Title: Science for policy: assessing genetically modified crops in the EU
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Introduction

The current state of genetically modified crops in the EU

The authorisation process for applications for the marketing or cultivation of genetically modified (GM) crops (GMCs) in the EU is considered by its proponents as one of the strictest in the world, and at present just one type, bt maize MON810, is permitted for commercial cultivation. It was approved in 1998 on the basis of an assessment by the Scientific Committee on Plants, but its cultivation first started in 2003 in Spain. The EU lifted the *de facto* moratorium after strict rules on the labelling and tracing of GM food and feed and guidelines on how to grow and separate GMCs were issued. The approval was renewed in 2009 on the basis of a favourable opinion of a successor scientific committee of the European Food Safety Authority (EFSA), the GMO Panel. Although the continued cultivation was approved, many countries invoked a safeguard clause to prohibit it on their territories[1] or simply did not grow it. The European Commission (EC) attempted to resolve the contradiction between the official European safety assurance concerning GMCs and the challenges to it from member states in 2015 by an amendment[2] to Directive 2001/18/EC allowing states to restrict or prohibit their cultivation on their territory. In the following year, two-thirds of the EU opted out of the cultivation of GMCs.[3] In the rest of Europe, GM maize was grown on a large scale only in Spain (Clive 2016). This situation is a result of growing opposition to GMCs in most of the EU. The stance has been viewed, however, as being based on unscientific reasons and therefore members can only ban their cultivation on grounds that do not fall under EFSA's remit, thus leaving the criticism of the Authority's procedures unaddressed. However, EFSA's risk assessment is a crucial step in the whole decision-making process concerning genetically modified organisms (GMOs). Before GMCs are allowed to be grown in the EU, the European Commission bases its decision about applications for the cultivation of GMCs on EFSA's risk assessment. The Member States Experts (MSE) Committee should then adopt or reject the draft decision by a qualified majority, which is rarely achieved. With a few exceptions, the EC adopted a final decision on the basis of positive opinions issued by EFSA because neither the MSE nor the Appeal Committee reached a qualified majority (Dolezel et al. 2011). EFSA has been criticised for issuing favourable opinions despite inadequate environmental risk assessments (ERA) submitted by applicants and improvements to the Authority's own ERA have been suggested (Cotter & Mueller 2009; Dolezel et al. 2009, 2011)

EFSA's procedures contested

EFSA was established in 2002 with the aim of gaining political authority for the European Commission's decision making by providing "sound science"; indeed, the Authority describes itself as striving for "scientific excellence" (EFSA n.d.). Notwithstanding, EFSA's opinions have been based on normative judgments about acceptable or relevant effects and uncertainties. The uncertainties about the evidence of risk were raised far more often than those of safety, thus downplaying the significance of adverse effects (Levidow & Carr 2007).

According to EFSA's own description, one of its key values is independence: *"EFSA is committed to safeguarding the independence of its experts, methods and data from any undue external influence and to ensuring that it has the necessary mechanisms in place to achieve this."* (EFSA n.d.). Nevertheless, its independence from economic interests and national and policy influences has been questioned by scientists, NGOs and national governments (Horel & Corporate Europe Observatory 2013; Levidow & Carr 2007). Moreover, EFSA's advice has been biased towards reaching consensus, and panel members have been appointed on this basis (Levidow & Carr 2007).

In the GMO Panel responsible for issuing the favourable report on GM maize MON810, more than half of its members had a conflict of interests (Corporate Europe Observatory 2011). Despite this, the Panel states that no member abstained from the discussion on the subject because of any possible conflict of interests (EFSA 2009). This entanglement is not specific to one term of office. The very first GMO Panel, established in 2003, was criticised and even after the adoption of the new policy on independence in 2011 the situation of EFSA's panels did not improve (Friends of the Earth Europe 2006; Horel & Corporate Europe Observatory 2013).

The existence of conflicts of interests does not necessarily imply malpractice, but may be a source of scientific bias (Diels et al. 2011; Domingo & Giné Bordonaba 2011; Klintman & Kronsell 2010). An apt illustration might be the influence of the International Life Sciences Institute (ILSI) on the development of EFSA's guidance for the risk assessment of GM crops (Then & Bauer-Panskus 2010). Harry Kuiper chaired the GMO Panel at the same time as he was working for ILSI, a *"key partner for the European industry"* (Corporate Europe Observatory 2015). Because of the links between the Authority and industry, a problematic concept of comparative assessment was established as a basis for risk assessment, leading to a less rigorous investigation of the possible risks posed by GMCs (Then & Bauer-Panskus 2010).

