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DOI

[10.1017/S1867299X00003615](https://doi.org/10.1017/S1867299X00003615)

Publication date

2014

Document Version

Final published version

Published in

European Journal of Risk Regulation

[Link to publication](#)

Citation for published version (APA):

Weimer, M., & Pisani, G. (2014). The EU adventures of 'Herculex': Report on the EU authorization of the genetically modified maize 1507. *European Journal of Risk Regulation*, 5(2), 208-212. <https://doi.org/10.1017/S1867299X00003615>

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The EU Adventures of 'Herculex'

Report on the EU Authorization of the Genetically Modified Maize 1507

Maria Weimer and Gaia Pisani*

The EU authorization process of the insect-resistant maize 1507, branded by its developer company Pioneer-DuPont as 'Herculex', is perhaps the most interesting and emblematic example of the current regulatory crisis of GMO regulation in Europe.¹ The case is particularly controversial, because it concerns the first risk assessment regarding the cultivation of a GMO issued by the European Food Safety Authority (EFSA) since its establishment in 2005.² It involves a long and complicated authorization process marked by persistent contestation of both the EFSA's risk assessment and the Commission's risk management; a total of six EFSA opinions; administrative delay; and ultimately a judicial condemnation of the Commission's behavior by the EU General Court.

This case is of particular relevance, because it registers a slight yet meaningful change in the EFSA's approach to GMO risk assessment including the way the EFSA has dealt with competing scientific opinions, risks and uncertainty involved in GMO regulation. Moreover, in the field of GMO authorizations under the new legislative framework, the European Parliament (EP) has actively intervened in the administrative authorization process. It should be noted that the outcome of this process remains unclear at the moment, given that at the time of writing the Commission has not yet taken its final decision on Maize 1507. The present report aims to offer an overview of this year-long and controversial process including the approaches taken by the relevant institutions involved therein.

I. EFSA's approach

In 2001 Pioneer-DuPont submitted a request for the authorisation of the placing on the market and cultivation of maize 1507. The latter is an insect-resistant genetically modified maize characterised by the insertion of two genetic constructs: one which produces *Cry1F*, a so-called *Bt*-protein³ that makes the maize resistant to certain *Lepidoptera*,⁴ and another

which makes the maize tolerant to *glufosinate ammonium*, a herbicide the use of which will be phased out in the EU by 2017.⁵ Both Member States and independent studies have raised concerns over potential risks to human health and the environment as well as strong objections as to the quality of the EFSA risk assessment.

In its initial risk assessments of 'Herculex' the EFSA remained reluctant to seriously engage with

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1 Maria Weimer, "Risk regulation, GMOs, and the challenges to deliberation in EU governance - politicisation and scientification as co-producing trends", in Christian Joerges and Carola Glinski (eds), *The European Crisis and the Transformation of Transnational Governance* (Hart Publishing, 2014, forthcoming).

2 Namely in January 2005. Another equally controversial EFSA opinion on the so-called 'Amflora' potato was issued by the EFSA in December 2005.

3 *Bt* (*Bacillus thuringiensis*) are bacteria naturally occurring in the soil. Some of them produce a protein crystal which is toxic to insects. *Bt Cry1F* is the result of a modification of the natural occurring *Cry1Fa2* gene.

4 Larvae of the European corn borer and of the Mediterranean corn borer.

5 Commission Implementing Regulation (EU) No 365/2013 of 22 April 2013 amending Implementing Regulation (EU) No 540/2011, OJ L111/27, 23 April 2013.

these contesting views. For example, EFSA's first opinion in 2005⁶ identified the potential risk of development of resistance in target organisms to the *Bt* toxin. However, the EFSA agreed with the applicant that general surveillance and risk management measures would suffice to minimise those risks. It concluded that the cultivation of maize 1507 'will not have adverse effects'⁷ (emphasis added) on human health and/or the environment. Note that the Commission request to EFSA was formulated in broad terms asking the EFSA 'to consider whether there is any scientific reason to believe' that maize 1507 'is likely to cause any adverse effects on human health and the environment.' (emphasis added)

