WRITTEN QUESTION E-3612/09
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to the Commission

Subject: Authorisation for all uses for GMO maize MON810 in Europe

Monsanto's GMO maize MON810 is currently subject to a renewal procedure for its authorisation for all uses by the European Commission. Citizens would like to be given reasonable assurance that MON810 is safe. In the (90-day) sub-chronic test on rats, the toxicology tests compare one group which consumes the GMO food (or receives the recombinant protein) with a control group that consumes a food that is as close as possible but GMO-free. Different parameters are measured for each individual in each group (weight, blood sugar etc.) and statistical tests are carried out to compare the means of each value obtained between the two groups. These statistical tests are used to determine what is called the null hypothesis (H0). For the studies on MON810, the null hypothesis is: H0 = the test group (with GMO) and the control group are identical. A test is performed which makes it possible to reject this hypothesis if significant differences are observed, or not to reject it if this is not the case, with a 5% risk of error (this is not an exact figure but a risk of error). If there is a significant difference, this means that, including this risk of error, H0 can be rejected because the GMO causes a difference. If there is no significant difference, the conclusion is drawn that no difference has been detected between the groups, but this does not mean that a difference can be ruled out. When carrying out statistical tests, it is necessary to ensure that the protocol used gives the tests sufficient discriminatory power (> 80, in practice). In France, the opinion on MON810 by the committee that was the predecessor of the High Authority[1] showed that the protocols used for MON810 do not have sufficient power to detect even major differences. The toxicological studies presented by Monsanto do not therefore fulfil their objective of ruling out the product's toxicity. The choice of the null hypothesis is also not satisfactory, as it is in fact important to know if, with an acceptable risk of error, it is possible to reject the hypothesis of the GMO's toxicity.

Can the Commission certify that the genetically modified maize MON 810 is not toxic, taking into account the standard risk of statistical error: i.e. if the null hypothesis H0 is that the test group and control group are different, can this be rejected and, if so, at what level of risk for all the parameters studied?

If so, can the Commission produce calculations to back this up?

[1] http://www.legrenelle-environnement.fr/IMG/pdf/Avis_emis_sur_la_dissemination_du_MON810_le_9_01_2008-2.pdf.