

What the French ban of *Bt* MON810 maize means for science-based risk assessment

To the Editor:

In February 2012, the French government, at that time headed by Nicolas Sarkozy, sent a document ('emergency measures'; **Supplementary Note 1**) to the European Commission (EC), supposedly providing new information on environmental risks of genetically modified (GM) MON810 maize varieties (MON810 expresses the Cry1Ab insecticidal protein isolated from *Bacillus thuringiensis* (*Bt*) and was developed by Monsanto (St. Louis) to control certain Lepidoptera insects). The release of this document was followed by the publication in March 2012 of a national ruling prolonging the existing ban on their cultivation. Despite canceling many other actions of the Sarkozy government, the new French government under François Hollande has elected to continue with the MON810 ban.

This correspondence examines the emergency measures document to analyze its scientific validity and consider the widespread implications for science-based risk assessment. Such an analysis is warranted because not only the French Government, but also several other European governments (that is, Austria, Germany, Greece, Hungary, Luxembourg and, most recently, Italy) invoked 'scientific' data to justify their bans.

Previously, in February 2008, the newly elected President Sarkozy formally suspended the cultivation of the MON810 maize varieties based on alleged data concerning the potential negative environmental impacts of these varieties. These hypothetical environmental impacts have always been rejected by the European Food Safety Authority (EFSA; Parma, Italy); for example, in June 2009, it recommended renewed approval of MON810 maize for cultivation.

It has become clear that the French government's position on MON810 was largely biopolitical—ministers decided on the move (against scientific opinion) to give the appearance of being green for the sake of political expediency¹. And this biopolitical issue is not only a local issue for GM crops in France, but it also has ramifications beyond the country's borders. Indeed, French actions on MON810 stimulated the German government to follow a similar path. In April 2009, German legislators formally suspended the cultivation of the MON810 maize varieties and justified this by citing alleged new data concerning potential negative

environmental impacts. Subsequently, these claims were rejected by both a scientific publication² and the German Central Committee on Biological Safety (ZKBS) in July 2009. Like the French emergency measures document (discussed below), the German document was produced by anonymous authors and bypassed the official biosafety national agency.

The French government's arguments presented in February 2008 were derived from a draft document of an official (although short-lived) scientific committee, most of whose members subsequently rejected this interpretation¹. To understand the reasons for governments to produce their own 'scientific' assessment, we must stress that, in Europe, GM organisms (GMOs) are regulated by EU law and that a ban on GMO cultivation must have scientifically justifiable reasons. Even so, bans (now implemented by nine EU member states) on the commercial cultivation of EC-approved MON810 maize had only political or economical motives.

In France, the ban on MON810 cultivation in 2008 was declared illegal in November 2011 by the country's highest judicial authority ('Conseil d'Etat'), following deliberations of the European Court of Justice in September 2011. Not discouraged by adverse rulings in French and European law courts, Nathalie Kosciusko-Morizet (then Minister of Ecology), immediately decided on a prolongation of the prohibition of MON810 cultivation. Her ministry originated the emergency measures document released on February 20, 2012 (**Supplementary Note 1**), which the Ministry of Agriculture submitted to the EC. This text purportedly contains new and crucial scientific data regarding environmental risks not previously examined by the EFSA GMO panel.

The invocation of environmental claims supposedly overlooked by the competent scientific authority, EFSA, has profound implications. Either these claims are true, which means the European risk evaluation system is faulty for not having identified them. Or they are false and this means that the French government—as well as the many other European governments following its example—is seeking to ban GMO cultivation by deliberately inventing specious allegations as to risk, when previous assertions of risk have been rebutted.

We have done a point by point science-based analysis (**Supplementary Note 2**) of the French emergency measures document. Its first part presents EFSA's opinion (December 2011; ref. 3) as follows: "In contrast to their previous conclusions on Bt11 or on MON810, EFSA underlines [...] the existence of environmental risks linked to the culture of these GMOs." In contrast, what EFSA stated in reality was as follows³: "The EFSA GMO Panel concludes that, subject to appropriate risk management measures, maize Bt11 [and MON810] cultivation is unlikely to raise additional safety concerns for the environment compared to conventional maize."

Two additional arguments found in the French emergency measures document—namely the possibility of the appearance of resistance among pests targeted by MON810 and of resurgence of minor pests (previously controlled by broad-spectrum insecticides), which can become major pests—are relevant to risk management and to integrated pest management strategies. This type of argument cannot be used to justify a ban, which needs to be based on an immediate and serious risk to the environment.

Another part of the emergency measures document is on dissemination and persistence in soil or aquatic environments of the Cry1Ab insecticidal protein produced by MON810. However, no scientific publications are cited demonstrating such an impact exists in nature. A 9-year study on *Bt*-maize cultivation in four different sites found that the Cry1Ab protein was not present in the soil in the spring of the following year⁴. This article was not cited in the emergency measures document and neither was additional literature, including long-term results from the United States (see **Supplementary Note 2** for references).

Similarly, the invoked risk for nontarget arthropods is allegedly substantiated by meta-analyses. But none of these meta-analyses (not even the most recently cited) actually provides "new data" from field studies (that is to say, information or data not previously examined by EFSA). These meta-analyses (e.g., ref. 5) only point to the following phenomenon: when pest management is efficient (due to either pesticides or to *Bt* plants), an unavoidable effect is to reduce the presence of arthropods that depend on the target host, either as

predators or as parasitoids. What's more, this effect is found mainly for a parasitoid that has never been reported in French fields.

