An Assessment of Current Regulation of GMOs in the EU and Proposals for Amending it

Vesco Paskalev

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Green House Post-growth Project

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But what if that diagnosis, which reflects mainstream wisdom, is all wrong? What if the crisis that we are currently experiencing is one which casts into doubt the entire edifice of capitalist economics that sets growth as the primary objective of all policy? What if the fight between those who say that without austerity first there can be no growth and those who say that we must invest and borrow more now in order to resume growth is a false dichotomy – because both sides are assuming 'growthism' as an unquestioned dogma?

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Edited by: John Blewitt and Ray Cunningham, with contributions from Molly Scott Cato, Andrew Dobson, Jonathan Essex, Brian Heatley, Andrew Pearmain and Rupert Read.
Go to http://londonpublishingpartnership.co.uk/the-post-growth-project/ for further details.

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Summary

The regime of centralised authorisation of production and trade of genetically modified organisms (GMO) in the EU is a shambles but recent amendment proposals do not even begin to address the problem.

Although in its own review the European Commission recognises that the regulation now in force does not work, it insists on keeping it intact, and is prepared only to allow recalcitrant states to opt out of it by banning GMO varieties which are already authorised by the EU.

The main problem with the EU approach to GMOs is in its narrow understanding of risk and safety. To overcome the persistent political controversy on the issue, member states have adopted a system where final decisions are heavily dependent on expert assessment of the safety of each individual variety. Thus 'science' is supposed to carry the day, and who can be 'against science'?

However, what counts as science is itself a contentious issue. The view that is enshrined in law confines science above all to laboratory experiments, e.g. whether rats fed on the GMOs develop abnormally. The effect of GMOs on the environment into which they are released is also taken into account, but such data is less readily available, especially data on longer term and larger scale effects. On the other hand, studies of, for example, the effect of GMO on existing farming practices and consumption patterns, or the costs imposed on farmers who wish to remain GM-free, are excluded completely. On this view they would be considered a matter of politics, and *non-science* — even if social studies can provide plenty of data for various adverse effects.

Further to this major design flaw, the present report identifies a number of other problems in the existing legislation:

— the expert assessment effectively preempts the judgement of the political institutions, such as the Commission and the Council. Such delegation is impermissible under the Treaty of Rome.

— in this way the precautionary principle is rendered inoperative.

To remedy the situation the regime must be amended. This report offers a number of specific amendments to the text of the relevant secondary legislation which boil down to the following:

- the responsibility of the Commission and the margin of discretion in any decision need to be recognised and made explicit.
- uncertainty of any assessment and provisionality of any judgement must be acknowledged; lack of evidence should not be equated with lack of effect.
- risk managers should be put back in charge of risk analysis by allowing them to feed back into the risk assessment requests for consideration of the anticipated *effect* of their final decision; in turn, risk assessors should consider various scenarios.
- procedural details and voting rules should be revised, to restore the functionality of the committees of national experts

('comitology') in order to restore the political control which has been blocked for a dozen years now.
- The independence of the risk assessor (the European Food Safety Authority, EFSA) should be restored by diversifying the expertise of its members and employees.
- Opportunity for public participation should be enhanced by requiring consideration of all factors which are relevant for the stakeholders rather than discarding most of their concerns as non-scientific.

Introduction

On 22 April 2015 the European Commission published a review of the current legislation regulating the authorisation, import, cultivation and marketing of genetically modified organisms (GMO) in the Union (the GM Review)[1] and tabled a proposal for its amendment (the GM Proposal).[2] The GM Proposal aims to allow Member States to ban the *use* on their territory of genetically modified organisms already authorised under the EU legislation. The proposal is analogous to the facility to opt out from the *cultivation* of authorised GMOs that was finally adopted earlier this year.[3] While the adoption of the latter amendment was difficult and took a full five years, the new proposal has managed to unite both environmentalists and the biotech industry in opposing it[4] and, after the European Parliament voted 577 to 75 against it, is as good as dead.[5] Yet its introduction, together with the Commission's official assessment of the GMO regime, has prompted the alternative evaluation of the existing legislation and practice offered by the present report. This report identifies several major problems of the regulation in force, criticises the Commission's failure to make any attempt to address them and makes a number of specific suggestions as to how the legislation should be amended.

By now, there is a wide recognition that the current regime for authorisation of marketing and cultivation of GMOs is inoperative. Indeed, a dozen years after the relevant legislation was established, only one decision for authorisation of a new GM crop has been adopted – the Amflora potato[6] – and that was annulled by the General Court.[7] Decisions for marketing have fared slightly better – there are a few dozen authorised GMOs – but still the decisions take many years, raise persistent controversies and are adopted without the support of the relevant committee of national experts. In the view of the present author, an adequate GMO regime should result in negative decisions because of the persistent scientific uncertainty.[8] Naturally, in the view of the biotech industry the opposite is true and the regime should smoothly yield positive decisions but everyone agrees that functioning governance should yield, above all, *decisions* one way or the other. It is remarkable that while the Commission has been persistently favourable to the authorisation of new GMO varieties, the assessments it relies on fail to convince the Member States, so the expert committees (and the Council) have *never* reached any decision in either direction. As the stalemate leaves the Commission in a position to proceed with the authorisations, it routinely does so, sometimes in defiance of a clear majority of Member States against it. This is a responsibility which the Commission should not bear and its current President rightly acknowledged this in his inaugural address.[9] Yet, instead of proposing a way to restore the credibility of the regulatory process – by making it more democratic and participatory – the Commission is proposing to do nothing and keep it 'intact', and only to allow the Member States to opt out of it completely.[10]

The following report takes the position that the dramatic failure of the existing regime is partly a matter of inadequate implementation of the rules, and partly a matter of flawed design of the framework itself. The problems with implementation - notably the

insufficient independence of the decision-makers in the authorisation process[11] and the flaws in the assessments of particular GMOs – have been addressed by a number of environmental organisations on various occasions, so the present report will stay focused only on the regime as a whole. It will also take into account established practices, as helpfully identified in Commission's GM Review. Thus, it will start with a general discussion of the current regime (Part I). In Part II the report will identify four major problems of the existing regime and *en passant* will discuss the Commission's own evaluation. It will demonstrate that these problems make the regime undemocratic, unscientific and - without going into too many technical details – illegal. In Part III, the report will make several concrete proposals for legislative *amendments which would address the identified problems*, without needing any fundamental overhaul of the legislation in force. Finally, Part IV will critically assess the Commission's own amendment proposal and show that it not only fails to solve the existing problems, but also creates some of its own.

