

Academic Forum on the Ethical, Social and Legal Aspects of Agrofood Biotechnologies: Towards a New Regulatory Framework for the GM Crops in the European Union

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Title: Quality and use of science for decision-making: the case of the EU renewal of authorisation for cultivation of genetically modified maize MON810

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Abstract

The authorisation process of applications for marketing of genetically modified organisms (GMOs) in the European Union (EU) is considered as one of the strictest in the world and at the present just one type of GM crop is permitted for commercial cultivation. We are repeatedly assured about its safety by the GMO Panel of the European Food Safety Authority (EFSA), the scientific commission for safety of GMOs in the EU. However, the quality and ethics of science for decision making about GMOs has been questioned as well as the EFSA practices. This becomes of particular interest as the new regulatory framework for GM crops that reserves the sovereignty in assessing risks for human and animal health for EFSA entered in force in April this year.

The aim of this study is to assess the quality of scientific studies focused on environmental risk assessment of GM bt maize MON810 and subsequently examine their use in the GMO Panel's Scientific Opinion on Application for renewal of authorisation of the MON810 maize from the year 2009.

In this study the "Reliability Rating and Reflective Questioning" method introduced by F. Wickson (2009) is employed, a framework in that risk assessment could be exposed to the type of extended review incorporating both natural and social science quality criteria and modes of reflection. The first step consists of a critical review of scientific studies cited in the section "Interactions between the GM plant and non-target organisms" of the Panel's Opinion and relevant additional studies available before the Opinion issuing. The next step is to assess how was the scientific information used in the Scientific Opinion.

The preliminary results are based on the examination of honeybees' studies, one out of ten groups of non-target organisms addressed in the Opinion. Seven scientific works are cited in

this section, 5 of which are original research papers. Literature survey revealed 9 additional scientific works relevant to the subject, some of them included in the review and/or meta-analysis cited in the Opinion. The scrutiny of the Opinion showed several shortcomings in the use of employed studies: I) studies are often misquoted (e.g. incorrectly cited to support certain statements or reduce the aim of the study to a certain area where no negative effects were observed), II) the assumptions embedded in the studies are not communicated, III) there is generally lack of critique, including cases that should have been reflected (e.g. inconsistencies, conflict of interests), IV) the results of all original research studies are selectively used: the pattern of omitting negative effects and further research requirements or suggestions is evident, V) other minor inconsistencies between the studies cited and information adopted are present.