However, several Member States maintained objections arguing that the EFSA opinion did not adequately address their concerns, especially regarding potential adverse effects of 'Herculex' on target and non-target organisms. The Commission, therefore, requested more specific information from the EFSA in this regard. In particular it asked to recommend more precise risk management measures taking into account, inter alia, of geographical regions. It also asked the EFSA 'to take bilateral contact with the relevant French scientific authorities, with the view of resolving the issue concerning baselines for the monitoring plans in relation to non-target organisms and to complement its scientific opinion with this information, as appropriate.'⁸ This shows, first, that national authorities pressured the EFSA to include monitoring and mitigation issues in its risk assessment; and second, that the Commission saw cooperation between the EFSA and national authorities as crucial in this regard.

The EFSA, however, initially considered the issue of adequacy of the applicant's monitoring plan in re-

lation to potential adverse effects on non-target organisms as being outside of the scope of risk assessment. It stated that the overall evaluation and implementation of the monitoring plan submitted by the applicant is outside its remit.⁹ While admitting knowledge gaps and uncertainties in relation to the impacts of *Bt* maize on non-target organisms as well as the risk of target organisms in developing resistance, the EFSA nevertheless concluded that these uncertainties and risks are manageable through post-market risk management measures.¹⁰ Finally, it reaffirmed its previous conclusions that maize 1507 is 'unlikely to have adverse effects on human and animal health or the environment.'¹¹

In 2008, the Commission again asked EFSA to review its previous opinion in the light of eleven independent scientific studies¹² on maize 1507 and other *Bt* maize. The GMO Panel dismissed the studies as not providing *new scientific information*. On this basis, the EFSA reaffirmed 'its previous conclusions on the environmental safety of maize 1507.'¹³ It is worth recalling that, in 2007, the EFSA also launched a call for proposal to gather scientific data on *Bt* proteins¹⁴, in order to better analyse their behaviour in GM plants.

In 2010, however, we can observe a slight turn of events. The Commission yet again went back to the EFSA, this time asking to review its risk assessment of Maize 1507 on the basis of a new scientific study conducted by Testbiotech, an independent institute.¹⁵ Testbiotech raised a number of objections to the EFSA's conclusions concerning the inadequacy of founding an environmental impact assessment on analogies with other *Bt* toxins as well as the necessity of undertaking further studies on the effects of 'Herculex' on the environment and biodiversity.¹⁶

6 Opinion of the Scientific Panel on Genetically Modified Organism on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds, Question No EFSA-Q-2004-072, The EFSA Journal (2005) 181, pp. 1–33.

7 *Ibid.* p. 2

8 EFSA, Annex to the opinions of the Scientific Panel on Genetically Modified Organisms on the insect resistant genetically modified Bt11 and 1507 maize (2006), p. 2.

9 *Ibid.* p. 5.

10 *Ibid.*, p. 5,6.

11 *Ibid.* p. 7.

12 For a comprehensive list, see EFSA, Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission to review scientific studies related to the

impact on the environment of the cultivation of maize Bt11 and 1507, *The EFSA Journal* (2008), 851, pp. 6–7.

13 See EFSA (2006), *supra* note 10, at 21.

14 EFSA (2007), Call CFP/EFSA/GMO/2007/01. Note that the call did not go through, so that EFSA did not actually gather any new information, yet it did dismiss all the new studies that the Commission put to its attention the year after.

15 The study at issue is A. Bauer-Panskus and C. Then, "Testbiotech opinion on the application for market approval of genetically modified maize 1507 (DAS-Ø15Ø7-1)", available at <www.testbiotech.org/en/node/365> (last accessed 30 April 2014). EFSA makes explicit reference to it in: EFSA, Minutes of the 61st plenary meeting of the scientific panel on genetically modified organisms held on 20-21 October 2010 in Parma, Italy (p. 7).

