The French government ban of Bt MON 810 maize undermines science-based risk assessment

Marcel Kuntz¹, John Davison², Agnès E. Ricroch^{3,*}

¹ Laboratoire de Physiologie Cellulaire Végétale

kuntz@ujf-grenoble.fr

UMR 5168 CEA CNRS INRA UJF

17 rue des Martyrs

38054 Grenoble cedex 9

France

² INRA de Versailles (retired)

jrndavison@gmail.com

Route de St Cyr

78026 Versailles

France

³ AgroParisTech

16, rue Claude-Bernard

75231 Paris Cedex

agnes.ricroch@u-psud.fr

Université Paris-Sud. CNRS. AgroParisTech.

UMR 8079

Laboratoire d'Ecologie, Systématique et Evolution

Bâtiment 360

91405 Orsay cedex

France

Telephone +33 (0)1 69 15 56 65

Fax +33 (0)1 69 15 46 97

*Correspondence to: agnes.ricroch@u-psud.fr

In February 2012, the French government, at that time under Nicolas Sarkozy, sent a document called 'emergency measures' (EM; see Supplementary Information 1 for an English translation) to the European Commission (EC), supposedly providing new information on environmental risks of genetically modified (GM) MON810 maize varieties (MON810 is a trait developed by the Monsanto Company to control some 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. This ban has not been discontinued by the new French government under François Hollande, who nonetheless cancelled many other actions of the Sarkozy government.

The present commentary examines the EM document to analyze its scientific validity and consider the widespread implications for science-based risk assessment, since not only the French Government but also other European governments (i.e. Austria, Germany, Greece, Hungary, Luxembourg, and more recently Italy) invoked ‘scientific’ data to justify their own ban.

Previously, in February 2008, the new elected President Sarkozy formally suspended the cultivation of the MON810 maize varieties on alleged data concerning the potential negative environmental impacts of these varieties. These hypothetical environmental impacts have always been rejected by EFSA (European Food Safety Authority), e.g. in its recommendation (June 2009) on the renewal of the approval for the cultivation of MON810 maize.

It became clear that the French position was largely “*biopolitical*” posturing as part of a green-washing political move ¹. It stimulated the German government to follow a similar path: in April 2009 it formally suspended the cultivation of the MON810 maize varieties and justified this by citing alleged new data concerning potential negative environmental impacts. These claims were rejected by both a scientific publication ² and the German Central Committee on Biological Safety (ZKBS) in July 2009. Like the French EM document (discussed below), the German document was produced by anonymous authors, bypassing the official biosafety national agency.

The French arguments presented in February 2008 were derived from a draft document of an official (although short-lived) scientific committee, of which most of its members subsequently rejected this interpretation ¹. To understand the reasons for governments to produce their own ‘scientific’ assessment, it is important to stress that, in Europe, GMOs are regulated by EU law and that a ban on GMO cultivation must have scientifically justifiable reasons. However, bans (now implemented by 9 European Member States) on the commercial cultivation of EC-approved MON 810 maize had only political or economical motives.

The French refusal of MON810 cultivation in 2008 was declared illegal in November 2011 by the highest judicial authority ('Conseil d'Etat') in France, following the 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 was at the origin of the EM document released in February 20, 2012 (see Supplementary Information 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 others) is seeking to ban GMO cultivation by deliberately imagining new specious allegations when the previous ones have been rebutted.

We have performed a point by point science-based analysis (see Supplementary Information 2) of the French EM document. Its first part presents EFSA's opinion (December 2011 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* ». While, in reality, EFSA stated ³: « *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 EM document, namely the possibility of appearance of resistance amongst pests targeted by MON 810 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 EM document is on dissemination and persistence in soil or aquatic environments of the insecticidal protein produced by MON 810 (termed Cry1Ab). However, no scientific publications are cited showing such an impact in nature. A 9-year study on Bt-maize cultivation in 4 different sites found that the Cry1Ab protein was not present in the soil in the spring of the following year ⁴. This article was not cited in the EM document and neither was additional literature, including long term results from the USA (see Supplementary Information 2 for references).