I. Principles of GMO regulation in the EU

Currently, in order to be cultivated, imported or marketed in any Member State of the EU, GMOs need prior authorisation.[12] As appropriate for an integrated market where a product in free circulation in one Member State is accepted in all of the others, the authorisation is centralised and if granted is valid for the whole Union. The details of the procedure vary, depending on whether the GMO is meant for food or feed or for other purposes, but essentially involve an application through a national authority, which is then forwarded to all other Member States and the Commission. If objections are raised by any Member State – that is always – the application is referred to a specialised agency – the European Food Safety Authority (EFSA)[13] to conduct a scientific assessment of its safety for human and animal health or the environment. The legislation in force provides quite precise and comprehensive guidelines on what the assessment should include; the Commission may ask additional questions; and national agencies can provide additional information too - so that ideally EFSA's opinion takes into account all the scientific information currently available. In cases of dispute meetings with national experts and possibly stakeholders are called where participants are expected to settle all the differences and reach an undisputable and 'objective' conclusion. Needless to say, in GMO matters this rarely happens.

Having completed the assessment, and taken into account any such information, EFSA produces a final opinion, which is forwarded to the Commission. On the basis of this the Commission makes a recommendation to a special Scientific Committee, consisting of experts from national ministries – the so-called comitology procedure – on whether or not to authorise the GMO. The voting rules in the committee mirror those in the Council. Although it consists of experts, these are not expected to be independent but to take instructions from their ministers, so this procedure can be perceived as a layer of political control.[14] In theory, the committee should be informed by EFSA's opinion but the final decision is their own; its members are free to vote either way and can chose to deviate from the recommendation. In general, comitology is famously consensual and almost all proposals are eventually adopted.[15] In stark contrast, when deciding on GMO authorisations, the committees have never managed to reach any decision either way and the GM Review now recognises officially that this layer of control is permanently blocked. In case of a stalemate, the comitology rules allow the Commission to make a decision; in GMO cases it often delays but eventually grants the authorisation. While the role of EFSA is supposed to be strictly advisory, with the committees of national representatives and the Commission in turn responsible for any decision, because of the stalemate in the former and the deference of the latter, the opinion of the scientific advisor effectively prejudices the ultimate authorisation.[16]

The EU system makes use of a scheme very common in risk regulation worldwide, which is reliant on the functional and institutional distinction between risk assessment and risk management. The former is considered to be an objective process that can be entrusted to unaccountable expert

bodies. Only the latter is believed to be a matter of judgement and properly assigned to more responsible authorities. Risk itself is perceived as the probability of a certain hazard occurring multiplied by the magnitude of the harm it can cause. It is noteworthy that this understanding of risk takes no account of the extent of the exposure to the hazard. Instead, the assessment seeks to identify a 'safe' threshold below which the product being evaluated has no adverse effects.[17] This approach is highly questionable, as the test conditions where the thresholds are identified are not always representative of the actual conditions where the hazard may occur. Yet, as the estimation of exposure is increasingly difficult given the variety of real life situations, it is widely used nevertheless.[18] Another criticism is that this system treats equally localised risks, whose impact does not spread, and risks with propagating impacts, which may cause irreversible systemic failure.[19] Complete destruction of a system is not the same as the destruction of one tenth of ten systems, so even if the probability of the former is extremely low, responsible policy makers should take whatever measures are necessary to avoid it.[20] Moreover, the existing approach to risk assessment is severely criticised even from a more traditional perspective. For example, a recent report commissioned by the European Environmental Agency (EEA) lamented the fact that risk assessment is not governed by the precautionary principle at all and that the same institutional patterns that led to disasters like asbestos, benzene and mad cow disease remain unchanged.[21]

Notwithstanding such criticisms, the legislation in force adopts this orthodox model of risk analysis. Thus, the expert body – EFSA in our case – is expected to make a precise and neutral assessment of the risk, which will inform the political institutions – the comitology committee and the Commission in turn - in making their *choice*. The academic literature has long since questioned whether such neat division is possible in practice.[22] When it comes to *novel* technologies, data is by definition scarce, so even the most up to date science cannot be conclusive in its estimates. It has been observed that risk assessors, and EFSA in particular, are intolerant of uncertainty and, following the principle of parsimony, tend to interpret lack of evidence as evidence for lack of effect.[23] Although the experts readily acknowledge the limits of their knowledge – academic papers usually start with a number of disclaimers – the employment of science is paradoxically understood as a way to provide certainty, neutrality and objectivity to the assessment. As the potential hazards cannot usually 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 by the assessor makes the risk manager redundant. Indeed, if a product is 'safe' there is no risk to be managed; on the other hand, if its safety is acknowledged to be uncertain, rarely will a politician authorise it under any circumstances. In both cases, the risk manager is placed in the position of rubber-stamping the conclusions of the risk assessor. This could still make some sense if risk assessment could be used as a neutral instrument to assert that "the risk of doing *x* is *y* per cent" or to specify risk thresholds which are not arbitrary. However, this is rarely possible, and risk assessment inevitably involves a considerable

measure of judgement; accordingly, the assessor inevitably enjoys certain discretion.[24] EFSA, for instance, cannot, and as a matter of practice does not, estimate that the risk of horizontal transfer of antibiotic resistance amounts to a certain *percentage* which can be communicated to the Commission.[25] All they can do is state what is in their opinion *likely* or *unlikely* to happen.

While the present author shares the view that the established system of regulation of risk is inappropriate for the case of *uncertainty* the present report will not argue for adoption of an alternative paradigm of the kind proposed by Read or Chapman. Instead, it will take the existing regime for granted and analyse the troubles it creates on its own terms.

II. Flaws of the existing GMO regime

The current GMO regime raises the following major legal problems. First, it operates in violation of the non-delegation doctrine, as established by the Court of Justice (the Court, ECJ) in *Meroni*.[26] Second, the Commission fails to discharge its duty to take into account the 'other legitimate factors' in contravention of the explicit provisions of the Food and Feed Regulation.[27] Third, the Commission is effectively allowed to adopt a decision for GMO authorisation against clear positions of an overwhelming majority of Member States and of the European Parliament (EP) to the contrary, in contravention of the principles of democracy set out in Art 10 of the Treaty on the European Union (TEU) and, in particular, contrary to the specific terms of recital 14 of Regulation 182/2011.[28] Finally, the existing regime defies the precautionary principle and jeopardises the high level of protection of health and environment required by Art. 3 (3) TEU. These problems will be addressed respectively in the following sections.

1) Delegation and Responsibility of the Commission[29]

As was elaborated in Part I, the precise numerical assessment of *risk,* understood as probability times magnitude, is impossible; what risk assessors and EFSA in particular usually do is to state what, *in their view*, is likely or unlikely to happen. Thus, EFSA's assessments, 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 non-delegation principle of EU law.
In one of its earliest judgments – *Meroni v. High Authority,* the Court of Justice of the EU (ECJ) sought to limit the possibility for major Union institutions to delegate their powers to other bodies and held that it can be done only if the exercise of these powers is subject to (1) strict criteria *and* (2) effective oversight. It is largely because of this doctrine that the European agencies as a rule have modest decision-making powers; they mostly gather information and provide expertise for the benefit of the Commission, Council or the EP who remain responsible for the ultimate decision. Thus, even though powerful European agencies have mushroomed during the last two decades, they do not have *regulatory* powers comparable to those of their American counterparts; if such powers were granted, they would most probably be found illegal in the European constitutional framework. When the *Meroni* conditions are applied to authorisations of GMOs, it follows that the Commission (and the comitology committees) may be required to take into account the opinion of EFSA, but should not lose the power to make the ultimate choice themselves. In theory, this is what the current GMO legislation provides for too.

