Title: How to implement a national opt-in mechanism for the cultivation of genetically modified crops in the European Union

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The cultivation of genetically modified (GM) crops in the European Union (EU) remains a highly polemic issue after many years of research, practical experience, and extensive discussions. The only GM crop event that is currently authorised for cultivation in the EU is the insect-resistant maize `MON810´, which was authorised in 1998 (http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=11). The GM potato variety `Amflora´ with improved tuber starch composition was approved for cultivation in 2010 (original approval document: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:053:0015:0018:EN:PDF; comprehensive overview of the Amflora case: http://www.europarl.europa.eu/RegData/bibliotheque/briefing/2010/100028/LDM_BRI(2010)100028_REV2_EN.pdf), however the authorisation for this crop was later withdrawn (press release on the annulation of the Amflora approval: https://curia.europa.eu/jcms/upload/docs/application/pdf/2013-12/cp130160en.pdf). One of the main reasons that not more GM crops are authorised for cultivation in the EU is that a regulatory gridlock persists in the authorisation procedure, with a recurring inability to reach a qualified majority for either approval or rejection in the designated committee [1].

Several EU member states experience domestic pressure from various stakeholders and/or the public against the adoption of GM crops by farmers within their territories [2,3,4,5]. A new piece of legislation was therefore developed by the European Commission (EC, Brussels), resulting in the Directive (EU) 2015/412 (see http://data.europa.eu/eli/dir/2015/412/oj) being adopted by the European Parliament (EP) in 2015. This Directive gives the member states the possibility to restrict or prohibit the cultivation of authorised GM crops in their territory. The request to exclude a particular GM event from cultivation on all or part of the territory may be communicated to the EC prior to decision (after risk assessment), or after authorisation decision provided that the cultivation restriction is in conformity with the EU law, reasoned, proportional and non-discriminatory as well as based on certain compelling grounds (for examples of compelling grounds, see Article 26b(3) of Directive 2015/412/EC). To date, 17 member states and two autonomous regions have used this possibility for one or more GM events; namely Austria, Bulgaria, Croatia, Cyprus, Denmark, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Slovenia and the regions Wallonia (Belgium) and Northern Ireland, Wales and Scotland (United Kingdom) (see http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en).

In parallel to the development of Directive 2015/412, the EC also proposed an analogous mechanism of opt-out from import of GM food and feed. However, this option was rejected by a large majority in the EP (see https://oeil.secure.europarl.europa.eu/oeil/popups/summary.do?id=1409673&t=e&l=en). This illustrates a paradox for GM crops in the EU, as 62 different GM products, having passed the risk assessment of the European Food Safety Authority (EFSA) and been authorised for food and feed use (as of February 2019, see GMO registry at https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm), are entering the EU as food and feed but cannot be cultivated.

While it is true that several EU member states have already adopted opt-out measures within their territories, it is also a fact that some member states are in favour of authorising the cultivation of certain GM crops given a positive risk assessment by EFSA, as judged by the voting pattern in the Regulatory

Committee 2001/18/EC (Committee for the adaptation to technical progress and implementation of the directive on the deliberate release into the environment of genetically modified organisms). We have therefore proposed a mechanism that would allow EU member states to take decisions individually on the authorisation ("opt in") of cultivation of GM crops, given a positive risk assessment by EFSA [6]. The response received from various stakeholders (colleagues, policy makers, media, the public, etc.) has been by far mostly positive (a selection of web links is available as supplementary material). However, many questions have also been raised about the implementation. Accordingly, there is a need to further elaborate on the various alternatives for implementing such an opt-in mechanism as well as to discuss the implications in a broader context. We here describe two main scenarios for implementing a national opt-in mechanism for the cultivation of GM crops given the current EU legislation.

Two scenarios

In the first scenario (Fig. 1A), the initial steps of the collective authorisation procedure remain exactly as today. After EFSA has delivered the risk assessment, the EC drafts a first decision which is subject to voting in the Regulatory Committee 2001/18/EC. In case a qualified majority is not reached either in favour of or against authorisation, the proposed opt-in mechanism enters into force, allowing individual member states to take a national decision to authorise the cultivation of the GM event in question. This scenario could eliminate the need for the remaining part of the collective procedure, such as the subsequent voting in the Appeal Committee. In case a qualified majority votes *against* the EU-wide authorisation of a GM event, the opt-in mechanism would not be available. The current opt-out mechanism through Directive 2015/412 remains available together with the safeguard clause (Article 23) of Directive 2001/18/EC (http://data.europa.eu/eli/dir/2001/18/2018-03-29), just as today, if there is a qualified majority voting *for* EU-wide authorisation of a GM event.

In the second scenario (Fig. 1B), the risk assessment is also kept under EFSA, but a positive assessment by EFSA means that the event would be immediately available for opt-in by the national competent authority in each member state. This scenario could eliminate the need for the entire collective authorisation procedure, in which case the opt-out mechanism and the safeguard clause would be rendered ineffectual as member states can instead simply refrain from opting in.

