

# GMO Regulation in Europe: Undue Delegation, Abdication or Design Flaw?

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## I. Introduction

On 22 April 2015 the European Commission published a review of the current GMO legislation (the GM Review)<sup>1</sup> and tabled a proposal for its amendment (the GM Proposal).<sup>2</sup> The GM Proposal aims to allow to the member states to ban on their territory the use of GMOs authorised under the EU legislation. This is very similar to the possibility for opting out from cultivation of authorised GMOs which was finally adopted earlier this year.<sup>3</sup> While this may look like a new trend, all the more interesting in the context of possible Brexit, Grexit and Danish opt-out from the provisions on Justice and Home Affairs, the present article will focus only on the GM Review, which essentially admits that the existing GMO regime is a failure.<sup>4</sup> Indeed, a dozen years after the relevant legislation has been adopted, only one decision for authorisation of a new GM crop was adopt-

ed – the *Amflora* potato – and it was annulled by the General Court.<sup>5</sup> Decisions for marketing have fared slightly better – there are a few dozen authorized GMOs – but still the decisions take many years, raise persistent controversies and are adopted without the support of the relevant committee of national experts. It is remarkable that while the Commission has been constantly in favour of the authorisation of new GMO varieties, its assessments persistently fail to convince the Member States so the expert committees (and the Council) have *never* reached any decision in any direction. As the stalemate leaves the Commission in position to proceed with the authorisations, and it routinely does so, sometimes in defiance of a clear majority of member states against it. This is a responsibility which its current President rightly believes it should not bear.<sup>6</sup> However, instead of finding a way to restore the credibility of the regulatory process, now the Commission is proposing to keep it ‘intact’, and only allow to the Member States to opt out of it.

In the next section I shall take the Commission’s understanding of its role in the existing regime on its face value and show that this is inherently contradictory and in violation of the EU law as interpreted by the Union courts. In the third section, I shall question the soundness of this interpretation of the case law and argue that it is wrong, and that in this way the Commission is abdicating from its responsibility to make informed *choices* itself. The concluding section discusses a possible way out of the trap.

## II. Delegation and Responsibility of the Commission

The current system for GMO regulation essentially involves three bodies – the European Food Safety Authority (EFSA), the Scientific/Appeal committee and the Commission. In a nutshell, the safety of any GMO is to be assessed by EFSA, its opinion is forwarded to a committee of national experts<sup>7</sup>, and if the latter fails to reach any decision, the issue is referred to the Commission.<sup>8</sup> While the role of EFSA is supposed to

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- 1 Communication from the Commission Reviewing the decision-making process on GMOs, COM (2015) 176 final, from 22.4.2015.
- 2 Proposal for Regulation amending Regulation 1829/2003 (Food and Feed), COM(2015) 177 final, 2015/0093 (COD) from 22.4.2015.
- 3 Directive (EU) 2015/412 amending Directive 2001/18/EC (Deliberate Release) from 11 March 2015. It is noteworthy that it took full five years for this simple change to be adopted.
- 4 The GM Proposal itself is discussed in Sara Poli’s paper in the present issue.
- 5 T-240/10 *Hungary v. Commission* [2013].
- 6 In his Opening Statement to the European Parliament on 15 July 2014 J-C Juncker stated that on the matter of GMOs “I would not want the Commission to be able to take a decision when a majority of Member States has not encouraged it to do so.”
- 7 Under the old comitology rules the issue could be raised to the Council, which routinely failed to reach any decision too.
- 8 The process is governed by Directive 2001/18/EC, hereinafter ‘the Deliberative Release Directive’ and Regulation 1829/2003 of GM Food and Feed, hereinafter ‘the Food and Feed Regulation.’ EFSA is established and governed by Regulation (EC) 178/2002 laying down the general principles and requirements of food law, hereinafter ‘the General Food Law.’ The proceedings of the committees of national experts are governed by Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers, hereinafter ‘the Comitology Regulation.’

be strictly advisory with the committees of national representatives and the Commission in turn responsible for any decision, the GM review admits that their control is inoperative in practice.