However, the limits to delegation are compounded by the increasingly common requirements for the Union institutions to base their decisions on scientific evidence. The role of scientific advice was clarified by the General Court in *Pfizer*.[30] This decision is generally understood to have severely limited the opportunity

of the administration to deviate from the received scientific advice – it can do so only if it can base its decision on alternative scientific evidence of equal standing. When applied to GMO authorisations it follows that if it is to remain compliant with the requirements for scientific justification set in *Pfizer*, the Commission must either defer to the advice of EFSA or outsmart its advisor.[31] Whenever the Commission cannot do the latter it will be unable to make a choice of its own, and this amounts to impermissible empowerment of the advisory agency, which under the *Meroni* doctrine is unlawful. Thus, the current GMO regime forces the Commission to violate either the legislative requirement for science-based authorisations, or the constitutional requirement for non-delegation. As the former is more apparent than the latter – to industry lawyers in particular – it is small wonder that the Commission always chooses to commit the latter violation.

Indeed, in its GM Review the Commission explicitly states that it considers itself unable to exercise any measure of judgement of its own and is under legal obligation *always* to defer to the recommendations of its advisor.[32] Yet, the GM Review stops short of making the obvious conclusion from the facts it has stated: that if the risk management stage is inoperative, this makes the risk assessor – EFSA – the decision-maker by default. In theory, this condition might be remedied by a layer of political control through the comitology. But as the GM Review now admits, the control that national experts were meant to exercise over the authorisation process does not function, so *all* of the decisions are adopted "without the support of the Member States' committee opinion."[33] **As long as the mechanism for supervision of the authorisation is effectively blocked, with the Commission considering itself bound to defer to EFSA's opinion, the latter becomes the risk manager *de facto*. This is a clear violation of the Treaties, at least as they are interpreted in *Meroni*.**

In the view of the present author, urgent legislative action is necessary to amend the authorisation process, and Part III of this report will propose a number of specific changes which could help. Those which are aimed to deal with the problem with discretion will be briefly sketched here. The first possible remedy is for the voting rules in the said committees to be amended in a way to ensure that they are able always to reach a decision, despite the unrelenting division between the Member States. In any event, in light of their persistent failure to exercise any meaningful control over GMO authorisations, the comitology committees should not remain the only source of democratic control in the process. Another way is 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.[34] The third way to avoid the undue fettering to the received advice is to re-emphasise the need to consider the 'other legitimate factors'. To allay any concerns that in deviating from EFSA's opinion the Commission may act arbitrarily, it could simply 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. This would limit the conferral of too much discretion on the Commission while also addressing another problem of the existing regime, which is discussed in the next section. Yet another way is for the

Commission to be required to take into account the stated positions of the Member States, and/or any relevant resolutions of the European Parliament.[35] In a recent example, a decision to authorise cultivation of Maize Pioneer 1507 was opposed by 19 Member States with only 5 in favour. The predominant position could hardly be any clearer.

This section has demonstrated that the existing regime for authorisations of GMOs stands in violation of the primary law as interpreted by the ECJ. The following section will show that by **failing to take into account the 'other legitimate factors' which are deemed "non-scientific", the system is also undemocratic and unscientific (sic!).**

2) Narrow basis of authorisation decisions

The present GMO regime was adopted after years of intense controversy and institutional deadlock. It was assumed that this 'political' controversy might be reduced if the decisions were taken on a purely 'scientific' basis.[36] This is not surprising, indeed, the Union itself was created to take certain decisions out of reach of national(ist) politicians and entrust them to experts. In line with this well-established tradition, the authorisations were effectively taken away from the political institutions and entrusted to a specialised supranational authority, as already discussed at length in the preceding section. This scientific underpinning was expected to bring about agreement at the political level. However, the established expert body – EFSA – failed to gain credibility and provide an 'objective' basis for broad agreement as had been hoped.[37] On the contrary - more than a decade since the adoption of the present rules, Member States are as divided as ever, with an overwhelming majority against cultivation of GMOs – in stark contrast with EFSA's opinions, which have been persistently favourable.[38] The biotech industry adamantly attributes this to 'politicisation' and 'public opposition to science'; however nothing can be further from the truth.[39] The view advanced by this report, and widely shared by environmentalists of all stripes, is that the problem is in the incomplete design of the risk analysis and the exclusion of contextual feedback in the assessment, as elaborated below.[40]

The root of the controversy is not the regime's reliance on scientific assessment, but in the narrow understanding of 'science' enshrined in the regulations and at the same time the overtaxing of this science with more than it can deliver. In the way science is defined by EFSA, most of the concerns of the citizens, and therefore of the Member States, are made irrelevant for the assessment of new GMO varieties. As Kritikos puts it:

> *the manifestations of the risks and benefits of genetic engineering acquire socioeconomic forms. These … include, inter alia, concerns about fairness, distribution of technological risks and benefits and consumer choice, the potential economic risks of the industrial capture of both biosafety research and biotechnology patenting, the potential dependence of local farmers on international GM-grain suppliers and industrial expertise, the effects of the commercial application of agricultural biotechnology*

> *upon organic dairying, the sustainability of rural economies and livelihoods, the preservation of traditional agronomic practices and the safeguarding of the existence of small farm units.*[41]

By leaving such concerns outside of the risk analysis, the current regime renders the analysis irrelevant for the respective citizens so it becomes impossible to gain credibility and legitimacy with regard to them.[42] In its GM Proposal the Commission goes as far as acknowledging the importance of the 'other factors' for the states opposing the technology and recognises the regime's failure to take them into consideration, yet insists on preserving it intact. This is puzzling: as 'guardian of the Treaties', the Commission is expected to seek ways to improve the credibility of the established Paneuropean regulatory regimes that it manages, rather than propose national opt-outs when they fail. In the view of the present author, in order to gain credibility, the GMO regime ought to broaden the scope of the relevant considerations. While in numerous other areas the EU makes every effort to reconnect to its citizens in order to overcome the existing democratic deficit, it is inexplicable why in this area the Commission remains committed to the exclusion of a number of the concerns of these citizens as inappropriate and 'political'.

