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ABNE Brief on the Long-term toxicity study of Roundup herbicide and Roundup-tolerant genetically modified maize (NK603) published by Seralini *et al* (2012)

Background

On the 19th of September, 2012, a study (hereafter the 'French rat study') was published in the Journal of Food and Chemical Toxicology with adverse findings on the safety of the GM maize NK 603 and the herbicide Roundup®. In this study, the scientists examined 200 rats (Virgin albino Sprague-Dawley rats). Some were fed GM maize (NK 603) sprayed with Roundup; the second group had just the GM maize with no herbicide present; and a third group consumed no GM material but had drinking water spiked with different levels of Roundup herbicide. A fourth group acted as the control, and ingested a non-GM maize and non-spiked water. The duration of the study was 24 months and at the end, it was reported that rats fed GM maize (NK603) with or without the herbicide and those on Roundup spiked water developed tumors and multiple organ damages and died earlier in life than those on a the control diet.

The data and conclusions reported in this paper have been the subject of review and public comment by numerous members of the broader scientific community. This short brief provides a synopsis of these opinions as well as examining previously published information on the food safety of GM crops. In summary, these opinions agree that the findings of the French rat study are probably flawed and are inconsistent with the large body of published biosafety data and the long history of safe use of NK603 and Roundup herbicide.

Review of French rat study

The study has been critically reviewed by experts in the scientific community, industry, and the European Food Safety Authority (EFSA) and has been widely criticized on several grounds including; the use of non-standard study protocol, poor experimental design, unconventional statistical analysis, and misleading interpretations and generalization among others. For instance, in some cases, rats fed on diets with more GM components were less affected than the group fed on diet with less or no GM component. Based on this data, there is a clear absence of correlation between dose (amount of GM corn fed to the rats) and incidence of disease which is critically needed to support such claims as increased mortality and tumor development.

The strain of rats used in the study are highly prone to developing tumors, even in the untreated controls, 70-80% of the animals developed tumors within 2 years. Thus to make any statistically

meaningful deductions, the control group must be large. The number of control rats used in this study was small (10 per treatment) and was found to be statistically inadequate to support their claims. The paper concludes that the over expression of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) in the GM maize could account for the effects seen in test group fed only GM maize. EPSPS derived from bacteria is the protein that confers herbicide tolerance traits to crops. There is no evidence to date that EPSPS contributes to tumor development.

But perhaps one simple question that may hold the key to unraveling this mystery is; what constitutes a normal diet for these rats in the laboratory where they are produced? Harlan laboratories, the company that supplied the rats for this study does not exclude GMOs from the normal diets of these laboratory rats. In an email correspondence with ABNE, the company wrote (ABNE emphasis in square brackets):

''…Harlan has been producing animals for many, many years, and during the last decade (the time of using GMO's[in their diet]) we do not find any abnormalities in the breeding indices. Also, our customers that purchase both animals and diets and use them in longer term studies (such as CRO's or pharmaceutical companies) have not informed us of such findings. I would think if the animals are developing tumors at rates higher than historical data, we would be informed and asked to comment on such findings'' ~ Harlan Laboratories

This means that these rats have been consuming GM maize (plus GM soy), including the herbicide tolerant events used in this study, as part of their normal diets in the US and none of these adverse findings were observed.

Indeed, in the review by EFSA, the European Union body responsible for Food and Feed safety risk assessment, it was noted that:

A recent paper raising concerns about the potential toxicity of genetically modified (GM) maize NK603 and of a herbicide containing glyphosate is of insufficient scientific quality to be considered as valid for risk assessment. EFSA's initial review found that the design, reporting and analysis of the study, as outlined in the paper, are inadequate. Therefore, based on the information published by the authors, EFSA does not see a need to re-examine its previous safety evaluation of maize NK603 nor to consider these findings in the ongoing assessment of glyphosate - EFSA (Oct. 4, 2012)

Existing scientific consensus on the safety of GMO

Several peer-reviewed studies have been conducted into the safety of GM foods. In April 2012, a review of some of these studies was published in the same Journal of Food and Chemical Toxicology (Chelsea Snell *et al*). This paper reviewed data concerning the effects of diets containing GM maize, potato, soybean, rice, or triticale on animal health. Twelve (12) long-term studies (of more than 90 days, up to 2 years in duration) and twelve (12) multigenerational studies (from 2 to 5 generations) were reviewed. Without exception, there was not a single report of any adverse findings, including data from crops that express the same novel protein as in NK603, and the same herbicide (glyphosate). In 2010, a report released by the European Commission funded-research from 130 projects involving 500 independent research groups over 25 years concluded that "There is, as of today, no scientific evidence associating GMOs with higher risks for the environment or for food and feed safety than conventional plants and organisms." Two other studies on chronic toxicity of herbicide tolerant soybean lasting 52 weeks and 104 weeks did not make any adverse findings. Findings as prominent as those in the French rat study would surely have surfaced somehow in some of these studies.

ABNE's position on the findings

ABNE is committed to building functional biosafety systems and regulatory capacities across Africa using sound scientific knowledge such that its stakeholders are empowered to be able to discern sound science and to identify real risk that may be associated with modern biotechnology, knowing that zero risk is neither practically achievable nor scientifically defensible. ABNE supports the large body of evidence so far gathered by the scientific community, regulatory bodies and organizations such as the World Health Organization and the Food and Agriculture Organization (WHO/FAO) that have come to the conclusion that GMOs are not less safe than their conventional counterparts until otherwise proven by sound scientific evidence. It is ABNE's position that the French rat study does not meet the appropriate scientific standards and does not demonstrate harm with regards to the use of GMOs for food, feed or processing. The findings of this study are clearly out of synch with the extensive body of knowledge and experience that has been gathered over the years concerning the safety of GMOs. As we build capacity of our stakeholders to conduct risk assessment, we believe they would have the requisite confidence to assess foods of biotech origin for real risks based on sound science.

We will continue to monitor the development and keep our stakeholders informed. Please follow hyperlinks in this document for further reading.

This was developed by the African Biosafety Network of Expertise (ABNE) to address possible fall-outs from the 'French rat study'. ***This brief is primarily for regulators, policy-developers and decision-makers.***

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