FIRST PEER REVIEWED LIFETIME FEEDING TRIAL FINDS “SAFE” LEVELS OF GM MAIZE AND ROUNDUP CAN CAUSE TUMOURS AND MULTIPLE ORGAN DAMAGE

The first animal feeding trial studying the lifetime effects of exposure to Roundup tolerant GM maize, and Roundup, the world’s best-selling weedkiller, shows that levels currently considered safe can cause tumours and multiple organ damage and lead to premature death in laboratory rats, according to research published online today by the scientific journal Food and Chemical Toxicology.

Researchers found that rats fed on a diet containing NK603 Roundup tolerant GM maize, or given water containing Roundup at levels permitted in drinking water and GM crops in the US, died earlier than rats fed on a standard diet. They suffered mammary tumours and severe liver and kidney damage.

The paper, “Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize” reports on a study conducted by a team of scientists led by molecular biologist and endocrinologist Professor Gilles-Eric Seralini, co-director of the Risk Quality and Sustainable Environment Unit at the University of Caen, France, who is an authority on studies into the health impact of GMO’s and pesticides. It was supported by independent research organisation, CRIIGEN.

Dr Michael Antoniou, molecular biologist at Kings College, London, and a member of the CRIIIGEN scientific council, says:

“This is the most thorough research ever published into the health effects of GM food crops and the herbicide Roundup on rats. It shows an extraordinary number of tumours developing earlier and more aggressively - particularly in female animals. I am shocked by the extreme negative health impacts.”

“The rat has long been used as a surrogate for human toxicity. All new pharmaceutical, agricultural and household substances are, prior to their approval, tested on rats. This is as good an indicator as we can expect that the consumption of GM maize and the herbicide Roundup, impacts seriously on human health.”

In the peer reviewed paper, the research team say they believe this is the first long-term animal feeding trial to examine the effects of Roundup, the world’s most used herbicide, and a commercial Roundup tolerant GM maize. Researchers studied 10 groups, each containing 10 male and 10 female rats, over their normal lifetime - two years.
Three groups were given Roundup in their drinking water, at three different levels consistent with exposure through the food chain from crops sprayed with the weedkiller: the mid level corresponded to the maximum level permitted in the US in some GM feed; the lowest corresponded to contamination found in some tap waters. Three groups were fed diets which contained different proportions of NK603 – 11%, 22% and 33%. Three groups were given both Roundup and NK603 at the same three dosages. The final control group was fed an equivalent diet with no Roundup or NK603 but containing 33% of equivalent non-GM maize.

Researchers found that NK603 and Roundup both caused similar damage to the rats' health whether they were consumed on their own or together. Females developed fatal mammary tumours and pituitary disorders. Males suffered liver damage, developed kidney and skin tumours and experienced problems with their digestive system. The team also identified a “threshold effect” where even the lowest doses were associated with severe health problems.

The report states: “Similar degrees of pathological symptoms were noticed in this study to occur from the lowest to the highest doses suggesting a threshold effect. This corresponds to levels likely to arise from consumption or environmental exposure, such as either 11% GM maize in food, or 50ng/L of glyphosate in R-formulation [the lowest concentration of Roundup in the rats’ drinking water] as can be found in some contaminated drinking tap waters, and which falls within authorized limits.”

- Up to 50% of males and 70% of females died prematurely (before deaths could be put down to normal aging) compared with only 30% and 20% in the control group.
- Across all treatments and both sexes, researchers found treated rats developed 2-3 times more large tumours than the control group, defined as 17.5mm in females and 20mm in males.
- By the beginning of the 24th month 50%-80% of females in all treated groups had developed large tumours, with up to three per animal. Only 30% of the controls were affected.
- The tumours “were deleterious to health due to a very large size”, making it difficult for the rats to breathe, causing problems with their digestion and resulting in haemorrhaging.
- The first large detectable tumours appeared after four and seven months in males and females respectively but only after 14 months in the female control group and 23 months in a control male. However, the majority of tumours were only detectable after 18 months.

Treated males suffered severe liver and kidney dysfunction. Liver congestions and necrosis were 2.5 to 5.5 times higher than in the control group. There were also 1.3 – 2.3 times more instances of “marked and severe” kidney disease.

