

Press release CRIIGEN - March 2007

A SERIOUS CONCERN : AUTHORIZED GM MAIZE IS UNFIT FOR CONSUMPTION *The case of Bt GM maize MON 863*

Abstract. For the first time in the world, an independent study on the health risks of a GM maize authorized for consumption shows signs of hepatorenal toxicity (1). It is a counter valuation performed by CRIIGEN (France), of a regulatory study by the Monsanto Company, on rats fed with a GM maize (MON 863) over a three-month period. The raw data were used to obtain the commercial release of this GM maize at an international level. These revelations are certainly sufficient to require an immediate ban of GM maize MON 863 and all its hybrids from human or animal consumption, as well new and more carefully conducted feeding studies. This maize cannot now be considered safe to eat. We are calling urgently for a moratorium on other approved GMOs while the efficacy of current health testing methods is reassessed.

For the first time in the world, an independent study on the health risks of a GM maize authorized for consumption shows signs of hepatorenal toxicity (1).

It is a counter valuation performed by CRIIGEN (France), of a regulatory study by the Monsanto Company, on rats fed with a GM maize (MON 863) over a three-month period. The raw data were used to obtain the commercial release of this GM maize at an international level. The symptoms discovered in re-analyzing the data are consistent, and are evidenced in comparison to control rats of the same genetic origin, the same age, and caged in strictly similar conditions. They have eaten a diet of equilibrated chemical composition, assessed as equivalent to controls, but without the Bt toxin which is the insecticide produced by the GM maize itself. On average, females show a gain of weight, a significant increase of sugar and fat in the blood, an increase of liver weight relative to body weight, and disruption of renal function. Inversely, the males lose weight, they are more sensitive at the renal level, the kidneys also lose weight in comparison to the body, and ions analyses are modified in urine. This may have a relationship with the diagnosed nephropathies. This latter phenomenon may be naturally developed with age in this rat strain, but in this case the rats were young, reaching only five months by the end of the experiment. Markers of hepatic function are also reached. We can notice that toxic products such as pesticides regularly provoke different effects according to the sex, like during a cancer initiation. It is not possible for such short tests to identify the precise beginning of a particular disease. However, the detoxification organs are reacting.

The body weight variations of these animals were not statistically evaluated by Monsanto, who published a study on this subject in 2006. Monsanto's paper also omitted the urine chemistry analyses. The statistics were not detailed enough and their protocols were questionable.

1/ We raise concern about the reasons why the authorities did not require an independent study of the statistical analyses performed by Monsanto, which would have exposed these problems.

2/ We question why the authorities did not require the renewal and the prolongation of these experiments, controversial since 2003.

3/ And we wonder why the authorities did not ask for the sexual hormones measurements, that may be disrupted because of the different effects based on gender.

The raw data of Monsanto that allowed this counter valuation were obtained via Court action. These data were considered as confidential not only by the Company, but also by European States and the European Community. The data thus concern the MON 863 maize producing a new insecticide called "modified Cry3Bb1" aimed at killing Chrysomelidae (coleopteran insect, *Diabotrica virgifera*). This insect is a particularly devastating pest to the maize. It was also recently introduced by plane several times in Europe. This recently authorized GM maize also contains a gene coding for antibiotic resistance. Monsanto's tests prove quite insufficient, although there are at the same time the most detailed, and the longest ones, ever performed over the world on mammals, after consumption of this plant ; and these are typical of the present regular tests for GMOs (lasting only 90 days maximum on rats).

Because it produces a new internal insecticide, this GMO belongs to the second most important category of cultivated and commercialized GMOs throughout the world. The other GMOs absorb an herbicide without dying. Thus, most of GMOs are pesticide-plants.

For the record, these tests were controversial from the outset in France, and in 2003 they provoked a disagreement between experts, in particular in the French CGB (Commission du Génie Biomoléculaire). CRIIGEN (the Committee for Independent Research and Information on Genetic Engineering) was concerned about possible scientific weakness, and asked the GM regulatory authorities for sight of the raw data. These data were kept confidential until Greenpeace Germany won a Court verdict against Monsanto; this forced the company to make public the blood and urine analyses of the rats under experiment. The raw data are contained within more than 1130 pages of tables of numbers and calculations. A group from CRIIGEN comprising Prof. Gilles-Eric Séralini (researcher on pesticides and governmental expert on GMOs, University of Caen), Dr. Dominique Cellier (biostatistician, University of Rouen), and Dr. Joël Spiroux de Vendomois (physician and specialist on environmental health), have concluded a study and re-evaluation of these data. The work has been done independently of Monsanto or any other GMO producer.

These revelations are certainly sufficient to require an immediate ban of GM maize MON 863 and all its hybrids from human or animal consumption, as well new and more carefully conducted feeding studies. This maize cannot now be considered safe to eat. We are calling urgently for a moratorium on other approved GMOs while the efficacy of current health testing methods is reassessed.

(1) The article, entitled "New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity" is by Gilles-Eric Séralini, Dominique Cellier, and Joël Spiroux de Vendomois. It is published on line http://dx.doi.org/10.1007/s00244-006-0149-5 (you may need to copy and paste the URL into your browser).) by the American journal *Archives of Environmental Contamination and Toxicology*. It will be printed in May. The editor is Dr. Doerge from the Food and Drug Administration (FDA).

Contacts : CRIIGEN Tél : +33 (0) 2 31 56 54 89 or 56 84 – mail : <u>criigen@unicaen.fr</u> CRIIGEN President Corinne Lepage + 33 (0) 6 11 17 50 97