Theoretically, 'non-scientific factors' are recognised as a legitimate basis for the decision on whether or not to authorise a new GMO variety for cultivation or marketing.[43] Thus, various stakeholders may be concerned about its socio-economic impacts, cost of co-existence imposed upon conventional farmers, and effect on national health and dietary policies, as well as about the preservation of existing farming practices and consumption patterns, preserving local skills and bottom-up innovation, environmental policy goals, agricultural policy, town and country planning, etc. These are compounded by concerns about the 'lock-in' effect of the adoption of any new technology. For example, as GMOs tend to breed resistance in pests and weeds – according to one estimate "superweeds" now infest 61 million acres (25 million ha) of US farmland[44] - so a 'safe' herbicide-resistant crop locks farmers, biotech industry and regulators in a cycle of competition between evolution and innovation.[45] The self-sustaining growth of demand for pesticides and herbicides which has thus been sparked is welcome for the industry but progressively increases the effect on the environment well beyond the initial estimates. Similarly, when a GMO becomes widespread in the food chain, it becomes increasingly difficult both for the industry and for the consumer to opt out of its use – for example it is already quite difficult, and increasingly more costly, to buy soybeans which are not genetically engineered anywhere outside of the EU. Thus, even if the availability of GMOs is often cast as increasing 'consumer choice', in the long run it risks actually reducing it.[46]

The importance of these factors for the legitimacy of any authorisation is now, at last, recognised by the Commission in its GM Review. However, it admits that it does not assess or take into account any of them. This clearly contravenes the existing legislation, namely Recital 32 of the Food and Feed Regulation, which stipulates that "scientific risk assessment alone cannot provide all the information … [and] other legitimate factors … must

be taken into account." In the same vein, its Art. 7 (1) requires the *Commission* to take into account the other legitimate factors along with the opinion of EFSA *when making its proposal to the committee* of national experts. Yet the Commission does not give a scintilla of an account of why it has not made any attempt to comply. This apparent abdication from its responsibility is even more puzzling when compared to its ambitious stance towards assessment of the impact of a great variety of effects of its proposals in all other areas. With the proposed amendment, the Commission seeks to absolve itself from the responsibility for any consideration of such impacts even at the risk management stage. The regime should be amended in the opposite direction – the Commission's responsibility as a risk manager ought to be restored, with the final decision being taken with regard to all relevant factors. A Paneuropean decision which defines what is 'safe' for health or the environment cannot be determined solely by the scientists themselves. Science, properly understood, cannot be equated with the opinion of a tiny group of experts, all specialised in a single narrow field and inevitably with a background in the industry they are called for to regulate.[47] Rather, science must *inform* the citizens of Europe, who should have the power to decide - via the established democratic processes at national and European level and on the basis of all factors *they* find relevant.

On the other hand, even "safety" issues cannot be adequately estimated without taking into account socio-economic considerations, notably the scale of the projected deliberate release of GMOs into the environment. As was pointed out by one dissent to the EFSA opinion on the safety of the Amflora potato, even very low probabilities of horizontal gene transfer should raise concerns when the number of incidents grows.[48] Yet the existing system is geared to take into account the number of cysts laboratory rats would develop, but not the number of potatoes being planted. As already mentioned in Part I, risk analysis does not take account of the extensiveness of the use of a technology, and EFSA does not have the capacity to consider the potential spread of the GMO cultivation or consumption. Nor can it even begin to consider potential systemic harm should resistance to certain antibiotic spread into the environment.[49] Note that the argument here is not that EFSA's opinion should have been negative – though in the version of precautionary principle suggested by Taleb and colleagues[50] it ought to have been so. The point of importance here is only that EFSA by design does not have the capacity even to begin to consider such issues, but that these questions are critical for the assessment. Yet as EFSA's opinion is the only one that counts as science under the current regime, they are bound to remain excluded.[51] Another problem of the current safety assessments is that safety is estimated with regard to the product being used "as prescribed by the label". Obviously, this does not take into account actual farming practices, nor the available capacity for control. To the extent that these practices deviate from the prescription, the assessment of safety will be inaccurate, sometimes significantly so. Environmental safety cannot be soundly assessed independent of farming practices, which in turn depend, especially in the longer run, on a wide variety of socio-economic, cultural and even psychological practices. Thus, besides being undemocratic, by exclusion of the "other" factors, the system becomes also *unscientific*.

Paradoxically, the inclusion of "non-scientific" factors does not make the system less scientific; on the contrary, it is a condition for the science to be sound. This is recognised in other areas and by other agencies; for example the European Environmental Agency stated that lay knowledge is complementary and sometimes has firmer grounding in real world operational conditions.[52] Thus, in the view of the present author, the Commission is able and should be required to give a clear mandate to EFSA to consider the safety of each GMO variety with regard to the projected use and anticipated changes in consumption patterns and farming practices.

Obviously, even if EFSA were mandated to take into account the other factors which are relevant for the safety assessment, it may not always be able adequately to do so because of the narrow expertise of the members of its specialist panels. Currently only four out of 15 members of EFSA's management board are supposed to have background in organisations representing consumer and other interests[53], which is far from optimal. There are no such requirements for the members of the GMO panel, which is dominated by microbiologists and genetic engineers, with only a minority of people with backgrounds in other sciences. This expertise must be diversified as proposed in Part III below. Yet it should be obvious that no amount of diversity of expertise can substitute for the voice of actual citizens. The tolerable level of risk can be properly estimated only via robust democratic participation of the stakeholders to which we shall turn shortly. Finally, both EFSA and the Commission should be clearly required when balancing all relevant factors *not* to give any preference to those which are measurable and quantifiable. The differently developed methodologies of the scientific disciplines is not a reason for differentiated treatment of their subject matter. The Commission's apparent preference for measurable and quantifiable forms of knowledge[54] may seem necessary in order to avoid appearance of arbitrariness, yet it has little basis even under the existing secondary law and should be ruled out explicitly.

The persistent failure of the current regime to account for the 'other factors' creates two further problems – dependency on the industry knowledge and redundancy of public consultations. First, given the "industry-driven character of biosafety research",[55] by making narrowly defined safety considerations pivotal for authorisation, the regime privileges the industry over all the other stakeholders. While the applicant is in possession of the data from all trials of the respective GMO variety, everybody else, including EFSA, is heavily dependent on his information.[56] All that those stakeholders wishing to contest the authorisation can do is to challenge the industry information, but such stakeholders are generally not in a position to possess data of their own. So they must fit their own arguments within the narrow framework established by the applicant. For example, the concern of farmers that the spread of a GM variety would increase their dependency on a certain herbicide[57] cannot be taken into account unless they can prove the precise amount of damage to the environment of this herbicide. *Their* dependency would be set aside as a non-scientific issue. If the authorisation regime is to be made legitimate, the concerns of each group of stakeholders should be considered

on its own terms, and farmers should not be required to reframe their concerns in the only terms that are currently acceptable – those of the industry. Thus, stakeholders should not merely be given opportunity to participate, but enabled to do so in a wider and open-ended discussion *on their own terms.*[58] As a general rule, independence is achieved by inclusion of all sides as co-equal, and by allowing everyone to argue on their own terms, rather than by exclusion of some claims as 'unscientific' or requiring some stakeholders to adopt the discourse of another.

