists around the world. It has risen up great attention by the media that had no chance of getting an external expert opinion due to unusual non-disclosure clauses. The initial unbalanced media coverage is causing damage to an important tool for global food security. It is also important to avoid unnecessary distress and pain of the animals (e.g. Directive 2010/63/EU), the experiment should not go beyond the point required to meet the scientific objectives. I urge you to take adequate measures to keep the high standard quality of publications that come to your journal. This paper as it is now, presents poor quality science and dubious ethics.

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