Wickson & Wynne (2012) point out further obstacles in the quality assurance of the safety of GMCs: important parts or applicants' whole risk assessment dossiers are unavailable for independent peer review; there is a lack of funding of independent research; there is *"inadequate time, resources, materials, and terms of reference"* for advisory body

scientists (Wickson & Wynne 2012, 335). Because of property rights, access to GM research material is limited by seed companies that require consultation concerning planned research and also require the publication of studies to be limited or controlled by them. These conditions lead to changes in experimental protocols and reduce the number of independent studies (Waltz 2009).

Furthermore, in 2015 national experts on the testing of GMOs challenged the EC and EFSA at a Brussels public discussion: *"The risk assessment by EFSA is based on an outdated concept. Many risks are not assessed: for instance, the combinatorial effects, the effects of pesticide use, and the possibility of uncontrolled spread are all disregarded."* (Anonymous 2015).

The aim of the study

The main purpose of this study is to address the disputes about EFSA's procedures by acknowledging the inherently uncertain and value-laden character of science for policy. Under such conditions an extended peer review can contribute to the quality assurance of the advice used for decision making (Funtowicz & Ravetz 1993). "Extended" refers to the inclusion of other experts and stakeholders, and to different quality criteria and modes of reflection of both natural and social sciences (Wickson 2009). For this purpose I chose the scientific work of the GMO Panel, which served as a basis for approving the only GMC grown in the EU over a longer period, GM maize producing a bt toxin to kill a pest that preys on it. The aim of the present study is to evaluate how the EFSA GMO Panel performed the risk assessment of bt maize MON810 for non-target organisms. The analysis is in the form of an extended peer review guided by the "Reliability Rating and Reflective Questioning" framework (Wickson 2009).

Methods

In this study I examine the "Scientific opinion on Applications for renewal of authorisation for the continued marketing of food, feed and seed for cultivation of GM maize MON810", referred to here as the Opinion (EFSA 2009). Among other issues, the Opinion deals with "Environmental risk assessment and monitoring", which consists of "Evaluation of relevant scientific data" and "Post-market environmental monitoring". In the first part scientific information is cited in order to assess the possible effects of GM maize, including its impacts on human and animal health, an abiotic environment and agricultural techniques. Given the nature of the genetic modification which enables the plant to produce a toxin targeted at a specific pest, the interactions between the GM plant and non-target organisms form a crucial part of the environmental risk assessment (ERA). This part assesses possible impacts on ten different groups of organisms that are not supposed to be affected by the toxin (Cry1Ab protein or simply bt protein/toxin). So far, I have analysed two groups: "Pollinating insects:

honeybees" and "Soil organisms: earthworms";[4] therefore the results cannot be extrapolated to the whole non-target section or the Opinion as such.

For the purpose of this extended peer review I adapted the "Reliability Rating and Reflective Questioning" framework developed by Wickson (2009). In the first part of the analysis, I assess the reliability of the scientific studies cited in the Opinion. The second part follows with an assessment of the way in which the scientific information was used in the synthesis in the Opinion. By combining these two steps I arrive at an evaluation of the adequacy and appropriateness of the Panel's conclusions.

To guide the first step, Wickson (2009) suggests asking four questions: "By who? Where? How?" was the study performed and "What Now?" I further broke down the "who" question to the authors' affiliation and the support for the study, in order to allow a more nuanced assessment of the origin of the study. Similarly, the question "how" was differentiated into "species" and its "life stadium", "exposure material", "event", referring to the type of genetic modification, and "exposure time". The "What now" question hides the status of the study (e.g. published, peer-reviewed) extended by its genre to assess the originality of the source (e.g. original research, review). Table 1 illustrates the concrete levels these criteria can assume. In addition, I examine whether the Opinion omitted relevant scientific information that was available before its issuing by searching the Web of Science, Scopus, Proquest Central and CAB Direct scientific databases.

