GMO RISK ASSESSMENT TIMELINES: IS THE EU LOSING THE INNOVATION GAME?

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RIGOROUS SAFETY ASSESSMENT REQUIRED

Genetically modified (GM) food and feed imports or cultivation of GM crops can only be authorised in the EU following a rigorous safety assessment by the European Food Safety Authority (EFSA)[1] that includes numerous studies, comparative assessments, field trials, molecular characterisation, and an assessment of potential environmental impacts.

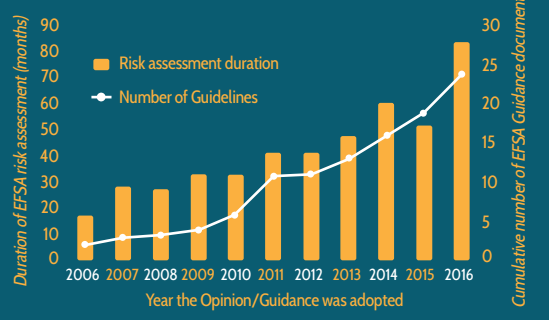
And guess what?

- Not a single substantiated case of ill effect in over two decades of GMO commercialisation.
- In fact, the European Commission already concluded years ago that GMOs "are not per se more risky than conventional plant breeding technologies."[2] A recent U.S. National Academies of Sciences, Engineering and Medicine report[3] on GM crops came to the same conclusion.

YET EFSA TIMELINES KEEP INCREASING

EFSA timelines for risk assessment more than doubled in the EU from well under 2 to more than 5 years in the past decade, despite a clear history of safe use.

- As of June 2016, over 40 GM applications are pending at EFSA level awaiting risk assessment. One assessment, for cotton, is even still pending after 8 years! [4]
- As a comparison, the average time required for a complete GM product approval is now under 2 years in the US, Brazil and Canada, all countries that have equally high standards for RA based on internationally recognised scientific principles.



THE RULES KEEP CHANGING

The fact is that new EFSA guidelines are sprouting like weeds! And the requirements and timelines keep constantly changing, adding to unpredictability and repelling investors.

- Since 2006, 19 guidance documents were issued, and up to 8 additional ones are expected by the end of 2017.[5]
- Data requirements are regularly re-interpreted, making it impossible for applicants to know what will actually be required to finalise the procedure.

NEEDLESS TESTING IMPOSED

As if the facts on increasing timelines don't already speak for themselves, results from a recent EU study confirmed in December 2015 that there is no scientific justification for new animal testing studies that have been needlessly imposed on the industry and animals since December 2013! EFSA has itself called the studies unnecessary.[6]

BUREAUCRACY IS PILING UP

While Europe gets buried further in a pile of meaningless bureaucracy, the rest of the world is moving ahead

- Unnecessary studies and increasing timelines that have no scientific basis undermine the credibility of the risk assessment process.
- They add further to undue delays of GMO approvals at the political level following risk assessment[7], impacting European livestock farmers, and ultimately consumers, who are highly dependent on imports of GM commodities.
- Longer timelines contribute to a waste of resources and tax payers' money and also feed fear and bias against promising technologies that already contribute substantially to Europe's sustainability and competitiveness.

SOMETIMES LESS IS MORE!

Isn't it time for EFSA and the EU to reduce unnecessary burdens whilst maintaining the highest safety standard and at least start playing by the rules, before it loses out on innovation?

1 What is the approval process for import of GMOs in the EU?. EuropaBio July 2014: www.europabio.org/what-approval-process-import-gmos-eu
2 A decade of EU-funded GMO research 2001-2010. European Commission. 2010: https://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf
3 Genetically Engineered Crops: Experiences and Prospects. NASEM. May 2016: http://nas-sites.org/ge-crops/2016/05/16/report-in-brief
4 Monsanto cotton MON88913xMON15985 was submitted to EFSA in April 2007
5 For 2016-2017, 2 GMO specific Guidances are expected and 6 horizontal Guidances which also have an impact on GMO risk assessment.
6 Devos, Naegeli, Perry, & Waigmann. Is the mandatory EU requirement fit for purpose? EMBO reports (2016): http://embor.embopress.org/content/early/2016/06/09/embr.201642739.full
7 Five reasons for EC to continue granting farmers freedom of choice. EuropaBio. 24 April 2015: http://www.europabio.org/sites/default/files/five_reasons_to_continue_authorisations.pdf

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