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Genetically modified crops safety assessments: present risks

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Purpose

We reviewed 19 studies of mammals fed with commercialized genetically modified soybean and maize which represent, per trait and plant, more than 80% of all environmental GMOs cultivated on a large scale, after they were modified to tolerate or produce a pesticide. We have also obtained the raw data of 90-day long rat tests, following Court actions or official requests. The data obtained include biochemical blood and urine parameters of mammals eating GMOs, with numerous organ weights and histopathology findings.



Methods

We have thoroughly reviewed these tests from a statistical and a biological point of view. Some of these tests used controversial protocols which are discussed, and statistically significant results that were considered as not being biologically meaningful by regulatory authorities, thus raising the question of their interpretations.

Results

Several convergent data appear to indicate liver and kidney problems as endpoints of GMO diet effects in the above-mentioned experiments. This was confirmed by our meta-analysis of all the *in vivo* studies published, which revealed that the kidneys were particularly affected, concentrating 43.5% of all disrupted parameters in males, whereas the liver was more specifically disrupted in females (30.8% of all disrupted parameters).

Conclusions

The 90-day long tests are insufficient to evaluate chronic toxicity, and the signs highlighted in the kidneys and livers could be the onset of chronic diseases. However, no minimal length for the tests is yet obligatory for any of the GMOs cultivated on a large scale; and this is socially unacceptable in terms of consumer health protection. We are suggesting that the studies should be improved and prolonged, as well as being made compulsory, and that the sexual hormones should be assessed too, and moreover, reproductive and multigenerational studies ought to be conducted too.

Transcriptomics, proteomics and other related methods are not ready yet for routine use in the laboratories, and moreover they may be inappropriate for studying toxicity in animals, and could not in any way replace *in vivo* studies with all the physiological and biochemical parameters that are measured with organs weight, appearance and histology. By contrast, afterwards, new approaches could well help to explain pathological results or action mechanisms of pesticides present in the GM plants or GM fed animals, if found.

To obtain the transparency of raw data (including rat blood analyses) for toxicological tests, maintained illegally confidential, is crucial. It has also become crucial to apply objective criteria of interpretation like the criteria described here: sex specific side effects or non-linear ones. Such data can be put on line on the EFSA website with a view to provide a fuller review to the wider scientific community, and in order to better inform the citizen to make biotechnologies more socially acceptable. Since fundamental research is published on a regular basis, it should be the same for this kind of applied research on long term health effects, as suggested by the CE/ 2001/ 18 and the corresponding 1829/ 2003 regulations.

We can conclude from the regulatory tests performed today that it is unacceptable to submit 500 million Europeans and several billions of consumers worldwide to the new pesticide-GM derived foods or feed, this being done without more controls (if any) than the only 3-month long toxicological tests, and using only one mammalian species, especially since there is growing evidence of concern. This is why we propose to improve the protocol of the 90-day studies to 2-year studies with mature rats, using the Toxotest approach, which should be rendered obligatory, and including sexual hormones assessment too, as previously underlined. The reproductive, developmental and transgenerational studies should also be performed. The new SSC statistical method of analysis is proposed in addition. This should not be optional if the plant is designed to contain a pesticide (as it is the case for more than 99% of cultivated commercialized GMOs), whilst for others, depending on the inserted trait, a case-by-case approach in the method to study toxicity will be necessary.

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