This regime relies on the functional and institutional distinction between risk assessment (RA) and risk management (RM). The former is considered to be an objective process which can be entrusted to unaccountable expert bodies. Only the latter is believed to be a matter of judgement so it properly belongs to more accountable authorities. Under this system, the expert body is expected to make a precise and neutral assessment of the risk which can inform the political institutions to make *their* choice. The academic literature has long since questioned whether such neat division is possible in practice.<sup>9</sup> Regulation of novel technologies, and GMO in particular, is by definition an area where the potential consequences cannot be known and their measurement, even by the latest science, is impossible. It has been observed that risk assessors, and EFSA in particular, are intolerant of uncertainty and, following the principle of parsimony, tend to interpret the lack of evidence as evidence for lack of effect.<sup>10</sup> Although uncertainty is readily acknowledged by the experts, the employment of science is paradoxically understood as way to provide certainty, neutrality and objectivity of the assessment. As the potential hazards cannot be established with sufficient rigour, scientific advisers tend to conclude that there is no evidence that any potential harm is caused by the product so it appears to be 'safe'. The problem with this separation of tasks is that the delivery of such an opinion often makes the risk manager redundant. Indeed, if a product is 'safe', risk management cannot be triggered; on the other hand, if it is said to be unsafe, rarely a politician in their right mind will authorise it under any circumstances. In both cases, the risk manager is in position to rubber-stamp the conclusions of the risk assessor. This could still make some sense if risk assessment could be used as a neutral instrument for measurement of risk and attainment of clearly specified risk thresholds. However, this is rarely possible, and risk *assessment* inevitably involves considerable measure of judgement; accordingly the assessor inevitably enjoys certain discretion. EFSA for instance cannot, and as a matter of practice does not, estimate that the risk of horizontal transfer of antibiotic resistance amounts to certain *percentage* to be communicated to the Com-

mission; instead it normally concludes what is, *in their view*, likely or unlikely.<sup>11</sup> Thus, EFSA's opinions, even if they are fully independent and unbiased, inevitably involve a measure of discretion which is not immediately obvious.

This condition, however, does not sit well together with the *Meroni*<sup>12</sup> doctrine. According to the latter, delegation of discretionary powers to Union bodies, other than those established by the Treaties, is unlawful unless the exercise of these powers is subject to strict criteria *and* effective oversight. Granting discretionary power, which "replaces the choices of the delegator by the choices of the delegate" in unlawful according to the Court. While this doctrine is quite dated, and has been under considerable pressure in the context of the authorities created in the aftermath of the Financial crisis, the common understanding is that the establishment of regulatory agencies with decision-making powers of their own is problematic.<sup>13</sup> The existing agencies, such as EFSA, are lawful only to the extent that their role is strictly advisory and the decision-making is retained by a Treaty body, which can exercise choice.

This limit to delegation is confounded by the increasingly common requirements for the Union institutions to base their decisions on scientific evidence. The role of the scientific advice was clarified by the General Court in *Pfizer*.<sup>14</sup> The Court held that the administration cannot deviate from the received advice unless it can base its decision on scientific evidence of equal standing. This is generally understood to enjoin it from taking a different view of the same evidence. On the other hand, under the Gener-

9 Sheila Jasanoff, 'Relating Risk Assessment and Risk Management: Complete Separation of the Two Processes is a Misconception' [1993] *EPA Journal* 37. For a more comprehensive study see Elizabeth Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart 2007)

10 Marjolein B. A. van Asselt and Ellen Vos, 'Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox' (2010) 11 *Journal of Risk Research* 281–300.

11 For an excellent primer how different agencies draw opposite conclusions from the same data see 'Weed Killer, Long cleared, Is Doubted', *New York Times* 27 March 2015. Notably, in 1999 the US Environmental Protection Agency reversed its own original conclusion from 6 years earlier on the basis of the very same mouse study.

12 Case 9/56 *Meroni & Co, Industrie Metallurgiche SpA v High Authority* [1958] ECR 152.

13 Operating Framework for the European Regulatory Agencies, COM(2002) 718 final, 5.

14 T-13/99 *Pfizer Animal Health SA v. Council* [2002] ECR II-03305

al Food Law, EFSA is mandated to gather *all* relevant scientific evidence available, including all evidence produced by the relevant national authorities, and to make its conclusion on that basis. Thus, whenever it fulfils its mandate, it would become impossible for the Commission to deviate from EFSA's opinion,<sup>15</sup> for it would not be able to rely on any scientific evidence which is not already taken into account by EFSA! It follows that if it is to remain compliant with the requirements for scientific justification set in *Pfizer*, the Commission must always defer to EFSA. However, whenever the Commission cannot choose to do otherwise, it fails to exercise its own responsibilities, and this amounts to impermissible empowerment of EFSA which the *Meroni* court aimed to prevent.