The second step was focused on assessing ways in which scientific information from the cited studies was used by the Panel. In this procedure I was inspired by the questions suggested by Wickson (2009): when reading the Opinion I reflected on how the scientific study was presented, the accurateness of the references, the representation of the study's methods and results, if information was selected and how, if critique was applied and how, what uncertainties and assumptions were embedded in the study and whether they were communicated. The shortcomings that were identified formed a pattern similar to the one previously found by Wickson (2009); therefore I adopted her categories of misuse of scientific information: Lack of critique: an uncritical reporting of the study and its results; Misleading presentation: a style of presentation that misleadingly suggests an increased strength in evidence; Misquotation: the inaccurate citation of a study in support of a statement; Selection of information: when information from a study is only selectively reported in the assessment; Inconsistent presentation: the results of a study being cited differently in various parts of the assessment; Qualifications removed: the study specifically indicates that further research is required but this is not reported in the assessment, and Misrepresentation: an inaccurate citation of a study's method. I newly added a category: Irrelevant critique: subject of critique, does not correspond to the original study.

Results and discussion

The misuse of scientific information in the Opinion

In this section I describe how the scientific information was used in the Opinion (the second part of the analysis). The identified shortcomings are summarised in the use of science categories according to Wickson (2009), and indicated in Table 2 along with the reliability assessment results. In the following text only selected results for two groups of non-target organisms, honeybees and earthworms, are presented because of space limitations.

In the section assessing the risks to honeybees three studies are cited to support the statement that bt maize/Cry1Ab protein causes "*no direct adverse effects on larvae and adult survival"* (EFSA 2009, 38) which is true only for adults as none of the studies used larval stages. In this case the Opinion adds information that cannot be found in the sources referred to.

From other cited works information is chosen selectively. Only parameters that were not affected are mentioned: *"no significant differences were reported in honeybee mortality, syrup consumption and olfactory learning performance"* (EFSA 2009, 38) while the one that was negatively influenced is omitted: *"foraging activity decreased during and after exposure to Cry1Ab protein"* (Ramirez-Romero, Chaufaux & Pham-Delegue 2005, 608). The authors' conclusion that *"negative effects of Cry1Ab protein on bees cannot be excluded over time."* (Ramirez-Romero, Chaufaux & Pham-Delegue 2005, 608) is left out of the Opinion. The Opinion continues by concluding that negative effects on foraging behaviour and learning performance are unlikely, despite the fact that the cited study (Ramirez-Romero et al. 2008) did not address the previously observed negative effect on foraging activity. The authors report instead *"disturbances in the feeding behaviours"* and the *"potential effect of sublethal doses of Cry1Ab on learning performance"*, which are unlikely to occur under natural conditions, stressing the need for further research (Ramirez-Romero et al. 2008, 330-331).

Similarly, the study of Rose, Dively & Pettis (2007) is presented as a field study omitting laboratory experiments that revealed a difference between the bt and non-bt treatment: "*More non-Bt than Bt pollen was consumed per bee."* (Rose, Dively & Pettis 2007, 3). Although the authors attribute the effect to pollen quality, the possible negative effect of bt protein on feeding behaviour cannot be excluded, especially in the context of other cited studies.

From the study of Babendreier et al. (2005) only the results for the development of the hypopharyngeal glands are presented, with the other aim of the experiments being left out. Traces of Cry1Ab protein were detected in the glands, leading the authors to conclude that the protein is unlikely to be transferred to larvae or, if so, in small amounts (Babendreier

et al. 2005). The Opinion thus again uses the information selectively and fails to address other possible routes of exposure.

In the section dealing with possible risks to earthworms, the claimed origin of Cry1Ab protein from plant material in soil is wrongly supported by a study by Webster et al. (2008). The authors investigated the chemical composition and decomposition of birch and conventional maize pollen in soil. No link can be traced to the source of the protein on the basis of the results of this study. To make sure it was not a citation error, the Web of Science database was searched but did not reveal any study that could be cited to support the statement.

Several studies are cited to support the claim that *"laboratory studies performed on some earthworm species (...) did not reveal significant adverse effects*" (EFSA 2009, 40). Nevertheless, among these studies are two (Vercesi, Krogh & Holmstrup 2006; Zwahlen et al. 2003) that reported negative effects of feeding on bt maize leaves on reproduction and weight in adult earthworms, respectively. The introductory claim therefore seems simplifying and misleading.

Only later in the text, where each of the cited studies is discussed, are the negative findings of Vercesi, Krogh & Holmstrup (2006) presented. It seems, however, that the original interpretation of the results was uncritically adopted. Vercesi, Krogh & Holmstrup (2006) consider the concentration of bt biomass in soil in which the negative effect was observed as relatively high, based on some assumptions and leaving out other routes of exposure to the bt toxin.