16 Notably, they claimed that maize 1507 produced a high concentration of *Bt* toxin in pollen, and that this evidence should have significantly altered the risk assessment outcome as to the development of insect resistance and the impact on soil, air and water.

They concluded that, instead of relying on partial information and overlooking the existent uncertainties, EFSA should have requested further data from the applicant in order for its final assessment to be reliable.

This time the EFSA delivered a more nuanced response partially acknowledging methodological flaws and the need for further studies. At a 2010 plenary meeting the GMO Panel first reiterated their view that ‘no new studies have been mentioned that would invalidate the previous Panel’s scientific opinion on the safety of maize 1507’.¹⁷ However, for the first time it acknowledged the need for improving the modelling scheme and the methodology used in order to produce a more accurate assessment of risks to non-target organisms. In 2011 EFSA published a new opinion, further updated in 2012¹⁸, where it acknowledged some potential risks. Firstly, it estimated that, in spite of what was stated in its previous opinions, the concentration of Cry1F in pollen of maize 1507 was about 350 times the concentration of Cry1Ab (another *Bt*-protein contained in the MON810 maize), and acknowledged potential risks in the absence of appropriate mitigation measures. Despite this acknowledgment, however, the Panel did not collect and analyse further data on the concentration of the *Bt* toxin on other parts of the plant, which would have been relevant, for instance, to the assessment of the impact on soil and water. Secondly, it identified potential risks in relation to the evolution of resistance to Cry1F in target pests and the toxicity of the protein to sensitive non-target *lepidoptera*, such as European butterflies. The Panel acknowledged the need for further studies to fill the knowledge gap, but did not consider this as sufficient to alter the outcome of its risk assessment. Instead, it proposed ‘appropriate management measures,’ notably insect resistance management strategies to *delay* the evolution of resistance in target pests and field studies to *monitor* the effects on non-target *Lepidoptera*. It concluded that maize 1507 is ‘unlikely to raise safety concerns for the environment.’

The EFSA further integrated its assessment with two other supplementing opinions, issued in October 2012¹⁹, in which it reiterated the potential risks in the absence of adequate monitoring and mitigation measures, suggested precautionary measures to protect particular ecosystems and geographical areas, and called on Pioneer to amend its post-market

environmental monitoring plan accordingly. Importantly, the Panel also acknowledged that existent studies on resistance evolution based on other geographical and factual circumstances might be misleading for a reliable assessment of the impact of Cry1F and that, therefore, further studies would be needed to evaluate the response of the European and Mediterranean corn borer²⁰.

We observe, therefore, that the pressure exerted on the EFSA by national authorities, independent scientific studies, and the Commission’s recurrent requests has forced the EFSA to engage more seriously with competing views and uncertainty information. However, the opening up in EFSA’s opinions did not result in a modification of its overall risk assessment of maize 1507. Rather, the EFSA increased its emphasis on the importance of post-market management.

II. The Commission’s approach

As shown above, the Commission’s requests to EFSA were formulated in a broad way asking for ‘any reasons to believe’ that there might be adverse effects. Furthermore, we observe that since the submission of Pioneer’s application in 2005 until 2013 the Commission has operated in a rather cautious and politically sensible way arguably at the expense of an efficient and timely administrative process. It engaged with national scientific authorities encouraging their collaboration with the EFSA. It put a lot of pressure on the EFSA to repeatedly respond to competing sci-

17 EFSA (2010), *supra* n. 14., p. 7.

18 EFSA (2012), Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize 1507 for cultivation, 9(11) *EFSA Journal* (2011), p. 2429.

19 EFSA (2012a), Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations on the genetically modified insect resistant maize 1507 for cultivation, 10(11) *EFSA Journal* (2012), p. 2934. EFSA (2012b), EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize 1507, 10(10) *EFSA Journal* (2012), p. 2933.