In theory, this condition might be remedied by a layer of political control through the comitology; indeed *Meroni* states that delegation of clearly defined executive powers is acceptable if it is subject to supervision. In the case of GMO the criteria for authorisation are sufficiently clear, however, as the GM Review now officially recognises, the supervision is missing. The political control is to be provided by the Scientific Committee(s) pursuant to Art. 28 of the Deliberate Release Directive and by the Appeal Committee, pursuant to Art. 30 thereof and the Comitology Regulation. In theory, they are informed by EFSA's opinion but the final decision is their responsibility; their members are free to vote either way and choose to deviate from the recommendation.<sup>16</sup> However, it is now officially recognised that this layer of control is blocked. The Commission admits what has been obvious for many years – that the control

which the national experts were meant to exercise over the authorisation process does not function so that *all* of the decisions are adopted “without the support of the Member States’ committee opinion.”<sup>17</sup> More importantly, it also recognises that the Commission considers itself unable to exercise any measure of judgement of its own and *always* defers to the recommendations of its advisor. The GM Review insists that the Commission is under legal obligation to do so. In the next section I will question this interpretation of the Union law, but it is true that this understanding is consistent with the *Pfizer* doctrine and in any event it is strictly adhered to by the Commission itself. Yet, the GM Review stops short of making the obvious conclusion from these factual statements – that the risk management stage of the authorisation process is inoperative thereby making the risk assessor – EFSA – the *de facto* risk manager. As long as the mechanism for supervision on the authorisation is effectively blocked, with the Commission considering itself bound to defer to EFSA's opinion, the latter wields all the decision-making power. This is a clear violation of the Treaties, at least as they are interpreted in *Meroni*.

In the wake of the Financial Crisis the *Meroni* doctrine may have been considerably weakened<sup>18</sup> and in the recent judgment on the establishment of European Securities and Markets Authority (ESMA)<sup>19</sup> the Court of Justice confirmed the legality of its considerable discretionary powers. It even held that the agencies could be delegated powers to adopt themselves decisions binding on third parties. However, there is one major difference: in the case of ESMA the delegation is made explicit in the relevant regulation while EFSA is meant to be advisory and to operate under control which fails to materialize. Its authority is conferred not by law but by an institutional impasse in the committees and Commission's willful abdication of its responsibilities. Thus, EFSA is turned into a regulatory agency by default. Another important difference is that ESMA and the new financial supervisors are “structurally intergovernmental”<sup>20</sup>, i.e. the decisions are taken by Boards composed of national representatives. According to Craig, “the legal and political reality is that the role played by Comitology committees ... is played by the national representatives.”<sup>21</sup> In contrast, the decisions in EFSA are taken by independent expert panels and the member states send representatives only in its advisory board. Thus, it is perhaps the most supra-

15 Although I do not think that this is the correct interpretation of the *Pfizer* case, this is precisely how the Commission understands its role in the authorization process, as per admitted in the GM Review. I shall discuss the problems with that in section 3.

16 In principle these committees may be constrained by *Pfizer* as much as EFSA and the Commission, but they are in better position to rely on the “other factors”. I will return to the role of the latter below.

17 See the GM Proposal, recital 4.

18 Jacques Pelkmans and Marta Simoncini, ‘Mellowing *Meroni*: How ESMA can help build the single market’ *CEPS Commentary* (2014).

19 *UK v. Council*, C-270/12. See also Paul P. Craig, ‘Comitology, Rulemaking and the Lisbon Settlement: Tensions and Strains’, 2014, *Oxford Legal Studies Research Paper No 75*.

20 Niamh Moloney, quoted by Craig, *ibid*.

21 *ibid*, 47.

national of all agencies. Now we know that its judgments on the substance are not supervised by anyone.<sup>22</sup>

Notwithstanding this, the Commission insists on keeping the existing regime ‘intact’. Instead of fixing it, the Commission proposes for the member states to be allowed to opt out of it. This could solve the problem with legitimacy of a regulatory decision taken in the face of 19 Member States against it,<sup>23</sup> but will do nothing to solve the problem with the violation of the Treaties.

