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Genetically modified crop consumption at large scale: Possible negative health impacts due to holes in assessment. Overview of the safety studies of GMOs performed on mammals[1]

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Background, aim and scope

Recently, a debate on international regulation is ongoing on the capacity to predict and avoid adverse effects on health and environment of new products and novel food/feed (GMOs, chemicals, pesticides, nanoparticles …). The health risks assessment cannot avoid the study of blood analyses of mammals eating these products in subchronic or chronic tests. Mammalian feeding trials have thus been usually performed for regulatory purposes, in order to obtain authorizations or commercialization for GM plant derived foods or feed. They may have been published in the scientific literature afterwards. We have obtained, following Court actions or official requests, the raw data of several safety, 28 day or 90 day long, in vivo tests on rats for GMOs (Séralini et al. 2007; Spiroux de Vendomois et al. 2009). We have thoroughly reviewed these tests from both a biological and biostatistical point of view. We focus here on the results of available 90-day feeding trials (or more) with commercialized GMOs, in the light of modern scientific knowledge.

Overview of the safety studies performed on mammals

Firstly we have focused our study on commercialized GMOs which have been cultivated in significant amounts throughout the world since 1994. These often analyze the biochemical blood and urine parameters of mammals eating GMOs, together with numerous organ weights and histopathology. We observe and emphasize that all the events correspond to soybean and maize which constitute 83 % of the commercialized GMOs, whilst the remainder are canola or cotton (Clive 2009). Then, some tests presented here show controversial results which can be discussed, or statistically significant results considered as not biologically significant by regulatory authorities, raising the question of the statistical and biological interpretation of results.

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First of all, the data indicating no biological significance of statistical effects in comparison to controls have been published mostly by companies from 2004, at least 10 years after commercialization in the world of these GMOs. This is a matter of grave concern. Moreover, only three events were tested more than 90d long or on more than one generation, and not by industry; even if a 90d period is considered as insufficient to evaluate chronic toxicity (Séralini et al. 2009; EFSA 2008). All these commercialized cultivated GMOs have been modified to contain pesticides, either by herbicide tolerance or insecticide production, or both, and thus could be considered as "pesticide plants" (Seralini 2004). These GMOs encode only for these two traits in spite of the advertising for numerous other characters possibly existing. Usually, pesticides are tested over a period of 2 years on a mammal to measure quite often side effects. Additionally, unintended effects of the genetic modification itself cannot be excluded, as direct or indirect consequences of insertional mutagenesis creating possibly metabolic effects (Rosati et al. 2008).

Some GMOs affect the body weight increase according to the authors (RR CP4 EPSPS and MON863) at least in one sex (Séralini et al. 2007; Zhu et al. 2004), a parameter considered as a very good predictor of side effects in other organs. Several convergent factors appear to indicate liver and kidney problems as endpoints of GMO diet effects in these experiments (Séralini et al. 2007; Spiroux de Vendomois et al. 2009; Vecchio et al. 2004; Kilic and Akay 2008). This is confirmed by our meta-analysis of all in vivo studies published on this topic (Table 1). On a total of around 9 % of all parameters disrupted, 2 times more than that could be obtained by chance only, surprisingly 42 % of those were concentrated on male kidneys for all commercialized GMOs, even if only around 25 % of the parameters measured concerned directly the kidney level. Even if our own counter-expertise is removed from the calculation, showing numerous kidney dysfunctions (Séralini et al. 2007), around 32 % of disturbances are still noticed in kidneys. However, other organs maybe reached such as heart and spleen, or blood cells (Spiroux de Vendomois et al. 2009).

Tab. 1: Meta-analysis of statistical differences of feeding trials with commercialized soybean and maize GMOs given to rats (Séralini et al. 2010). Parameters are classified per tissues according to Séralini et al. (2007). Statistical differences are reported according to the statistics of the authors. All these data revealed that the kidney is particularly reached, concentrating 42 % of all parameters disrupted in males.

Parameters in GMOs in vivo studies of toxicity	**Measured by organ (%) / Total (721-719)**		**Disturbed in each organ (%) / Total disrupted parameters (~ 10 %)**	
	Females	Males	Females	Males
Liver	23.4	23.5	26	24.3
Kidney	23.9	23.9	27.5	41.4
Bone Marrow	30.8	30.9	34.8	27.1
Total for 3 tissues	88.1	88.3	88.3	93.4

Conclusion

We can conclude from regulatory tests performed today that it is unacceptable to submit 500 million Europeans and several billions of consumers worldwide to these new pesticide-GM derived foods or feed, and this without more controls than if any only 3 month long toxicological tests, and this with only one mammalian species, especially given the evidence of worrying problems.

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