The lowest dose tested in the study (50 nanograms per litre) is below safety limits for glyphosate in water and crops. EU legislation sets the maximum permitted concentration (MPC) in water at 0.1 µg/litre, 1 mg/kg in maize, and 20 mg/kg in other animal feeds like soy, oats and barley. The US sets a Maximum Residual Level (MRL) in some animal feed of 400mg/kg.

The research findings raise serious questions about the current regulatory process for licensing industrial chemicals, pesticides and other novel crops. The scientists observe that GM crops have been approved safe for consumption on the basis of 90-day animal feeding trials. They also point out that only Roundup’s active principle, glyphosate, has been tested rather than the commercial product, which includes ingredients that enable the glyphosate to penetrate plants more efficiently.
The research also highlights the urgent need for more research into the long-term effects of all GM food crops, which are currently grown on 1.8% of the world’s agricultural land. In the US, 70% of processed foods contain GM ingredients without GM labeling, and 85% of maize now grown in the U.S. is GM. In the UK and Europe, GM maize is not consumed directly by humans but it is widely included in animal feed. Hundreds of thousands of tons of GM maize are imported to the UK each year for use in the diets of chickens, pigs and dairy cows. Meat and dairy products from animals fed on GM are currently sold in British supermarkets without any requirement for GM labeling.

**Patrick Holden, Founder and Director for the Sustainable Food Trust, says:**

“The research exposes a critical deficiency in the regulatory process which, due to the short-duration of the required feeding-trials failed to identify the serious, long-term health consequences of consuming these crops.

“To ensure that the public is protected against further exposure, there is an urgent need for a fundamental overhaul of the regulatory framework. We can no longer afford to continue to rely on short-term trials conducted by the industry without independent verification, which have been proved to be inadequate”.

“In the meantime, in order to protect the rights of consumers all foods containing imported GM maize or its derivatives, should be clearly labeled.”

The researchers hypothesize that the reason why NK603 GM maize, NK603 sprayed with Roundup, and Roundup on its own, all produced very similar negative health outcomes, is that both the GM maize and the weedkiller Roundup “may cause hormonal disturbances in the same biochemical and physiological pathway.”

Glyphosate, the active ingredient in the herbicide Roundup is a known endocrine disruptor, and previous research has shown that it can cause liver and kidney failure if consumed above maximum permitted residue levels. However, this is the first research that suggests that even very low levels, such as those found in drinking water, are harmful when consumed over an extended period.

The paper says: “The results of the study presented here clearly demonstrate that lower levels of complete agricultural glyphosate herbicide formulations, at concentrations well below officially set safety limits, induce severe hormone-dependent mammary, hepatic [liver] and kidney disturbances.”

It suggests that overexpression of the GM “transgene” EPSPS, which makes NK603 tolerant to Roundup in the field, may disrupt biosynthetic pathways and cause similar problems. Most edible GM crops use EPSPS to make them tolerant to Roundup.

Prof Seralini’s co-authors are Emilie Clair, Robin Mesnage, Steeve Gress, Nicolas Defarge, Manuela Malatesta, Didier Hennequin, and Joel Spiroux de Vendomois.

**Copies of the research can be obtained on request from CRIIGEN www.criigen.org and from Food and Chemical Toxicology www.journals.elsevier.com/food-and-chemical-toxicology**
For more information, interviews, film footage and pictures of the rats, please contact:

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Patrick Holden – Founder, Sustainable Food Trust – 07774 846858
Dr Michael Antoniou – Molecular geneticist and GM Expert and member of the CRIIGEN Scientific Council, Kings College, London
Requests to interview Prof. Gilles-Eric Seralini should be directed to Laurent Payet – Laurent@lp-conseils.com +33 6 89 95 48 87

Further resources are available on the SFT website including: pictures; a graphic showing premature death among female rats; and a backgrounder on the GM debate. research.sustainablefoodtrust.org

Notes to Editors:

CRIIGEN - Committee of Research and Independent Information on Genetic Engineering
The Committee of Research and Independent Information on Genetic Engineering (CRIIGEN) is a non-profit organization set up by Professor Gilles-Eric Seralini, Professor of Molecular Biology at Caen University, and former French ecology minister Corinne Lepage MEP, to offer scientific expertise on pollutants to health and environment. It is particularly focused on GMO’s and their impact on agriculture, food, medicine and human health. Professor Seralini was in charge of risk assessment for two government commissions and has advised the European Commission, Parliament and Councils and a number of governments on the use of GMO’s commercially.