The second related problem is that the narrow framing of the questions makes the public consultations – mandated by recital 10 and Art. 9 of the Deliberate Release Directive[59] and Art. 6(7) of the Food and Feed Regulation – all but meaningless. It is recognised that participation is especially important in cases where the level of uncertainty, complexity and/or ambiguity is higher, so that a greater variety of actors needs to be involved.[60] While the current approach to participation allows for a wide variety of participants at various points in the process – indeed anyone may submit an opinion via an online platform – the general public is invited to speak, but *cannot* be heard. To the extent that the Commission, by its own admission, is basing its decisions *exclusively* on the opinions of EFSA's GMO panel, which in turn views public comments incompatible with the "objective" character of the assessments,[61] the arguments are certain to be ruled out as irrelevant. Indeed, many studies of public participation confirm that the Commission's attempts to encourage public participation do not provide a way for representation of any groups outside of techno-scientific communities.[62] This redundant participation to the exclusion of the actual concerns of the stakeholders is what makes EFSA – and by implication the existing regime – "insensitive and far-*removed from reality*."[63]

While the rigour of the scientific method is most welcome in the area of risk regulation, its essence is reductionist: in order to estimate certain causal effect, the risk assessor reduces the immense variability of natural and social systems to a few variables which are easily mapped, modelled and measured.[64] As Chapman points out, the test conditions have to be controlled and standardised to enable replicability of the result; this makes the conclusions more rigorous scientifically, but less representative of the actual conditions prevailing where the substance will be used.[65] If the conclusions are to be valid outside the lab, account should also be taken of the circumstances in the real world, and the involvement of the stakeholders is a way to achieve this. Besides making the assessment more scientific, this would also generate trust in the decisions based upon it.

In the view of the present author, the proposed substantive engagement and inclusion of citizens' concern in the process of authorisations of GMO would not change fundamentally the nature of the current regime; indeed, the suggested amendments are needed to avoid the violations of the existing rules which persist in practice. The proposals in that regard, elaborated in detail in Part III below, would not make the regime less scientific. The opposite is true – they would make the scientific assessments more sound and closer to the real world. They would abolish, however, the *normative* authority which the current regime

accords to the statements of certain scientists and the opposition between 'science' and 'democracy' which this generates. Neither would the proposals undermine EFSA's independence. On the contrary: the current insulation undermines its independence as it renders it solely dependent on the expertise developed by the industry.

While the GMO regime, and risk regulation in general, must be democratised by increased participation and inclusive integration along the lines suggested in this and the preceding section, the following section addresses another problem of the existing regime and suggests a more direct way to provide for democratic control of the GMO authorisations.

3) Excessive supranationalism

Further to the violation of the non-delegation principle discussed earlier, the current GMO regime raises a related concern about the appropriate institutional balance. It is commonly accepted that the balance of powers between the main Union institutions reflects the balance between the Union itself and the Member States. By making the Commission the decision maker by default in the matter of GMO authorisation, the balance is shifted towards supranationalism, which in this case is uniquely unchecked by any of the other political authorities, in contravention to the established constitutional principles of the Union. The adoption of decisions by the Commission despite the clear position of the Member States against them also defies the existing consensual culture, whereby institutions follow an unwritten rule to abstain from decisions on sensitive matters until a compromise solution is found. Member States are usually portrayed by the biotech industry as 'stubborn',[66] but this criticism ignores the fact that the regime is *meant* to allow for the Member States to take into account the concerns of their citizens. In the view of the present author, the persistent opposition to authorisations is a symptom of the failure of the existing system to produce convincing evidence and to generate trust in its integrity. The purpose of the adopted mechanism of decision by committees of national experts – the comitology – is to mediate between the supranational and intergovernmental principles in the EU constitutional system. The comitology is celebrated as a successful model for consensus-building,[67] yet in this case, as was finally admitted by the Commission itself, it fails to do so, and the committees fail to reach any decision either way. This failure uniquely empowers the Commission to decide as it pleases.[68] The European Parliament is uniquely ignored – elsewhere, even if it is only consulted, its resolutions would be expected to carry some persuasive force. Instead, in the GM Review the Commission explicitly states that it is "unable" to take into account EP's opinion, as it feels bound to follow the assessments delivered by EFSA and nothing else. There are few other cases where the Commission is empowered to decide alone, without any form of control via comitology or opinions of the Parliament, and these are explicitly provided for by the legislation. The unique situation in the GMO area of empowerment by default requires exceptional measures for the constitutional balance to be urgently restored. As the root of this problem is the persistent stalemate in the committees, one obvious solution is for the required majority to be relaxed and the national representatives to be allowed to adopt decisions by simple

majority. The other way to restore political control is to provide for some measure of involvement by the European Parliament.[69] Specific proposals with that regard will be made in Part III below.

4) Precautionary principle rendered inoperative

We have already seen in Part I above that even though the GMO authorisation process is allegedly compliant with the precautionary principle (Recital 8 and Art. 1 & 4 of the Deliberative Release Directive), the latter is rendered inoperative. This amounts to a violation of Art. 191 (3) of the Treaty on Functioning of the European Union (TFEU) and of the requirement of Art. 3 (3) TEU to achieve a high level of protection of human health and the environment.

The precautionary principle is meant to correct classical risk analysis and *empower* the Union institutions to take action in cases where the analysis cannot deliver certain outcomes.[70] However, the Communication on the Precautionary Principle[71] adopted an interpretation that incorporates the principle *within* the risk analysis and the Union judicature, notably in the *Pfizer* case, read this interpretation into the law. This brought in "the largely discredited reliance on the expert-centric probabilistic techniques for regulation of new and controversial technologies though the back door."[72] In the view of the present author, this would be compatible with the Treaty objective of a high level of protection if, in the established system of strict division between risk assessment and risk management, the principle is applied in both phases. As elaborated already in Part I, in the current regime of firm separation between risk assessment and risk management, precaution is confined to risk management only, apparently to preserve the alleged scientific objectivity of risk assessment. Paradoxically, even though precautionary *action* is taken out of the hands of experts, their role as assessors gives them "the gate-keeping function to trigger precaution."[73] Indeed, the precautionary principle is hardly ever mentioned in the authorisation dossiers. One is justified in wondering where the difference is between ordinary risk analysis, which does not claim to be precautionary, and the existing system, which does.[74] **As the cited provisions of the Treaties make the precautionary principle *a matter of law*, the GMO regime, which renders the principle redundant on a permanent basis, stands in violation of the primary law.[75]**

Notwithstanding the advisability of the more radical alternatives advocated by Taleb and colleagues and by Chapman mentioned earlier, the precautionary principle may easily be made operational once again within the current system. As Quist and colleagues explain:

> *precaution has a role to play in the scientific risk assessment itself in two fundamental ways. First, applying precaution within risk assessment practice also means applying more robust scientific standards — that is, the need for precaution and the need for scientific rigor are not incompatible but complementary. Second, particularly when testing hypotheses, value judgements within science practice may be informed by precaution, including levels of evidence, directions of error, and by*

> *acknowledging and communicating what we know, do not know, and cannot know with existing methodologies. The formal acknowledgment of uncertainties and the choice of error type from the risk assessment and their communication to decision-makers are key components of rigorous science-based risk assessment.*[76]

