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#### **GMOs**

# Divergence of opinion within EFSA highlights serious shortcomings with assessment process

Since the beginning of the year, the European Commission has proposed eight new authorisations for commercialisation of genetically modified (GM) plants in the EU, a further two authorisations for cultivation and the renewal of the authorisation for cultivation of the GM-maize Mon 810. The debate about <u>five of these authorisations</u> is still ongoing, focusing on recurring questions about the undemocratic decision-making process as well as doubts about the quality of the assessment of these GMOs.

More than 60 GM plants are currently authorised for use in food and feed in the European Union. These plants are mainly imports, as only maize Mon810 is authorised for cultivation in the EU, and that only in 10 member states. Most citizens are aware that GMO cultivation is rare in the EU and they rely on the labelling of food to avoid them - not knowing that most GM plants used in the EU are imported for use in animal feed, and that the products from these GMO fed animals are not labelled.

Before the authorisation process for any GM plant can begin it has first to be evaluated by the EU safety agency EFSA. EFSA almost invariably issues a positive opinion on GM plants, casting doubts on their evaluation procedures. Two recurring reproaches are the fact that this evaluation is mainly done on the basis of confidential studies produced by the companies producing the plants and their use of the 'weight of evidence' approach which leads to an artificial underestimation of risks. This approach consists of comparing the number of studies that have found no problems with a particular substance or GMO to the number of studies where problems have been found and then simply following the opinion of the majority. This is problematic as the studies finding problems are usually valid scientific peer-reviewed studies, produced independently of the companies concerned, and as such their findings should carry more weight, especially in an area where the vast majority of the studies are paid for and conducted by the industry.

As if this weren't bad enough, one type of GM plant is raising even more questions - those that contain several different modifications of the genome (or 'events' as they are known). The interaction between these so-called 'stacked events' are both poorly understood and badly evaluated. In this case, the 'weight of evidence' approach is even less appropriate than for single event GM plants.

This is one of the reasons behind the so-called <u>minority opinion</u> from one of the EFSA's own scientists (Dr Jean Michel Wal, a member of EFSA's GMO expert panel) concerning a variety of GM maize that 'stacks' five different events[1]. He also questioned the lack of an uncertainty analysis[2], which is however required by EFSA's new draft guidance document on uncertainty.

Under its founding regulation, EFSA is legally obliged to publish minority opinions, but that didn't prevent EFSA to deliver a positive opinion on this GM plant in August.

The EU member states will soon have to vote on whether to authorise this GM maize for commercialisation in the EU. Given the clear difference of opinion within EFSA on this product - and the wider problems with EFSA's evaluation procedure (in general but in particular for stacked events), we hope that the national authorities will have sufficient courage to block the authorisation.

Unfortunately, the standing committee of member states experts in charge of GMO authorisation never reaches a qualified majority in favour or against any of the GMO authorisation proposals that are submitted to them. This means that the decision to authorise or not is left each time to the Commission, which always falls back on EFSA's position, which is almost always positive.

We consider this to be unacceptably undemocratic and a clear indication that both EFSA's evaluation procedure and the decision-making process for the authorisation of GMOs need to change. Commission President Jean-Claude Juncker has admitted as much himself in recent times - but now we need to urgently see real action to match the rhetoric.

[1] Bt11 (resistance to the maize corn borer and tolerance to a family of herbicides) x 59122 (resistance to Coleopterans and Diabrotica and tolerance to a family of herbicides) x MIR604 (resistance to Diabrotica) x 1507 (resistance to the maize corn borer and tolerance to a family of herbicides) x GA21 (tolerance to glyphosate)

[2] Uncertainty analysis is the detailed examination of a circumstance, condition, or event in order to gain adequate understanding so as to be able to assign credible probabilities to its possible outcomes

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Juliette Leroux

Advisor on Agriculture and Rural Development

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