Since its establishment, CRIIGEN has campaigned for more transparency in the genetic engineering trials carried out by commercial organisations, the biotech companies. It also lobbies the governments to improve the quality of risk assessment for GMO’s.

Previous research by CRIIGEN has included reanalysing existing studies into GM crops. One of these in 2007 concluded that the GM crop, MON 863, adversely affected liver and kidney function in rats. A further reanalysis of three more industry studies in 2009, reaffirmed CRIIGEN’s results regarding the crop’s toxicity. In 2011 CRIIGEN published a review of 19 published reports on animal GM feeding studies, which found that kidney and liver problems can arise even in 90-day trials. This has become a seminal work and the most consulted report on the topic, downloaded by more than 60,000 scientists from the SpringerOpen databank.

Professor Gilles Eric Séralini – Professor of Molecular Biology and President of the Scientific Board at Committee of Independent Research and Information on Genetic Engineering (CRII-GEN)
Gilles Eric Seralini is Professor of Molecular Biology and co-director of the Risk Quality and Sustainable Environment Unit at Caen University, France, and an expert on pesticides, pollutants and the effects of GMO’s on health. As a result of his research work into cancer and the
disruptors of reproduction, he started to investigate possible pollutants in air, water and food.

He established CRIIGEN – Committee of Independent Research and Information on Genetic Engineering – with Corinne LePage, in order to conduct more thorough scientific research into GMO’s. He is now the President of the Scientific Board.

Professor Seralini was in charge of risk assessment for two French governmental commissions to evaluate GM food and in 2003 he was appointed as an expert for the European Commission to prepare the defence case for the moratorium on commercial GMO’s against the US/Canada and Argentina.

He has written more than 100 scientific articles and conference papers for international symposiums and spoken globally about the impact of GM food and pesticides on animal and human health. In 2011, he was involved in a high profile law trial where he sued researchers from the French Association of Plant Biotechnologies (AFBV) for defamation when they tried to discredit his reanalysis of Monsanto trials. The court in Paris ruled in his favour.

**Dr Michael Antoniou – Reader in Molecular Genetics, Kings College, London School of Medicine, and Member CRIIGEN Scientific Council**

Dr Michael Antoniou is an expert in molecular biology and GM technology. He has worked as a molecular biologist for 32 years using genetic engineering technology to investigate gene organisation and control, making contributions to the field of human gene therapy. He holds a degree in Biochemistry from the University of Oxford and a PhD in molecular biology from Reading and has over 500 peer-reviewed publications of original work.

**The Sustainable Food Trust**

The Sustainable Food Trust was set up by the former director of the Soil Association, Patrick Holden. The charity aims to bring together the many groups and individuals working internationally in this area to help transform our present food system and meet the multiple challenges of climate change, resource depletion, food security and population growth. One of its particular areas of interest is in comparison between different systems of agriculture and their impact on human and environmental health.

Professor Seralini approached The Sustainable Food Trust to help communicate the results of the study on a global scale with Dr Michael Antoniou, who is a Member of the CRIIGEN Scientific Council.

**Patrick Holden, Founding Director, Sustainable Food Trust**

Patrick Holden is the Founding Director of the Sustainable Food Trust, an international organisation established to promote the sustainable food movement through the collective power of organisations, people and communities.

Between 1995 and 2010, Patrick was the Director of the Soil Association and became a much sought after speaker and campaigner for organic food and farming. He spearheaded a number of prominent food campaigns around BSE, pesticide residues and GM food. More recently, he was a member of the UK Government’s working group on the Foresight report into Future of Food and Farming and is Advisor to the Prince of Wales International Sustainability Unit.

Patrick is a farmer and has had a dairy farm in West Wales since 1973. It is now the longest established organic dairy farm in Wales, with a herd of 75 Ayrshire cows – the milk from which is made into raw milk cheese by his son, Sam.
In 2005, Patrick was awarded the CBE for services to organic farming. He is the Patron of the Biodynamic Agricultural Association, Living Earth Land Trust and the Soil Association Land Trust. He is an internationally renowned expert on food systems and speaks at conferences around the world on the future of food and to encourage global cooperation amongst those working in sustainable agriculture.