To restore the role of the precautionary principle – in GMO regulation and elsewhere – by extending its application to the risk assessment stage, it must be recognised that it is possible for the same scientific data about the likelihood of certain risk to be interpreted differently. The reclassification of Roundup™ as possibly carcinogenic for humans by an agency of the World Health Organisation (WHO) *on the basis of the same data* used by the US Environment Protection Agency (EPA) to authorise it is just the most recent example.[77] An earlier instance, which raised a major controversy in the course of the authorisation of the Amflora potato, was of two antibiotics considered to be unimportant by EFSA but important by the WHO and the European Medicines Agency.[78] It must be formally acknowledged that such differences are legitimate and are *not* a matter of temporary shortage of information. Further to this, it must be recognised by law that the same probability estimate, even if accurately and precisely established, may be seen as low by some Member States or Union bodies and high by other Member State or Union bodies. EFSA's role should be limited to emphasising the relationships and highlighting the trade-offs, but it must be made explicit that the final *judgement* does not belong to it. As the interpretation of the existing data is a matter of choice this choice must be explicitly guided by the precautionary principle.

This may be difficult under the existing regime, notably the *Communication on the precautionary principle* and the jurisprudence of the Union courts, but nothing in the Treaties prevents an amendment of the secondary law in that sense. Advocate General Sharpston has tried to impress upon the Court of Justice that "new conclusions drawn from existing data may constitute new scientific evidence within the meaning of Art. [114(5)] of the Treaty."[79] The Court did not follow her opinion, and adopted stricter requirements for "newness" of the evidence. If this is the correct understanding of the applicable secondary law, then it must be urgently amended to restore the functionality of the precautionary principle so that the Treaty objective of a high level of protection is not jeopardised any further.

Having exposed the major legal problems which the existing regime creates, in the next part this report will make several specific proposals for amending the legislation currently in force, which if adopted can alleviate these problems.

III. Proposals for changes in the secondary legislation

As elaborated in the previous part of the report, under the current GMO authorisation regime the Commission is obliged, according to its own understanding of the case law, to defer to the conclusions of EFSA. It declines the responsibility to weigh controversial evidence itself and uncritically accepts the weighing done by its advisor. It also refuses to take into consideration the other relevant factors, in violation of the regulations in force. To remedy this situation, which as established above is both undemocratic and illegal, a series of amendments to the existing rules will be considered. They are intended (1) to restore the responsibility of the Commission to take a decision based on its own judgement of the contested evidence, rather than rubber-stamping the received advice; (2) to strengthen the Commission's responsibility, whenever the contingencies of the authorisation procedure place it in a position to decide, to ensure that other factors are taken into account as required by the Food and Feed Regulation; and (3) to restore the functionality of the committees of national experts in the authorisation process. It should be borne in mind that in this extremely sensitive area the national experts sitting on these committees are invariably acting upon clear instructions from their ministers, which are supposed to be responsive to the concerns of the citizens. The decision-making mechanism thus established, if it were functioning as intended, would enjoy a much higher degree of legitimacy than the Commission when acting by default., It is therefore essential that the current situation whereby the committee level cannot ever reach a decision either way be remedied. In addition, or as an alternative, the possibility for (4) strengthening of the role of the European Parliament should be considered. Currently the EP has no part in the GMO authorisation process and in comitology in general, but the old regulatory procedure with scrutiny under Council Decision 1999/468 (now repealed) could be a workable model, for the GMO area at least. Further, (5) amendments strengthening the role of the precautionary principle should be considered, as in practice it is rendered inoperative. Finally, it is suggested (6) to diversify the expertise employed by EFSA and (7) to enhance the rules for participation of other interested parties, which would have the additional advantage of reducing the currently disproportionate influence of the industry on the process.

1) Restoring the responsibility of the Commission

a) Margin of discretion

The following recital should be added to the Food and Feed Regulation:

> *Whereas the decision for authorisation of new GMO varieties must be informed by the scientific risk assessment conducted by EFSA, it is nevertheless recognised that any such assessment inevitably involves a degree of judgement; and while the Commission is bound to take into account the opinion of EFSA, it is by no means bound to accept it. On the contrary, it is responsible for making a reasoned and*

informed decision, on the basis of its own weighting of all information which is made available to it and in compliance with the precautionary principle.

The purpose of this amendment would be to acknowledge that all stages of the risk analysis, including risk assessment, involve a certain measure of discretion and it is incumbent upon the Commission to make the final judgement, which must be informed by the opinion of the scientific advisor, but should not be prejudiced by it. In the view of the present author, the proposed recital is just stating the obvious and is in full conformity with the legislation already in force. Yet, it calls for a radical departure from the way the Commission currently understands its function, unquestioned in its GM Review: that its discretion is limited and that it is obliged to follow the received advice.

b) Recognition of uncertainty

The following paragraph should be added at the end of Annex II of the Deliberate Release Directive:

E. Without prejudice to the employment of the most comprehensive and rigorous scientific methodology for assessment of the effects as required by the preceding paragraphs, it is recognised that all conclusions about the likelihood of adverse effects involve a great measure of judgement. Since the accurate measurement even of known adverse effects is often impossible, it is therefore recognised that all such judgements are made on the balance of evidence and different authorities may legitimately disagree in their weighting of the same evidence.

It is further acknowledged that the effect of novel technologies when introduced in complex systems is inherently uncertain, and the lack of evidence for certain effect cannot be taken as evidence for lack of effect.

The purpose of this amendment is the same as that of the amendment detailed in 1) above, with regard to the environmental risk assessment (ERA). It would allow the Commission to take a different view from EFSA, and also to national authorities to remain in disagreement with both EFSA and the Commission. If it is acknowledged that assessment is a matter of balancing, it would become all too obvious that the judgement belongs to the Commission, or the other accountable authorities as per the proposals below.

For the sake of greater visibility, this paragraph could also be added as a new recital in the preamble to the Deliberative Release Directive.

c) Cyclical risk analysis[80]

The following paragraph should be added to the recitals of the General Food Law[81]:

It is recognised that a universally applicable estimate of the risks associated with a new technology is rarely possible, as the magnitude of the potential risk inevitably depends on the scale and the context of its use. Therefore the assessment of risk cannot be completely separated from its

> *management, but all expected effects of the possible adoption of the technology, with or without any risk management measures, must be taken into account in the assessment.*

Also Art. 5 of the Food and Feed Regulation should be supplemented with the following paragraph:

> *The Commission, having first consulted the national authorities, and after a period of public consultation, shall provide the EFSA with detailed terms of reference, which include a broad range of contextual factors and plausible scenarios with regard to which the application must be assessed.*

The purpose of this amendment is to require risk assessment to be informed by "other", especially socio-economic, factors, like the projected scale of use of the technology, farming practices and consumption patterns, and **also by the change of these patterns and practices which the technology itself may be expected to bring about.** An important implication is that when EFSA is required to assess the safety of a new GMO variety, it should not itself be free to determine the scope of its assessment and the factors which it will consider, but must be given specific terms of reference in which the Commission, or any of the national authorities, may include various public concerns. These should not be considered unscientific; contextual factors are taken into account by any good scientific research, and risk assessments should not be an exception. For example, EFSA should not be able to conclude that the probability of a GMO food conferring antibiotic resistance to gut bacteria is "small" in the abstract, but must consider its magnitude *with regard to the amount consumed*, and also with regard to the likely changes in the consumption patterns the authorisation may bring about.