Though the findings on the negative effects on the weight of adult earthworms observed by Zwahlen et al. (2003) are discussed further in the Opinion, the results are misrepresented. The study is incorrectly cited to support parameters that were not examined by the authors: *"The ingestion of the Cry1Ab protein by earthworms was confirmed through the detection of the protein in their gut and faeces (e.g., Zwahlen et al., 2003b)."* (EFSA 2009, 41). Similarly, Zwahlen et al. (2003) did not perform field surveys *"during the cultivation of Bt-maize"* (EFSA 2009, 41), as the Opinion suggests, but used dried bt maize leaves instead. The imprecise representation of the results reads that: *"the growth of adults (...) significantly declined thereafter in Bt-exposed earthworms up to 200 days."* (EFSA 2009, 41), whereas Zwahlen et al. (2003) indicate more importantly that this decline differed significantly from the non-bt-maize-fed earthworms, whose weight increased.

In the Opinion the study of Clark & Coats (2006) is incorrectly cited as having found no negative effects on the reproduction of earthworms, an impact not examined by the authors. This parameter was thus examined in only one cited study (Vercesi, Krogh & Holmstrup 2006) and in one species, *Aporrectodea caliginosa*, with the results of adverse effects on the cocoon hatchability rate, which decreased significantly with increasing bt

concentration. The wrong statement of there being no negative impact on reproduction is false counter-evidence to the findings of Vercesi, Krogh & Holmstrup (2006), who advise further research with earthworms in field experiments under long-term cultivation.

Table 1. Key to Table 2. Levels the reliability criteria may assume, ordered from the weakest, in red, to the strongest, in green.

Affiliation and support	Status of the study	Where	Exposure material	Event
state/public	original research, peer-reviewed and published	field within Europe	plant	MON810
various incl. state and industry	not clear if peer-reviewed, published	field outside Europe	plant material	other Cry1Ab maize
industry	review/meta-analysis, peer-reviewed and published	semi-field	purified Cry1Ab protein	
applicant	not peer-reviewed and/or unpublished	laboratory	insecticide	

The adequacy and appropriateness of the conclusions for honeybees

The EFSA concludes that *"...the likelihood of adverse effects on honeybees is expected to be very low."* (EFSA 2009, 39). The conclusion is based on information from eight scientific works of relatively high reliability and stemming from generally reliable resources. The only possibility of honeybees' exposure to the Cry1Ab protein through pollen is backed by a review (Bartsch et al. 2009). The Opinion leaves out other exposure routes such as nectar (Babendreier et al. 2008) and possibly worker jelly (Babendreier et al. 2005).

Five original research studies, one review and one meta-analysis are then used to assess the hazards and exposure of honeybee larvae and adults to the Cry1Ab protein. A closer look reveals, however, that larval stages are addressed only in two studies of the cited meta-analysis by Duan et al. (2008). The meta-analysis focused on various cry proteins, while only four works exposed honeybees to the Cry1Ab protein: one of them is cited in the Opinion (Rose, Dively & Pettis 2007), an omitted peer-reviewed study (Hanley, Huang & Pett 2003) and unpublished studies by Monsanto (Maggi & Sims 1994a, b, as cited in Duan et al. 2008). Although a meta-analysis has a higher credibility, the use of the study by Duan et al. (2008) is of questionable value for the assessment as only four studies exposed honeybees to the Cry1Ab protein expressed in MON810. Furthermore, half of the experiments cited come from non-peer-reviewed studies issued either by the US Environmental Protection Agency or the Monsanto Company. The first and third authors of the meta-analysis have a conflict of interests, being employed by Monsanto, which produces and markets bt crops. Though clearly declared in the original paper, none of these limits is reflected in the Opinion.

Table 2. Results of the reliability rating and reflective questioning assessment. The columns show the criteria of reliability and use of science. The rows represent studies cited in the Opinion (EFSA 2009). The colour codes are explained in Table 1, grey cell: no available information for the criterion (review), blank cell: criterion not relevant. Row in red font: study reported negative effects. Only results for earthworms shown.

