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Answer to “Food Standards Australia New Zealand” (FSANZ).

On the review of the paper on MON863 entitled "New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity" from CRIIGEN published in **Arch. Environ. Contam. Toxicol. (2007) 52 (4) 596-602.**

Different advisory bodies have already reviewed this CRIIGEN international peer-reviewed paper on the toxicology of a GMO, which remains the most detailed published toxicological analysis of a commercialized GMO. These bodies, each one waiting for the advice of the others (AFSSA, CGB, EFSA), have developed similar arguments. CRIIGEN has already answered them (www.criigen.org), and we ask that our critique should be read and considered first. FSANZ was in any case waiting for the EFSA opinion, as indicated, before giving its own.

We underline that all these bodies had reviewed the same crude data as we did in our paper, and had concluded that MON863 was safe, with each one waiting for the confirmation of the others. Publishing our study and concluding that MON863 might not be safe, we knew that these bodies would be questioned again. Their approvals of this GMO could not be taken to confirm the absence of possible signs of toxicity anyway.

Our paper has demonstrated undoubtedly significant effects of GMOs on health parameters that cannot be denied. However, the relevance of these significant effects can be discussed as appropriate. In any case, our paper has not only taken into account differences between test and control groups as claimed by FSANZ. The so-called “reference groups” added by Monsanto (formed by rats eating diets of several different chemical compositions) are considered in our Table 2. This criticism of our work in the FSANZ executive summary is completely wrong and reveals a defective understanding of our paper.

On the other hand, it is absolutely clear that we consider that the gross composition analysis of a food and a chemical characterization of a new protein cannot lead to a prediction of all possible signs of toxicity following consumption. In our view the subchronic and chronic consumptions of this GMO, with following studies of all the organs of the animals, are the only way to really approach the safety of a product. This is true overall if the product is designed to synthesize a new kind of insecticide in a food or a feed, as is the case for this MON863 maize.

FSANZ then again publishes scientific mistakes, for example on p.2, l.12. Of course the GM maize may be part of the usual diet of mammals today (including farm and laboratory animals) as

it is in the experiment analyzed (11 or 33%). We recall that it is an equilibrated diet. And of course, for pesticides or drugs, subchronic or chronic toxicity studies represent the best means (with pre-clinical or epidemiological studies) for discovering their physiological effects.

All these scientific considerations create an immediate gulf between our views and those of FSANZ, CGB, AFSSA and EFSA.

Statistical matters have been discussed in our previous answers, and we confirm the validity of our statistical approach in comparison to the approach used by Monsanto, which was a faulty one in spite of being approved by some bodies such as FSANZ.

For instance, if the number of crude reticulocytes and their relative number are simultaneously changed in GM fed animals, this reduces the risk that this effect could have arisen by chance alone, and does not increase it.

On the other hand, to take into account only a dose-related effect (overall with two doses chosen a priori) is stupid, for instance in hormonology. Moreover a subchronic or chronic toxic effect of a chemical is rarely identical in males and females, since the detoxification organs and hormonal glands function differently.

The body weight changes that we have found (and as confirmed by a CGB report at least for females) may be important even if <5%. Sexual hormones have not been measured in the Monsanto experiment and they would be the first indicators of hormonal disruption before any histopathology. This possible histopathology cannot always, in any case, be related to metabolic changes.

We interpreted the significant effects as signs of toxicity if the parameters measured were different between GMO treated rats and controls, and coherent (for instance in females increases of blood sugar and fat, liver weight, and body weight, plus kidney problems shown by urine composition disruptions). Moreover we checked that this was not the case when we compared all the six normal diets together, and that there were still effects when we compared the GMO-eating group to all other groups. FSANZ said it was not a problem because the values were not outside "historical" values, without defining those. This cannot be a scientific argument for us.

Of course we agree that all signs of liver and renal toxicities are not lighted on; a beginning effect that could be amplified after 3 months would be rather like that. There is no rule in physiology which says that at one given step an unknown product should modify a particular parameter rather than another one, and to argue the contrary would be foolish. The expected modification of all the parameters cited by FSANZ as being necessary before admitting any toxicity is not scientific, and does not follow the appropriate rules for the protection of the consumer.

The argument (6) developed by FSANZ is wrong even according to Hammond et al. from Monsanto that describe the contrary: the GM-fed rats had a chronic progressive nephropathy (index 18/20) in comparison to controls (14/20). This has to be related to the disrupted urine chemical composition of the GM group. FSANZ has not considered the file in detail.

In conclusion we consider that the toxicological interpretation strategies described by FSANZ are highly questionable, and we refute their arguments.