### III. Flawed Legal Analysis

Thus far we have taken Commission’s claim that it is under *legal obligation* to defer to EFSA at its face value and there is no doubt that this is what the Commission does – in this area there is not a single example where the Commission failed to follow what is supposed to be an opinion by an advisory body. Yet, this position is questionable and the Commission does not offer much of a justification. It does not mention *Pfizer* or the latter case of the Court of Justice *Gowan*<sup>24</sup> which lend support to this interpretation, but makes a few brief references to cases which are largely irrelevant for the issue.

One case mentioned in the GM Review is C-390/99 *Canal Satellite Digital SL*. But the issue in that case was the legitimacy of *national* measures restricting the free movements while GMOs are subject to harmonized *Pan-European* rules. It is true that the Court of Justice applies, in principle, Art 34 TFEU also to Union measures (e.g. *Denkavit*<sup>25</sup> and *Alliance for Natural Health*<sup>26</sup>). However, Union measures, by definition, do not fragment the single market so the scrutiny of its measures is by far less rigorous than the review of national measures. This is made clear in *Alliance for Natural Health*, where the Court of Justice stated that in the area of food safety the Union institutions

must be allowed a *broad discretion* ... which entails *political, economic and social choices* on its part, and in which it is called upon to undertake *complex assessments*. Consequently, the legality of a measure adopted in that area can be affected only if the measure is *manifestly inappropriate* having regard to the objective which the competent institution is seeking to pursue ... (para 52, emphasis added).

Similar light-touch approach was adopted in earlier cases: *British American Tobacco*,<sup>27</sup> *UK v Council*,<sup>28</sup> and *National Farmers Union*.<sup>29</sup> The same light touch approach was adopted even in case *Kokopelli*,<sup>30</sup> which the Commission ineptly refers to, where the Court stated that it will find a Union act unlawful only if it is “manifestly inappropriate, having regard to the objective which the competent institution is seeking to pursue”. Although in most of these cases, the act under review was legislative, in *Pfizer* the General Court applied the same standard to an implementing measure of similar legal nature as the decisions for GMO authorization. *Pfizer* is widely understood to severely constrain the discretion of the institutions,<sup>31</sup> yet even in that case the General Court made clear that the same test of manifest error applies and held that with regard to the high values at stake, the decision to deviate from the received scientific advice was justified. Arguably, Union institutions retain their discretion on condition that they can justify the alternative choice on other compelling reasons. In any event, nowhere is said that these are to be drawn from the EFSA’s opinion alone.

The GM Review refers also to several cases where Commission’s failure to decide on applications for GMO authorization for a very long time was found illegal. Certainly, its practice, very common in the GMO matter, to keep on returning the dossiers to EFSA and fail to *decide anything at all* is against the law. However nothing in these or any other cases sug-

22 Certainly, after the Commission rubber-stamps the authorization, it can be subject to judicial review, but the courts are unlikely to assume responsibility to make judgements where the Commission abdicates. Thus, EFSA will be allowed the same broad discretion accorded to the Union institutions as discussed in the next section.

23 The case in point is the vote in Council on 11 February 2014 where 19 member states were against the proposal for authorization of Pioneer Maize 1507.

24 C-77/09.

25 C-15/83.

26 C-154/04.

27 C-491/01, para 123.

28 C-84/94, para 58.

29 C-157/96, para 61.

30 C-59/11.

31 For the standard interpretation see Damian Chalmers, Gareth Davies, and Giorgio Monti, *European Union Law* (2nd edn, CUP 2010). However, it can be understood just as a requirement for rigorous reasoning, see Vesco Paskalev, ‘Courts as Academies: Balancing of Scientific Arguments in Regulation of Uncertainties’ in A. Santosuosso (ed), *Young Scholars Informal Symposium (2012)* (Pavia University Press 2013).

gests that it would be illegal if the Commission decided *against* the authorizations. The Commission seems to have forgotten that such an option exists.

#### IV. The Importance of the ‘Other Legitimate Factors’

The GM Review makes a welcome recognition of another flaw of the current regime. It is that the ‘other factors’ – that is everything that does not pass for ‘scientific’ in the narrow sense – are routinely not taken into account, despite the explicit requirements of the Food and Feed Regulation and the Deliberative Release Directive on the contrary.<sup>32</sup> These may include socio-economic impacts, cost of co-existence, national health and dietary policies, preservation of existing farming practices and consumption patterns, environmental policy goals, agricultural policy, town and country planning, etc. The Commission reconns that “the reasons invoked by member states to justify that they abstained or voted against a draft decision of authorisation ... are usually not based on science but on other considerations.”<sup>33</sup> It implies that the reasons ‘not based on science’ are inappropriate, or at least not equally important as the scientific ones. This is a bit puzzling, as the other factors are not only legitimate but there is a legal obligation for them to be taken into account within the centralised authorisation process.<sup>34</sup> It is beyond the scope of this article to discuss the role of the ‘other factors’ in regulation of risk, but the issue is relevant here to the extent that it offers one possible way out of the *Pfizer-Meroni* trap.<sup>35</sup> Instead of keeping them out, the Commission should take them into account. The legislation needs to be amended to make clear that the decisions for GM authorisation are to be taken on an

