Why the European Union needs a national GMO opt-in mechanism

To the Editor: On March 27, 2017, the European Union (EU; Brussels) Appeal Committee on Genetically Modified Food and Feed and Environmental Risk voted on draft regulations for approving the placement of three genetically modified (GM) maize events on the market for cultivation in the EU[1]. The Appeal Committee once again did not reach a qualified majority for either approval or rejection. The March vote result was similar to the preceding vote in the Regulatory Committee 2001/18/EC on January 27, 2017 (ref. 2). This case was the first of its kind since the amendment of the EU legislation on GM crop cultivation (Directive 2015/412, the so-called 'opt-out Directive')[3] came into force in 2015. The opt-out Directive allows EU member states to restrict or prohibit cultivation of GM crops in their territory based on "compelling grounds such as those related to: (a) environmental policy objectives; (b) town and country planning; (c) land use; (d) socioeconomic impacts; (e) avoidance of GMO presence in other products [e.g. crops that would be subject to cross-border 'contamination']; (f) agricultural policy objectives; and (g) public policy"[3]. This possibility was introduced to acknowledge that decisions on the cultivation of GM crops raise complicated issues other than safety, which are best dealt with at a national level and also to improve the process for authorizing GM crops in the EU.

And yet, the votes on January 27 (ref. 4) and March 27 (ref. 5), 2017 demonstrate that the opt-out Directive has not improved the process as intended, and, furthermore, that a large number (about six to ten) of EU member states prefer—in line with the law—to allow the cultivation of certain GM crops given a favorable risk assessment.

The opt-out Directive has been in development since 2009, when 11 member states sent a joint letter urging the European Commission (EC; Brussels) to develop a proposal assigning discretionary powers to member states in deciding national GM cultivation decisions[6]. Some stakeholders[7,8] considered that this change in the regulatory infrastructure could eventually result in breaking the regulatory gridlock[9] that persists in the EU for authorizing GM crops. However, despite the 17 countries and two autonomous regions that have already implemented the opt-out Directive[10], the prediction of Smart *et al.*[9] that most countries would not change their voting behavior has largely proven true as the voting of January 27 and March 27, 2017, demonstrate.

We therefore suggest that the EC develop a new Directive that will allow individual member states to authorize cultivating a GM crop in their territories after the European Food Safety Authority (EFSA) has, pursuant to this Directive or to Regulation (EC) 1829/2003, concluded that the GM crop in question is as safe as the organism from which it is derived.

This proposal would keep a collective risk assessment procedure led by EFSA, which has the benefit of accessing broad scientific knowledge and expertise, capitalizing on greater financial and human resources for specialization and in-depth studies, as well as facilitating the collection of multiple sources and viewpoints[11]. A positive statement from EFSA will therefore be a requisite for national authorization of GM crop cultivation under the scheme proposed here.

A so-called 'opt-in Directive' would overcome many of the problematic issues with the current regulatory system. First, it would better conform to the subsidiarity principle, as it allows for either adoption or non-adoption of GM crop cultivation in acknowledgment of country-specific arguments that may under certain circumstances favor GM crop cultivation. Second, it would facilitate a proper weighing of risks and benefits in particular contexts (e.g., a certain GM trait developed to meet the needs of farmers in a particular EU region). Third, it would offer the potential of consistency, providing a more predictable marketing situation for seed companies, as well as reducing unnecessary regulatory delays. Fourth, it would no longer force the EC to make decisions that may go against the will of several member states. Finally, the proposed opt-in mechanism would take the political edge out of the procedure. Unlike in the opt-out scenario, countries with a politically significant opposition to GM crops do not need to take a vote in favor (with all its fallout risk in the media) before they can exercise their discretion to opt out, but can simply refrain from opting in.

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COMPETING FINANCIAL INTERESTS
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