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CRIIGEN answers to European Food Safety Authority
critique of MON 863 study
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In June 2007, the European Food Safety Authority (EFSA) issued a press release¹ describing recent analyses of our publication² in an international journal. Our study represents to date the most detailed statistical peer-reviewed paper on one of the longest toxicological studies on a commercialized GMO.

After careful consideration of the June 28 EFSA review on the GM maize MON 863 toxicological test, we indicate here our 5 main points of disagreement for the international scientific community, government authorities and the public. These are listed below by order of importance with EFSA views and supporting organisations or societies:

1. We disapprove the politics of absence of transparency on the original crude data of the toxicological tests accepted by EFSA. Normally, all scientists should have access to all blood, urine, organs and weight analyses for rats eating a commercialized GMO. Accepting such data as confidential, EFSA blocks the normal peer-review functioning of science and the knowledge of any toxicological effect not seen before. We recall that this was the case for MON 863, and there was a Court Appeal by Monsanto Company in Germany to avoid the public data release. The case was lost. The Directive CEE/2001/18 asks for transparency of environmental and health impacts of GMOs. Having in its confidential files similar data for other GMOs, EFSA blocks the scientific comparisons that could allow a better understanding of what happens after MON 863 consumption on mammalian physiology. This is very important.
2. CRIIGEN disagrees with EFSA in accepting the fact that GMOs are safe for humans and farm mammals, if detailed blood and numerous organ analyses are available only for rats at a mammalian level. This is also a crucial point and a scientific weakness that EFSA wrongly accepts. It is serious, even if scarce nutritional data are there in addition on other

¹ EFSA reaffirms its risk assessment of genetically modified maize MON 863, Parma, June 28 2007.

http://www.efsa.europa.eu/etc/medialib/efsa/press_room/press_release/pr_efsa_maize-mon863.Par.0001.File.dat/pr_efsa_mon863.pdf

² New Analysis of a Rat Feeding Study with a Genetically Modified Maize Reveals Signs of Hepatorenal Toxicity by G.E. Seralini, D. Cellier & J. Spiroux de Vendômois, Arch. Environ. Contam. Toxicol. 52, 596–602 (2007).

species. We note that for pesticides and drugs, at least three mammalian species are studied at a detailed toxicological level, before commercialization. This MON 863 GMO and more than 99% cultivated commercialized GMOs do contain new pesticide residues that have unknown effects on human and animal health.

3. CRIIGEN disagrees with the fact that EFSA accepts 90-day feeding trials for mammals as the longest necessary from a toxicological point of view (with detailed analyses on numerous organs). The current scientific void regarding safety of GMOs without longer feeding trials (two-year tests, tests run for the duration of a lifespan, and tests on more than one generation). EFSA supports this lack of knowledge, even though it has the capacity to ask for more data from companies before commercialization. As a result, EFSA has accepted an enormous responsibility in case of any accident or chronic effect of a GMO product for humans or animals.
4. EFSA acknowledges the fact that we have evidenced 40 significant differences on physiological parameters between rats eating GMOs and their controls. EFSA demonstrates in its counter-valuation of our study that what we have concluded is true: there is not 100% probability that all these 40 effects are only due to chance. Thus EFSA should conduct a very detailed toxicological analysis completely removed from their report on our study. By concluding that MON 863 is safe, EFSA accepts Monsanto reasoning on the fact that the effects are negligible since they are not proportional between the two doses (11 and 33% of GMO in the diet), and that they varied by sex. In our opinion these are significant departures from scientific principles. For instance, in the case of endocrine disruption, effects may not be proportional for two doses chosen arbitrarily a priori, and are rarely identical in males and females! Moreover there were signs of dysfunction (that we refer to as signs of toxicity) in liver and kidney that were different between rats fed the GMO diet and all other diets used in this experiment (6 diets in total, too many to study the GMO effect properly). EFSA has failed to consider the fact that the Monsanto study was not designed to observe a dose-response relationship (requiring more than two doses), that comparison of outcomes between GMO-fed rats and the entire variation of six reference groups is inappropriate, and that endocrine differences by sex (effect modification) requires separate analyses.
5. EFSA discusses our weight curves for the animals at length, concluding that our comparisons were insufficient in accounting for individual variability. We note that we were the first to do this study that could have been performed by EFSA before. This demonstrates the lack of questioning of Monsanto tests by EFSA, since even in using methods that take a maximal account of individual variability, EFSA and the French Commission du Genie Moleculaire (CGB) still evidence some statistical effects on the variations of the female weights, as we do.

In conclusion, we appeal to the scientific community, government authorities and the public to question the EFSA scientific methodology in this case. Our recent paper stands as robust testimony to the questionable safety of this genetically modified food for humans and animals.

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