	Reliability					Use of science							
Study	Affiliation and support	Status of the study	Where	Exposure material	Event	Lack of critique	Selection of information	Misquota-tion	Inconsistent presentation	Qualifica-tions removed	Irrelevant critique	Misleading presenta-tion	Misrepre-sentation
Clark and Coats, 2006													
Bartsch et al., 2009													
Saxena et al., 2002													
Saxena et al., 2004													
Anonymous, 2006													
Schrader et al., 2008													
Krogh et al., 2007													
Saxena and Stotzky, 2001													
Webster et al., 2008													
Vercesi et al., 2006													
Clark et al., 2005													
Icoz and Stotzky, 2008													
Stotzky, G., 2004													
Zwahlen et al., 2003													

Adverse effects were observed in three of four cited original research studies that exposed honeybees to purified Cry1Ab protein and/or plant material. However, in the Opinion the negative effects of the Cry1Ab protein on feeding behaviour and possibly on learning performance are left out (Ramirez-Romero, Chaufaux & Pham-Delegue 2005; Ramirez-Romero et al. 2008; Rose, Dively & Pettis 2007). Only negative impacts presented by Ramirez-Romero et al. (2008) as being unlikely to occur under natural conditions are cited in the Opinion. The authors of the original studies suggest that negative effects cannot be excluded and call for further research (Ramirez-Romero, Chaufaux & Pham-Delegue 2005; Ramirez-Romero et al. 2008; Rose, Dively & Pettis 2007).

Selective reporting of the results seems to be based on an assumption that adverse effects will not occur in nature. This belief assumes a known and stable concentration of the Cry1Ab protein produced by plants and that pollen is the only source of the protein. Both suppositions were being questioned by the time the assessment was performed, even in some of the cited studies (Babendreier et al. 2005, 2008; Lorch & Then 2007; Nguyen & Jehle 2007). Moreover, a negative effect was also observed using the actual plant material (Rose, Dively & Pettis 2007), pollen from bt11 maize expressing the Cry1Ab protein at a comparable concentration to the assessed event MON810 (EFSA 2009). The assessment is further based on studies using bacterially produced purified Cry1Ab protein assuming the interchangeability with the one produced by plants and assuming no other differences between the conventional and GM plant except of the novel protein, assumptions challenged in the scientific literature including a cited study by Clark & Coats (2006).

The conclusion continues with a generalisation: *"The EFSA GMO Panel has no reason to consider that maize MON810 will cause reductions to pollinating insects..."* (EFSA 2009, 39). The whole section concerns, however, one species exclusively: the honeybee. Available studies testing other pollinating species are lacking, and thus, the general conclusion on pollinating insects has no support.

A literature search for further relevant works revealed three articles that present additional information or provide further support for claims that are insufficiently backed in the Opinion. The identified studies are of equivalent quality to the cited ones, i.e. original research articles, peer-reviewed, published and using maize producing the Cry1Ab protein or the protein itself. Two of them were included in the cited review by Malone & Burgess (2009) and one in the meta-analysis (Duan et al. 2008). In these cases the Opinion referred to secondary literature instead of using original sources of information.

By omitting relevant studies, misquoting and selectively citing results, the GMO Panel failed to perform a comprehensive risk assessment for honeybees. An alternative conclusion based on the cited and omitted studies could then read: "No adverse effect on honeybee adult survival was observed in one field and six laboratory studies using the Cry1Ab protein

and/or pollen from maize expressing protein. A limited number of studies reported no impact on honeybee behaviour, intestinal bacterial community, colony performance and larval survival and development. Negative effects on feeding behaviour and learning performance were identified. Further research is needed to confirm the relevance of the observed effects in natural conditions and to explore the effects on honeybee larvae and other key pollinators."

The adequacy and appropriateness of the conclusions for earthworms

The conclusion of the section on earthworms reads: *"The EFSA GMO Panel is of the opinion that there is no evidence to indicate that the placing of maize MON810 and derived products on the market is likely to cause adverse effects on earthworms in the context of its proposed use."* (EFSA 2009, 42). It is based on four reviews, nine original research studies and one study not relevant for the assessment. Although the scientific information stems from generally reliable resources and the reliability of the studies is relatively high, the shortcomings in its use by the GMO Panel limit the conclusion. Studies are often misquoted and information selectively used. The Opinion does not state any uncertainties, nor does it require any further research, which contrasts with the cited findings of negative effects of bt maize on reproduction and weight (Vercesi, Krogh & Holmstrup 2006; Zwahlen et al. 2003). An additional literature search did not reveal any relevant studies for the ERA of earthworms.

The authors of the Opinion fail to reflect and critique the methods and results of the cited studies. Nevertheless, critique could be applied e.g. to the duration of the experiments and choice of the test organisms. In virtually all of the cited studies (except that of Zwahlen et al. 2003) the exposure time was short compared to the life spans of earthworms, which generally live for more than four years in the laboratory and approximately one year in natural surroundings (Edwards 1998, as cited in Marvier 2002). Moreover, the relevance of particular test species for arable land could be reflected. Only two of the cited studies (Schrader et al. 2008; Vercesi, Krogh & Holmstrup 2006) used the only unambiguous and perhaps most appropriate species, *A. caliginosa*, which is abundant in agricultural soils (Anonymous 2006; Viktorov 2008). Critique was applied only to that study which reported an adverse effect (Zwahlen et al. 2003) or it was mechanically adopted from another study (Saxena & Stotzky 2001).