Similarly, the invoked risk for non-target arthropods is allegedly substantiated by meta-analyses but none (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. 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 presence

of arthropods that depend on the target host, either as predators or as parasitoids. Actually this effect is found mainly for a parasitoid which has not been reported in French fields.

Finally, it should be mentioned that many of the cited articles are laboratory studies (often worst-case scenarios) which, as is well accepted from the Monarch butterfly controversy⁶, cannot alone be used to infer a risk in a natural context.

In conclusion, the French EM document not only contains no new scientific evidence, but authentic scientific reports, including those of the EFSA GMO Panel, are distorted, misquoted and falsely interpreted. Other scientific articles (at least 8 since 2008) relevant to the subject and providing a different picture are ignored. On the most important points we have obtained direct supporting evidence from several authors of the cited scientific articles and from other experts in the field (see Supplementary Information 2).

It is significant that the French Biosafety Authority (*Haut Conseil des Biotechnologies*, HCB) was not consulted on this EM. Consequently, the Chairman of the HCB wrote to the French Prime Minister expressing the “*emotion*” 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. The Prime Minister did not reply. The actual authors of the EM document, as well as their scientific qualifications, if any, remain unknown; which transgresses scientific ethical norms.

Following the release of the EM document (whose purpose was to inform the EC, according to European law), a national ruling (*arrêté*) was published on March 16, 2012 re-implementing a moratorium irrespective of the EC decision on the EM (again without consultation of HCB). This ruling includes a recent laboratory study claiming to observe a deleterious impact of Cry1Ab on ladybirds⁷. The conclusions of this study are inconsistent with numerous other publications on this topic and with the meta-analyses cited in the EM document, and it has already been criticized (see⁸). EFSA has rejected the arguments presented by the French government⁹.

The history of the bans in EU, cited here, documents a pattern of behaviour in which politicians cite and/or misuse scientific publications to suit their political desires. Risk analysis is divided into risk *assessment* and risk *management*. The former being an exclusively scientific process and is the domain of scientists and not politicians. Unlike risk *perception*, risk *assessment*, and science in general, is not a “*social construct*” (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 risk = hazard x 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 is criticized here is that governments interfere with science to justify their political handling of risk management and bypass European and national agencies in charge of risk assessment of biotechnology under the European directives. This behaviour seems to become the norm since the Italian government used a simple translation of the French EM in its justifications sent to the EC for its ban on April 4, 2013 ¹¹. The Italian government could not ignore that the French EM had already been rejected by EFSA almost one year previously.

The new French ban was imposed only a few months before important political elections in spring 2012 (in which the government was defeated). Declarations to the press of the Minister of Ecology in February 2012 openly admitted that a national ruling will be imposed “*in case of failure of the Commission to react*” (that is to say that the Minister was disregarding, in advance, potential opinions by official EC bodies) in order to stop farmers planting GM maize this season.

It is a general trend that decisions for regulations specific to GM crops are getting increasingly non-science-based in the EU ^{1, 2, 12}. This trend would be amplified should 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 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 stringent ¹⁴, 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 NGOs 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 majority ¹². 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 towards EFSA, resulting in unjust accusations of being biased and in league with the biotechnology industry (see EFSA's response ¹⁵). Such accusations degrade the validity not only of EFSA opinions but 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 EM document, these events have not triggered wide criticisms. Of course criticisms will not originate from the new French government which follows the

same anti-GMO policy. We propose that the silence of the media and of scientific institutions, etc. 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. It is a great contradiction of the EU policy, that it simultaneously defends a ‘science-based’ approach while, at the same time, it is stuck in a postmodern framing which denies that science can approach objective truths.