‘all things considered’ basis, rather than on the grounds of the scientific advice *alone*.<sup>36</sup> This is not to say that ‘other factors’ should trump ‘science’,<sup>37</sup> it is only to say that if EFSA and the Commission were taking into account also the socio-economic factors their opinions and proposals would be more persuasive in the first place, and in any event this would provide a sound basis for the Commission to justify possible deviations from the received opinions of EFSA. In the GM Review the Commission asserts that it is unable to consider such factors. This is striking in the context of its ambitions in all other spheres of economic and social life – indeed, when proposing any major policy, the Commission claims to have assessed comprehensively its potential impact well beyond what is measurable and assessable by strictly scientific means. Yet in the area of GMO, instead of finding a way to fix the problem, it proposes to enshrine it even deeper by stronger separation of risk assessment and risk management, this time at EU and national level respectively. This is a step in the wrong direction: the adoption of any new technology is a complex matter where many factors are intertwined, so that socio-economic factors are unavoidable part of the decision and should not be consigned to another decision-making level to spare the Commission of the trouble.

Thus, in view of the present author the regime need to be amended in two related directions, both different from the proposed opt-out. First, it is essential *to restore the responsibility of the Commission, as the default risk manager, by clearly stating in the relevant secondary law that it may deviate from the opinion of its advisor*. A step in that direction has already been made with the Comitology Regulation. In a notable departure from the earlier rules, its Art 6 (3) provides that where the Appeal committee fails to deliver opinion, the Commission *may* adopt the act as proposed so it is no longer required to do so.<sup>38</sup> Notwithstanding this change, the Commission still feels compelled to adopt the initial proposal, with no legal basis as was shown in the previous section. In any event, the substantive legislation can be also amended to restore Commission’s control over EFSA as required by the *Meroni* doctrine and also by the general principles of democratic accountability. The second direction is to add more emphasis on the need to consider the ‘other legitimate factors’ so that the Commission is unable to abdicate from its responsibility in that regard either. The adequate inclusion of

32 See the extensive analysis of Mihail Kritikos, ‘Traditional risk analysis and releases of GMOs into the European Union: space for non-scientific factors?’ (2009) 34 *European Law Review* 405–432.

33 GM Review, 3.

34 Art. 7 (1) Food and Feed Regulation.

35 The other way is to abandon the system of rigid separation of risk assessment and risk management altogether.

36 This is what the current regulation requires even now, but the practice deviates from that so the relevant provisions need to be strengthened.

37 For the falsity of this dichotomy see Fisher, *Risk Regulation and Administrative Constitutionalism* (n 7).

38 The old comitology Decision provided that is ‘shall’ adopt it, see Decision 1999/468.

the other considerations should allay any concerns that in deviating from EFSA's advice the Commission may act arbitrarily. It simply *may be required to justify its decision to do so by taking into account other circumstances, which, by their nature, cannot be adequately considered by EFSA.*

To sum up, the present paper made obvious the link between two problems identified in the GM Review – the need for reasoned decisions and the need to consider all relevant factors. As the Commission correctly notes, Art. 41 of the Charter of Fundamental Rights requires it to give reasons for its decisions, including those for authorisation of GMOs. However, nothing in the Charter or elsewhere in the prima-

ry law requires these reasons to be limited to those prompted by the EFSA opinion. On the contrary – the secondary law explicitly calls upon the administration to take other legitimate reasons into account and the Treaty requires *effective* supervision of delegated powers. The obligations to justify its decisions and to take other factors into account are, in fact, complementary. Respecting them will not only respect the law as it is, but will allow the Commission to find the narrow path between the Scylla of *Pfizer* and the Charybdis of *Meroni*. If the Commission fails to respect both of them – as it recognises it does – it is necessary to amend the law to *make it* do so, rather than give to the recalcitrant states a way to walk out.