Without favouring any of these two projected scenarios, we estimate that the first one described may be the more realistic in terms of political viability as well as being more in line with the overall EU principles. This scenario would maintain a certain degree of harmonisation within the EU while at the same time providing the member states with more discretionary power whenever comitology in this context fails to deliver a decision based on qualified majority. Maintaining an initial degree of harmonisation in the risk management of GM crops would also underline the importance of a collective risk assessment procedure as managed by EFSA. The first scenario would also, in a less disruptive way, re-establish the balance in subsidiarity that was distorted in 2015 with the opt-out mechanism. As member states have the right to opt out from GM crop cultivation they should also have the corresponding right to opt in. For countries that are currently cultivating EU-authorised GM crops (such as Spain cultivating the insect-resistant MON810 maize [7]), it may also be more politically sensitive to take national opt-in decisions that may go against the policies of neighbouring countries (such as France that has opted out of cultivation of MON810) than to rely on EU-wide authorisation.

The second scenario is attractive in its simplicity. Such a procedure would provide a higher degree of depoliticisation at the EU level in the risk management of GM crops, while it would facilitate decisions based more narrowly on scientific knowledge and evidence for countries that do not experience a high level of opposition against the cultivation of GM crops. Scientific risk assessment is undertaken by EFSA at the EU-wide level without political considerations. Instead, political risk management decisions are transferred to the national level where local considerations can be weighed unencumbered by any prior position taken by the Regulatory Committee 2001/18/EC and signals delivered therein by individual member states.

Issues to address

There are some issues related to legal matters, procedural details and trade that would need to be addressed regarding a national opt-in mechanism for GM crop cultivation. Both scenarios for an opt-in mechanism would apply only to the *cultivation* of GM crops. Therefore the effect on trade and the EU internal market for food and feed products will be limited as access of the resulting products to the market will remain covered by the EU-wide regime of Regulations (EC) 1829/2003 and (EC) 1830/2003 on the authorisation of GM food and feed.

A reasonable expectation is that varieties with GM events other than MON810 could be included in national catalogues of agricultural plant varieties and hence available for agricultural production in some EU member states. The consequences in terms of cross-border drift may therefore be exacerbated as a member state opting in for a particular GM event may have neighbouring member states that have not opted in (in either of the two scenarios described above). We would envisage that the same provisions that are included in the opt-out Directive would apply. There, the member state in which GM crops are cultivated is responsible for taking appropriate measures in border areas of their territory to avoid possible cross-border drift into the neighbouring member state(s) in which the cultivation of those GM crops is not authorised.

Specific to the second scenario, it needs to be established whether the right to request further information from EFSA, after delivery of the assessment, should lie with the EC (as today) or with the member states. Another detail that may also need to be addressed is the development of a procedure whereby the applicant, or any other, can approach any member state in addition to the one where the application was filed initially, in order to trigger an opt-in decision (i.e. after positive EFSA assessment, and in any of the two scenarios described above).

An unorthodox solution?

A national opt-in mechanism for GM crops may not fit readily with the EU internal market philosophy. However, the very distinct political context of cultivation of GM crops in the EU justifies to look for unorthodox solutions. Besides, also the opt-out mechanism introduced by Directive 2015/412 has been characterised as atypical in terms of the EU internal market policy [8,9]. As the current implementation of the EU legislation arguably does not fulfil the criteria of legal certainty, non-discrimination and scientific adaptability [10], we suggest that the proposed opt-in mechanism, in any of the two scenarios described above, would provide for a more balanced regulatory setting particularly as it would facilitate science-based considerations in the implementation in certain member states.