To be able to conduct such an assessment, EFSA would have to be provided with a broader range of expertise, and notably must include social scientists in its panels as suggested below.

2) Consideration of all relevant factors

Recital 32 of the Food and Feed Regulation should be strengthened as follows:

> *It is recognised that scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors must be taken into account.*
>
> *Whereas a democratic society should be able to select the technologies that are going to be developed, adopted or abandoned, it is recognised that the safety of a new technology, even if undisputed, cannot be a conclusive reason for its adoption, but must be weighted together with the other values protected by the Treaties.*

This change of a recital amounts to a substantial departure from the existing regime of distorted science-based regulation, where experts alone are able to impose new technologies on societies, on the sole ground that they are considered (by the experts) as safe.

Yet it still fits within the overall framework of the existing regime, which currently allows that other legitimate factors may be considered. By the Commission's own admission it currently fails to do so. As a result the text needs to be strengthened. The suggested version would allow Member States to seek annulment of a decision that has not considered any other factors at all, though the Commission would still enjoy wide discretion in the balancing of these factors.

Recital 32, amended as suggested, should be followed by a new one stating the following:

> *Whereas some legitimate considerations, which are not easily measured, are not given less weight than those which can be estimated precisely and where the unavailability or the impossibility of accurate estimation cannot be taken as evidence for lack of effect.*

A new recital should be added both to the Deliberative Release Directive and the Food and Feed Regulation confirming the following:

> *It is recognised that the Commission has developed an immense capacity to assess the effects of its policy proposals in all areas of economy, society and the environment, and is therefore in a position to take into account a wide variety of other legitimate factors when reaching its decision as to whether or not to authorise the cultivation or marketing of new GMO varieties without acting arbitrarily. It is further recognised that since such capacity is also being developed by the European Parliament, the latter body will be able to hold the Commission to account in that regard, or make an informed decision of its own, whenever it is given a voice in the authorisation process (as proposed below).*

The effect of this amendment would be twofold. On the one hand, it is a necessary follow-up to the amended recital 32, which recognises that because the Commission routinely assesses other factors, its abdication of responsibility to consider them in the case of GMO authorisation is unjustified. On the other hand, it emphasises that the consideration of such factors will *not* render the decisions arbitrary. On the contrary, this would make the authorisation process more accountable.
To ensure that these strengthened requirements are not ignored, as they currently are, Art 4 (3) of the Food and Feed Regulation should be amended as follows:

> *No GMO for food use or food referred to in Art 3(1) shall be authorised unless the relevant authority has satisfied itself that such authorisation is supported with adequate and sufficient evidence that the requirements of paragraph 1 of this Article are met as well as other legitimate factors and concerns as per the (amended) recital 32 and subsequent.*

An analogous amendment should be added to Art. 16 with regard to the GMO feed authorisations.

The effect of this amendment also would be twofold. It changes the focus from the applicant, who is currently responsible for demonstrating safety,

to the public authorities – EFSA, the committees and the Commission in turn – who have to be convinced by that demonstration. In addition, the relevant authorities are reminded that they can move the authorisation forward only if they are satisfied with regard to the full range of legitimate factors.

3) Restoring the functionality of the committees of national experts

Two alternative ways to overcome the persistent deadlock within the committee stage of the authorisation process can be considered.

a) Simple majority in the Scientific Committee/Appeal Committee

Art 35 (2) of the Food and Feed Regulation and Art 30 (2) of the Deliberate Release Directive could be amended in the sense that the committees (in this area) take decisions by simple majority of the Member States:

> *Where reference is made to this paragraph, by way of exception from Regulation 182/2011, the Committee shall adopt its decision by a simple majority of its component members.*

While we recognise that voting by simple majority is rather exceptional in the Council or the committees of national representatives which normally mirror it (yet it is the rule under the Advisory procedure, Art. 4 of *Regulation 182/2011*), in the view of the present author this is an adequate response to the persistent stalemate of committees over the past two decades. It should also be noted that the present system in effect requires a decision by qualified majority vote (QMV) for a GMO application *to be rejected*. This "reverse QMV" is even more exceptional and allows a minority of Member States in effect to force a new GMO upon the rest. On the other hand, this proposal is in line with the Commission's own stated objective that "rules should be changed to ensure that the majority view of Member States is taken into account."[82]

b) Commission obliged to respect the predominant view of the Member States

The following recital can be included in the Deliberative Release Directive and the Food and Feed Regulation:

> *Without prejudice to the Commission being fully responsible for the adoption and content of any decision to authorise cultivation or marketing of a GMO, it shall take due account of the position of the Member States (and possibly the European Parliament) as expressed in the relevant committee.*

A stronger form of this would be:

> *Without prejudice to its responsibility for the adoption and content of any decision to authorise cultivation or marketing of a GMO, the Commission should abstain from any authorisation whenever a majority of Member States remain unconvinced by the risk assessment and express their objection to the decision which*

> *is proposed on the basis thereof.*

Both formulations are a weaker version of the previous proposal (a), as they preserve the present reverse QMV in the committees, yet they require the Commission to follow the predominant position of the states rather than the position of EFSA. The Commission is already required to take into account the predominant position of the appeal committee by recital 14 of Regulation 182/2011. This text can be strengthened by adding an explicit statement to it that

> *The failure of the committee to take a decision by qualified majority vote cannot be considered as indicating that no predominant position of the Member States is available.*

The words 'as far as possible' should be *removed* from recital 14.

To confine this to the GMO area, this provision can be added to the Deliberative Release Directive and the Food and Feed Regulation instead of Regulation 182/2011 itself.

4) Involving the European Parliament

Another way to restore the democratic control in the process is to involve the EP, the only legitimate representative of the citizens of the Union. Again, this is possible in two forms. The first is express involvement, as in the old regulatory procedure with scrutiny where, upon failure to reach any decision in the committees, the proposal laid before the EP is accepted unless voted down within four months. Art. 5a of Decision 1999/468 (now repealed) provides a workable model for this procedure. It can be introduced as a new Art 35a in the Food and Feed Regulation and Art 30a in the Deliberate Release Directive to apply respectively.

A weaker alternative is for a recital to be added to the Food and Feed Regulation and the Deliberate Release Directive, committing the Commission to take into account any relevant resolutions of the EP as follows:

> *Without prejudice to its responsibility for the adoption and content of any decision on cultivation or marketing of a GMO, the Commission should abstain from authorisations whenever the European Parliament remains unconvinced by the risk assessment and adopts a resolution objecting to the decision which is proposed on the basis thereof.*

This amendment is meant to oblige the Commission, whenever a resolution is passed (as in the case of Maize Pioneer 1507), to decide against the authorisation.