20 EFSA (2012), *ibid*, p. 3 states “The EFSA GMO Panel recommends caution when predicting future responses of the European and Mediterranean corn borer in the EU based on experiences elsewhere, as resistance evolution in target insect pests is dependent upon many factors”.

entific views expressed either by national authorities or independent studies. Likely aware of the resistance on the part of the Member States that it might encounter in the comitology process, the Commission tried to accommodate different concerns in a pre-emptive manner.

However, the Commission ultimately did not consider that the scientific uncertainty and limitations in the risk assessment of ‘Herculex’ indicated in the EFSA opinions are sufficient to trigger the use of the precautionary principle. The Commission drafted a proposal authorizing maize 1507 relying on the EFSA’s statement that there is no evidence of the adverse effects of maize 1507 on human and the environment, and taking over the EFSA’s suggestions for risk management to minimise potential risks. The proposal was sent to the relevant comitology committee.

The successive process of authorisation of maize 1507 was marked by delay, inaction, and, ultimately, a ruling of the EU General Court in 2013.²¹ As usual for GMO authorisations²², in 2009, the comitology committee failed to reach a qualified majority either in favour or against the Commission draft proposal.

However, the Commission did not continue the procedure by submitting its proposal to the Council (as required by the relevant EU rules²³) until November 2013, when it was forced to do so by the finding of the EU General Court that the Commission has breached its procedural obligations, and had failed to act in the sense of Article 265 TFEU.

In November 2013, twelve years after the filing of the Pioneer application, the Commission sent to the Council a new draft proposal authorising maize 1507. In this draft the Commission states that following the information submitted by the applicant and the EFSA opinions there is ‘no evidence to indicate that the placing on the market of Zea mays L. line 1507 is likely to cause adverse effects on human and animal health or the environment in the context of its proposed use.’ (emphasis added) It further subjects the authorization to the implementation of certain post-market surveillance measures, case-specific monitoring and instructions to farmers. The Commission justifies its proposal upon the basis that the EFSA had not identified new scientific publications that would have invalidated its previous opinions on the safety of maize 1507.²⁴ What is most striking about this proposal is the absence of any references²⁵ to the potential risks and uncertainties identified by the EFSA in its latest more nuanced opinions (see above).

III The European Parliament’s approach

It is also noteworthy that the Commission proposal to authorise maize 1507 led the European Parliament – for the first time ever – to intervene actively in the comitology procedure.²⁶ In a parliamentary resolution of January 2014, the Parliament called on the Council to reject the Commission proposal as it considered the Commission proposal to exceed the implementing powers conferred on the Commission under Directive 2001/18, and called on the Commission not to authorise any new GMO variety and not to renew old ones until the risk assessment methods had been significantly improved.²⁷ It follows, therefore, that in the case of ‘Herculex’ the European Parliament has emerged as a new political actor in the comitology procedure, filling the political vacuum created by the disagreement and the failure of deliberation in both the comitology committee and the Council.²⁸

21 EU General Court, Case T-164/10, *Pioneer Hi-Bred International v European Commission*, 26 September 2013. Overall, it took two court actions by Pioneer to move the procedure along. The first one was brought in 2007 (Case T-139/07) forcing the Commission to submit a draft proposal to the comitology committee, after which the EU Court filed the case because there was no need to adjudicate anymore.

22 Weimer (2014) *supra* n. 2; M. Pollack & G. Shaffer, “Risk Regulation, GMOs, and the Limits of Deliberation”, in D. Naurin & H. Wallace (eds), *The European Union Council of Ministers* (Palgrave MacMillan, 2008).

23 Note that the old comitology rules of Council Decision 1999/468/EC are still applicable to this authorization procedure.