We therefore encourage the EC to launch an initiative whereby a wide range of stakeholders is invited to discuss this proposal to amend the EU GMO regulatory framework and to bring these issues forward at a high political level in the EU. Article 2 of Directive 2015/412 states that the EC shall present, no later than 3 April 2019, a report to the EP and the Council regarding the use the member states made of the opt-out mechanism, possibly accompanied by any legislative proposals the EC considers appropriate. It is therefore now high time for the EC to consider drafting a legislative proposal complementing the opt-out mechanism with others such as the opt-in discussed here. We are looking forward to such an initiative and are available should any political or non-political stakeholder on the EU arena wish to further discuss and develop the concept of a national opt-in mechanism for the cultivation of GM crops in the EU.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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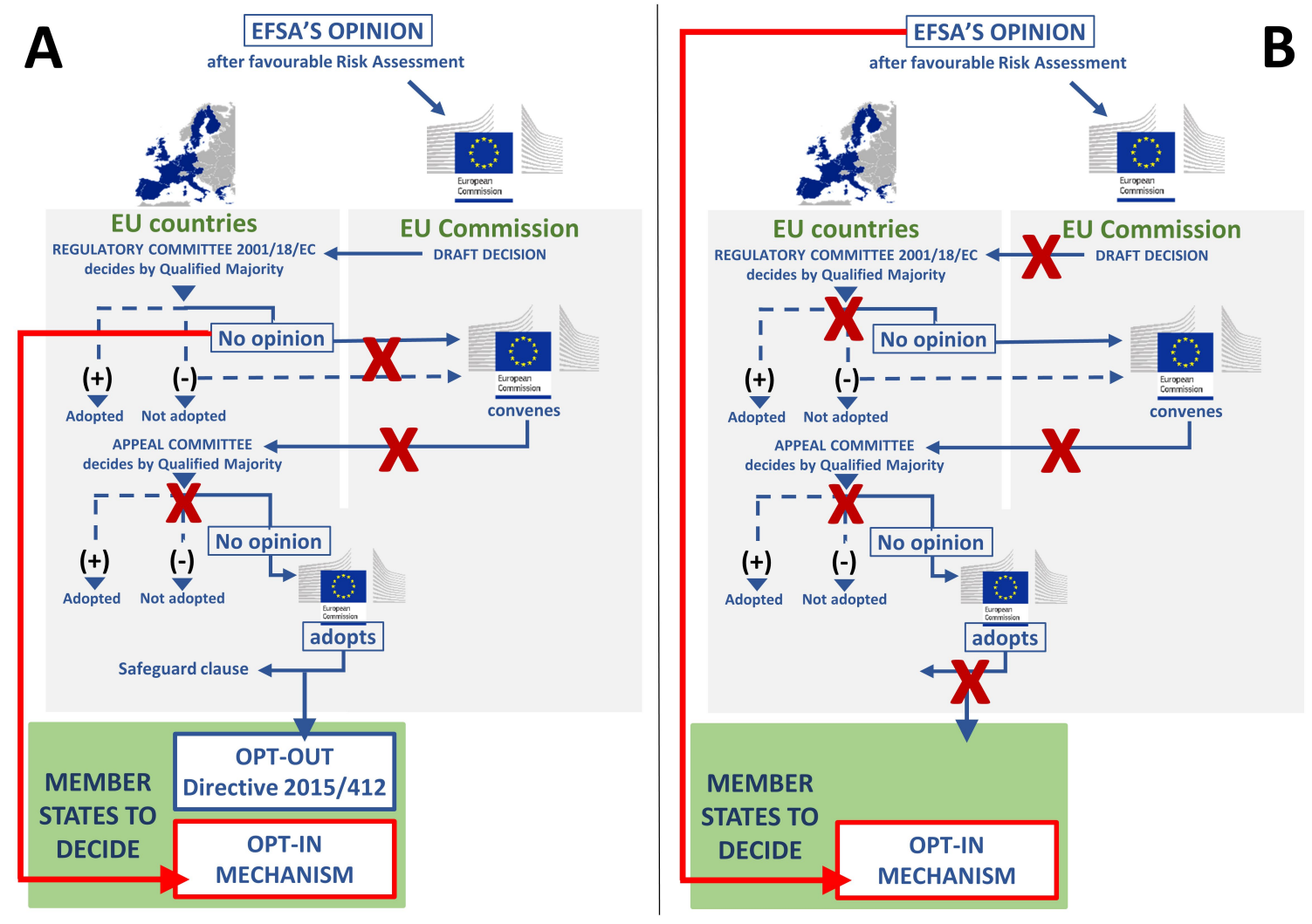
Figure legend

Figure 1. Two scenarios for how to modify the existing authorisation procedure in order to provide for a national opt-in mechanism for the cultivation of genetically modified (GM) crops. *(A)* If Regulatory Committee 2001/18/EC fails to deliver a decision based on qualified majority, the opt-in mechanism enters into force. *(B)* The opt-in mechanism enters into force immediately after a positive risk assessment by the European Food Safety Authority (EFSA), and this could eliminate the need for the entire collective authorisation procedure. The figure is adapted and modified from the European Commission (EC), https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_auth_decision-making-process.pdf. The modifications are in red, with lines indicating added details and crosses indicating superseded existing details in the decision-making procedure.


A
EFSA'S OPINION
after favourable Risk Assessment
European Commission
EU countries
REGULATORY COMMITTEE 2001/18/EC
decides by Qualified Majority
EU Commission
DRAFT DECISION
No opinion
(+)
Adopted
(-)
Not adopted
European Commission
convenes
APPEAL COMMITTEE
decides by Qualified Majority
No opinion
(+)
Adopted
(-)
Not adopted
European Commission
adopts
Safeguard clause
MEMBER STATES TO DECIDE
OPT-OUT
Directive 2015/412
OPT-IN
MECHANISM
B
EFSA'S OPINION
after favourable Risk Assessment
European Commission
EU countries
REGULATORY COMMITTEE 2001/18/EC
decides by Qualified Majority
EU Commission
DRAFT DECISION
No opinion
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MEMBER STATES TO DECIDE
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