Finally, it should be mentioned that many of the articles cited in the emergency measures document are studies (often worst-case scenarios) carried out in the laboratory rather than in the field. It is well accepted from the Monarch butterfly controversy⁶ that laboratory studies alone cannot be used to infer a risk in a natural context.

In conclusion, the French emergency measures document not only contains no new scientific evidence, but also distorts, misquotes and falsely interprets authentic scientific reports, including those of the EFSA GMO panel. Other scientific articles (at least eight since 2008) relevant to the subject and providing a different picture are ignored. On the most important concerns raised by the emergency measures document, we have obtained direct supporting evidence from several authors of the cited scientific articles and from other experts in the field (Supplementary Note 2).

It is significant that the French Biosafety Authority (Haut Conseil des Biotechnologies; HCB) was not consulted on this emergency measures document. Consequently, the chairman of the HCB, Jean-François Dhainault, wrote to the French prime minister expressing the displeasure of the HCB members and their shock that "other expertise" was seemingly used for the preparation of the document and that the conclusions of previous HCB reports had been ignored. No reply was received from the prime minister. The actual authors of the emergency measures document, as well as their scientific qualifications, if any, remain unknown (a clear transgression of scientific ethical norms).

Following the release of the emergency measures document (the purpose of which was to inform the EC, according to European law), a national ruling (arrêté) was published on March 16, 2012, re-implementing a moratorium, disregarding the EC decision and questioning its legitimacy (and again failing to consult the HCB). The ruling included a seemingly cherry-picked recent laboratory study claiming to observe a deleterious impact of Cry1Ab on ladybird beetles⁷, the conclusions of which are inconsistent with numerous other publications on this topic⁸, and with the meta-analyses cited in the emergency measures document. EFSA has rejected the arguments presented by the French government⁹.

The history of bans on MON810 maize in the EU cited here documents a pattern of behavior in which politicians blatantly cite and/or misuse scientific publications to suit their political ends. Risk analysis is divided into risk assessment and risk management, the former being an exclusively scientific process and the domain of scientists and not politicians. Unlike risk perception, risk assessment and science in general are not 'social constructs' (despite what the postmodern school of thought often claims¹⁰): risk assessment is the implementation of the scientific method. Risk is a scientific term defined as $\text{risk} = \text{hazard} \times \text{exposure to hazard}$. In contrast, risk management may operate in a broader context: technological, political and legal means are used to control risks and alleviate them.

What we find most heinous about the French and other European bans on MON810 maize is the clear evidence of government interference with science to justify political handling of risk management and bypass European and national agencies in charge of biotech risk assessment under European directives. This behavior appears to be increasingly the norm; the Italian government used a simple translation of the French emergency measures document in its justifications sent to the EC for its ban on April 4 this year¹¹. It is hard to believe that the Italian government was not aware that the EFSA had already rejected the evidence presented in the French emergency measures document almost one year previously.

The new French ban was imposed only a few months before important political elections in spring 2012 (in which the Sarkozy government was defeated). In February 2012, the minister of ecology openly admitted to the press that a national ruling would be imposed "in case of failure of the [European] Commission to react" to stop farmers planting GM maize this season. In other words, the minister was publicly stating that any potential opinion from official and expert EC bodies that contradict the French government's position would be summarily disregarded.

We note that decisions for regulations specific to GM crops are getting increasingly non-science-based in the EU^{1,2,12}. This trend is likely to be amplified should EU member states be given the possibility of banning GMO cultivation on their own territory without having to provide any scientific evidence relating to new risks, as proposed by the EC in 2010 (ref. 13). Implications for such political decisions go far beyond GMOs.

EFSA is an independent scientific body founded in 2002 by the European Parliament and the Council of Europe following a proposition of the EC. The current burden of safety assessment of transgenic crops in Europe is probably too stringent¹⁴, and in a context dominated by the precautionary principle, EFSA's advice is certainly obligatory and necessary for risk-evaluation of GMOs. Nevertheless, EFSA is under constant politically motivated criticism from some environmentalist nongovernmental organizations and EU member states, including France. GMO approvals must pass by the Council of Agricultural Ministers though this body has never been able to reach agreement with a qualified majority¹². In such case, the decision reverts to the EC, which usually agrees with the EFSA recommendations (although often with delays counted in years). This has caused antagonism toward EFSA, resulting in unjust accusations of being biased and in league with the biotechnology industry (see EFSA's response¹⁵). Such accusations degrade the validity not only of EFSA opinions but also of scientific risk assessment in general.

One may wonder why, after more than one year of such malpractice of scientific expertise, as is contained in the emergency measures document, these events have not triggered wide criticism. Of course, criticism is unlikely to originate from the new French government that follows the same anti-GMO policy that is politically expedient. We propose that the silence of the media and of scientific institutions is at least partially attributable to the diffuse, contemporary, postmodern and relativist ideology that science is a 'social construct', a particular 'framing' of truth, and finally is simply an opinion, no better than any other opinion¹⁰. In such a context, those who insist on scientific truth will inevitably face accusations of 'positivism' or 'scientism'¹⁶. This is the great contradiction of the EU policy that simultaneously defends a 'science-based' approach while, at the same time, embracing a postmodern framing, which denies that science can approach objective truths.

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M.K., J.D. and A.E.R. co-wrote the manuscript and edited the final draft.

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