24 Commission proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests, COM(2013) 758 Final, 6 November 2013.

25 With the exception of the potential Bt toxin resistance in corn borers, for which the Commission refers to an EFSA opinion from 2005.

26 Pursuant to Article 8 (1) of Council Decision 1999/468/EC (‘old comitology rules’). These rules remain applicable to the authorization procedure of maize 1507 because it is a pending procedure in the sense of Article 14 of Regulation 182/2011.

27 European Parliament resolution of 16 January 2014 on the proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests (2013/2974 (RSP)).

28 See Weimer (2014) *supra* n. 2.

IV. The Council's approach

In February 2014 the Council voted on the authorisation of maize 1507. Nineteen Member States opposed the proposal, five were in favour, and four abstained²⁹. Despite the high number of opposing Member States, no qualified majority was reached against the Commission proposal paving the way for the Commission to approve 'Herculex' for cultivation. At the time of writing, the Commission has not yet taken its final decision on Maize 1507, but the debate is far from over. The vote in the Council was, according to the Greek Minister of Foreign Affairs and current President of the Council Evangelos Venizelos, not a formal one but rather an expression of voting intentions. Following that vote twelve national ministers³⁰ addressed a letter to the responsible Commissioner Tonio Borg formally asking the Commission to withdraw its proposal in the light of the broad opposition of the majority of stakeholders.

V. Concluding remarks

The 'Herculex' authorization process shows an interesting development in two respects. Firstly, the pressure exerted by national authorities and independent research studies as well as the recurrent referral back to the EFSA by the Commission seems to have forced the agency to engage more seriously with competing views and uncertainty information.³¹ It moved from providing a definite answer ("maize 1507 will not have adverse effects") to a more nuanced answer (if monitoring and mitigation measures are taken, maize 1507 is "unlikely to raise safety concerns for the environment") while indicating knowledge gaps and remaining uncertainties. Secondly, however, this ultimately did not alter the substantial outcome of

the EFSA's risk assessment, namely, the finding of safety of maize 1507. Potential risks and uncertainties arising from the cultivation of 'Herculex' were treated as manageable through post-authorisation measures such as monitoring and mitigation.

The Commission's approach, despite of initial efforts to act in a politically sensitive way, and to foster scientific deliberation between the EFSA, national authorities and other scientific authorities, nevertheless epitomizes the persistent problems of GMO regulation, namely procedural delay and a Commission paralyzed between the EFSA and the Member States.³² However, an end of the EU adventures of 'Herculex' is not yet in sight, and the Commission's reaction to the strong political opposition to the authorization is to be awaited. It does not seem unlikely that the high political salience of the 'Herculex' authorization, together with the important changes that 2014 will bring to the EU institutions (namely the elections of a new Parliament and the establishment of a new college of Commissioners) might deter the Commission from taking further steps in the next few months. However, even at this very last stage the outcome of the authorization process for 'Herculex' remains difficult to predict.

29 Spain, the UK, Finland, Estonia and Sweden voted in favour, Portugal, Czech Republic, Belgium and, quite surprisingly, Germany abstained. France, Italy, Hungary, the Netherlands, Slovenia, Slovakia, Austria, Poland, Greece, Romania, Bulgaria, Croatia, Cyprus, Latvia, Ireland, Denmark, Malta, Luxembourg and Lithuania voted against the Commission's proposal for approval.

30 From Austria, Bulgaria, Cyprus, France, Hungary, Italy, Latvia, Lithuania, Luxembourg, Poland, Slovenia and Malta. The text of the letter is available at http://m.greenpeace.org/greece/Global/greece/image/2014/gmos/gmo_general_petition/2379_001.pdf (last accessed 10 April 2014).

31 On this term, see Marjolein van Asselt and Ellen Vos, "Wrestling with Uncertain risks: EU Regulation of GMOs and the Uncertainty Paradox", 11 *Journal of Risk Research* (2008), p. 281.

32 See Weimer (2014) *supra* n. 2.