Possible sources of the Cry1Ab protein in soil do not include the faeces of wildlife and livestock and effluents from biogas facilities (Bartsch et al. 2009). On the other hand, a cited exposure route of earthworms to the protein through plant material is wrongly backed by an irrelevant study (Webster et al. 2008).

Four studies examined the effects of bt maize plant material on adults and three on juveniles in laboratory and/or field conditions. The exposure had no effect on earthworm

survival and growth and the population density, number of species and biomass of *Lumbricidae.* According to Vercesi, Krogh & Holmstrup (2006), bt maize residues had a negative impact on cocoon hatchability. The relevance of this effect under natural conditions is questioned and field experiments to confirm the results are required by the authors. Significant weight loss in bt maize-fed earthworms was observed by Zwahlen et al. (2003). The authors conclude that sublethal long-term effects cannot be excluded and further research is needed. In the Opinion studies reporting negative effects are either criticised or the ecological relevance thereof is questioned, making the results inappropriate and invisible. The findings of adverse effects thus do not find their way into the conclusion.

An alternative conclusion based on the cited studies could read: "In laboratory and field studies with plant material from maize expressing the Cry1Ab protein no adverse effect on either earthworm survival and growth or the population density, number of species and biomass of *Lumbricidae* was observed. An adverse effect on reproduction and weight in adult earthworms was identified. Further research is needed to confirm the relevance of these effects in natural conditions."

Conclusion

According to EFSA's own words, the Authority aims to *"provide high-quality scientific advice based on the expertise of its network of scientists and staff and the quality of its science-based information and methodologies, which are grounded in internationally recognised standards."* (EFSA n.d.).

The results of this extended review of a section of the Scientific Opinion issued by the EFSA GMO Panel show that the science-based information used in the Opinion originates from independent and reliable sources but sometimes from secondary literature. The quality of the studies alone is relatively high, with some limitations related to the character of the experiments, i.e. laboratory studies prevail over field ones, and some use only a purified toxin or do not use the assessed event MON810. However, how the Panel uses the scientific information leads to the opposite of "high-quality scientific advice". Studies are often misquoted and information used selectively, leaving out negative effects and further research requirements. A critique of the methods used and the Panel's own reflection on uncertainties and the relevance of the results under natural conditions are missing. Moreover, the cited information is not comprehensive, as evidenced by additional relevant studies found through a literature search.

Thus the conclusions of the Panel that *"there is no evidence to indicate that the placing of maize MON810 and derived products on the market is likely to cause adverse effects on [honeybees/earthworms] in the context of its proposed use"* (EFSA 2009, 39, 42) are inadequate as a result of the often incorrect use of scientific information. An alternative

conclusion based on the cited studies and additional relevant ones could read: “Negative effects were identified on feeding behaviour and learning performance in honeybees and on reproduction and weight in adult earthworms. Further research is needed to confirm the relevance of the observed adverse effects in natural conditions and to explore the effects on honeybee larvae and other key pollinators.”

Along with the author of the method I used (Wickson 2009), I would like to emphasise that the aim of this extended review was not to perform a “true risk assessment”, but rather to contribute to robust advice for decision making.

I can only speculate as to whether the misuse of scientific information results from the conflicts of interests of half of the Panel members, from constraints imposed by time and resources, from the pressure to achieve consensus or a combination of these. Further research is needed to reveal if the identified shortcomings are specific to two randomly chosen sections of experimental species or characterise the whole risk assessment for non-target organisms. However, this limited analysis already indicates that EFSA’s claim to scientific excellence cannot be justified and is in agreement with previous critiques (Cotter & Mueller 2009; Dolezel et al. 2009, 2011; Testbiotech 2015).

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[1] The s*afeguard clause was invoked successively by Austria, France, Germany, Greece, Hungary, Italy, Luxemburg, Poland and Romania.*

[2] *Directive 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.*

[3] *The opt-out was introduced in 17 member states and in regions of Belgium and the United Kingdom.*

[4] *The aim is to analyse at least one more group: "Water-dwelling organisms" to cover different ecosystems non-target organisms inhabit. Ideally, all ten groups would be reviewed, in order to make an exhaustive assessment.*