References

1. Morris, S., & Spillane, C. EU GM crop regulation: a road to resolution or a regulatory roundabout? *Eur. J. Risk Regul.* **4**, 359–369 (2010).
2. Ricroch, A., Bergé, & J.B., Kuntz, M. Is the German suspension of MON810 maize cultivation scientifically justified? *Transgenic Res.* **19**, 1–12 (2010).
3. Statement supplementing the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize Bt11 for cultivation *EFSA J.* **9**, 12, 2478 (2011).
4. Gruber, H., Paul, V., Meyer, H.H.D., & Müller, M. Determination of insecticidal Cry1Ab protein in soil collected in the final growing seasons of a nine-year field trial of Bt-maize MON810. *Transgenic Res.* **21**, 1, 77-88 (2012).
5. Naranjo, S.E. Impacts of Bt crops on non-target invertebrates and insecticide use patterns. *CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources* 1-11 (2009).
6. Sears, M.K., Hellmich, R.L., Stanley-Horn, D.E.S., Oberhauser, K.S., Pleasants, J.M., Mattila, H.R., Siegfriedi, B.D., & Dively, G.P. Impact of Bt corn pollen on monarch butterfly populations: A risk assessment. *Proc. Natl. Acad. Sci. U.S.A.* **98**, 21, 11937–11942 (2001).
7. Hilbeck, A., McMillan, J.M., Meier, M., Humbel, A., Schläpfer-Miller, J., & Trtikova, M. A controversy re-visited: Is the coccinellid *Adalia bipunctata* adversely affected by Bt toxins? *Environmental Sci. Europe* **24**, 10 (2012).
8. Romeis, J., Álvarez-Alfageme, F., & Bigler, F. Putative effects of Cry1Ab to larvae of *Adalia bipunctata* - reply to Hilbeck et al. (2012). *Environ. Sci. Europe*, 24 (2012). 18 doi:10.1186/2190-4715-24-18

9. EFSA. Scientific Opinion on a request from the European Commission related to the emergency measure notified by France on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003. *EFSA J.* **10**, 5 (2012) 2705.doi:10.2903/j.efsa.2012.2705
10. Kuntz, M., The post-modern assault on science. *EMBO reports* **13**, 885-889 (2012)
11. <http://www.salmone.org/wp-content/uploads/2013/04/lettera-balduzzi-per-bruxelles.pdf>
12. Davison, J. GM plants: science, politics and EC regulations. *Plant Sci.* **178**, 94–98 (2010).
13. Sabalza, M., Miralpeix, B., Twyman, R.M., Capell, T., & Christou, P. EU legitimizes GM crop exclusion zones. *Nat Biotechnol.* **29**(4):315-7 (2011)
14. Giddings, L.V., Potrykus, I., Amman, K., & Fedoroff, N. 2012. Confronting the Gordian Knot. *Nat. Biotech.* **30**(3):208-9
15. EFSA. Independence. <http://www.efsa.europa.eu/en/topics/topic/independence.htm>
16. Kuntz, M. Why the postmodern attitude towards science should be denounced. *EMBO reports* **14**, 114-116 (2013)

Author information

Affiliations

Marcel Kuntz
Laboratoire de Physiologie Cellulaire Végétale
UMR 5168 CEA CNRS INRA UJF
17 rue des Martyrs
38054 Grenoble cedex 9
France
marcel.kuntz@ujf-grenoble.fr

John Davison
INRA de Versailles (retired)
Route de St Cyr
78026 Versailles
France
jrndavison@gmail.com

Agnès E. Ricroch^{*}
AgroParisTech.
16, rue Claude-Bernard
75231 Paris Cedex
France

Université Paris-Sud. CNRS. AgroParisTech
Laboratoire d'Ecologie, Systématique et Evolution
UMR 8079
Bâtiment 360
91405 Orsay cedex
France
agnes.ricroch@u-psud.fr
Telephone +33 (0)1 69 15 56 65
Fax +33 (0)1 69 15 46 97

*Correspondence to: agnes.ricroch@u-psud.fr

Contributions

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

Competing financial interests

The authors declare no competing financial interests.

Supplementary Information 1

Translation of the EM document

Supplementary Information 2

A point by point analysis of the arguments put forward by the French government on the 20th February 2012, for a case of emergency concerning maize MON 810