5) Restoring the functionality of the precautionary principle in risk analysis

As discussed in the analysis of the current legislation, despite the clear commitment to the precautionary principle (Recital 8 of the Deliberate Release Directive), the current understanding of the Commission is that it applies only in the phase of risk management. As EFSA is not required to apply it at all, whenever its

assessments conclude, for lack of sufficient evidence to the contrary, that a GMO is 'safe' the risk manager is precluded from applying it. Thus, the principle is made redundant in all stages. In order to make it operative, it is essential to extend its application to risk assessment and emphasise that its aim is to empower, rather than constrain, the risk manager.

Recital 8 of the Deliberative Release Directive, should be amended as follows:

> *The precautionary principle has been taken into account in the drafting of this Directive and must be complied with when implementing it; it must be applied at all stages of risk analysis.*
>
> *Further, it should be recognised that lack of agreement on the risk assessment, and in particular, failure of the relevant committee to reach any decision, indicates that there is no certainty about the safety of the GMO being assessed. This, by itself, is sufficient to justify precautionary measures, if the risk managers – the Commission, and where applicable the committees (or the European Parliament) – choose to adopt such in response to citizens' legitimate concerns.*

The second paragraph is not intended to introduce a requirement for "zero risk" but to assert that the stalemate itself *may* constitute a ground for precautionary action.

6) Strengthening the independence of EFSA and diversification of its expertise

The following recital should be added to the Food and Feed Regulation:

> *It is incumbent upon EFSA to generate public confidence in its assessments; it is recognised that the failures of the relevant committees to adopt a decision either way is evidence that the completeness or the rigour of its assessment are contested, and the conclusion remains insufficiently convincing.*

This amendment would underline the responsibility of EFSA to persuade the public and gain trust in its assessments, and undermine the claims of the Commission that the job is done and the problem is one of "public misunderstanding of science".

The following recital should be added to the Deliberative Release Directive:

> *The Commission and its advisory bodies shall conduct independent assessments wherever possible and in any event shall aim to reduce their reliance on information provided by the applicant.*

Further, Art. 4 (2) of the Directive should be supplemented as follows:

> *The environmental risk assessment will be submitted to the European Environmental Agency for peer review.*

The purpose of the amendment is to increase the informational independence of EFSA. While it is unfeasible to require that all necessary

information is gathered by the Union agencies, they may be held to account politically and also judicially, to strive in that direction.

The following text should be added to Art. 28(4) of the General Food Law:

> *The scientific panel on GMO shall consist of members from various scientific disciplines, including from the social sciences, with a view to ensure balanced representation of all expertise which may be relevant for a comprehensive risk assessment.*

This amendment is necessary to enable EFSA to consider the safety of GMOs with regard to the relevant contextual factors as per the amendments suggested above. It is along the lines of the recent proposal by the European Ombudsman for the Commission's expert groups in general.[83] Currently an overwhelming number of the panel members are microbiologists and genetic engineers. Even if they were, as individuals, completely independent from the industry, their narrow specialisms assure that they share similar views. It is essential to ensure adequate representation of experts from other relevant fields such as ecologists and agronomists, and to allow adequate consideration of contextual factors including feedback from social scientists on the risk management measures.

7) Enhancing public participation

The following text should be added after paragraph 7 of Art. 6 of the Food and Feed Regulation:

> *The Authority shall take due account of the opinions gathered. It shall prepare a summary of the concerns raised by the participants and take care to address them in its assessment. It shall forward them to the Commission, which may revise the terms of reference given to EFSA. The Commission shall take any such concerns into account in its own decisions with regard to the authorisation.*

Analogous text should be added after paragraph 1 of Art 9 of the Deliberate Release Directive:

> *The opinions gathered shall be forwarded to the Commission, which shall take any such concerns into account in its own decisions with regard to the authorisation. Where appropriate, it may refer the issue to the relevant advisory bodies or revise the terms of reference given to any such body which has already been involved in the process.*

Current legislation provides an opportunity for public participation but fails to make even a token requirement that the opinions submitted via this channel will be taken into account in *any* way. The suggested amendment would make a commitment that the information gathered is fed into the assessment and used for identification of other factors which may be relevant.

Art. 36 of the Food and Feed Regulation should be amended as follows:

> *Any decision taken under, or failure to exercise, the powers vested in the Authority by this*

regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person or non-governmental organisation, provided that

(a) it is an independent non-profit-making legal person in accordance with a Member State's national law or practice;

(b) it has the primary stated objective of promoting environmental protection in the context of environmental law;

(c) it has existed for more than two years and is actively pursuing the objective referred to under (b);

(d) the subject matter in respect of which the request for internal review is made is covered by its objective and activities.

The purpose of this amendment is to extend the application of the Aarhus Convention to GMO authorisations. The conditions mirror those in Regulation 1367/2006 and would allow established environmental organisations which were ignored in the consultation pursuant to Art. 6 (7) to raise their concerns with the Commission.

In summary, most of the suggested proposals are intended to make explicit the political nature of GMO authorisations and emphasise the discretion and the associated responsibility of the Commission. Notwithstanding this, the proposals do not call for a fundamental change, such as giving a central role to the Council or the European Parliament, or adopting the more radical approaches to risk and precaution suggested by Chapman and Taleb and colleagues. Rather, the proposals would change the existing system so that the Commission is no longer able to hide behind its advisors and can be held accountable through the existing political channels.

IV. The Commission's amendment proposal

The most important elements of the Commission's own GM Review and GM Proposal have already been mentioned in the preceding parts. This part will only highlight how the Commission's conclusions confirm the claims made in Part II. For reasons of space it will skip a number of fallacies in the Commission's analysis of the existing legislation and case law, and will demonstrate that the proposal, if adopted, would set the Member States on a collision course with the provisions of the EU Treaties and possibly their WTO obligations.

1) Welcome recognition of the flaws of the GM regime

In its GM Review and Proposal the Commission officially admits that control over the authorisation process through committees of national experts is dysfunctional with the effect that the decision-making layer needed to confer legitimacy to the decisions is short-circuited. The second equally troubling admission is that it always defers to the opinions of EFSA. Its interpretation of the law, and especially of the Charter of Fundamental Rights and the jurisprudence of the Union courts, is that it is obliged to do so. While this is arguable and not supported in the academic literature, the Commission itself strictly follows this interpretation; making this explicit is also welcome. In Part II it was demonstrated that this deference to the advisor *taken together* with the lack of functioning control amounts to unlawful delegation and renders the authorisation process illegal. Further to the purely legal argument, it is obvious that it is illegitimate for an obscure advisory body with no democratic underpinning to be in a position to decide sensitive questions on behalf of 500 million citizens, disregarding the expressed position of their lawfully elected representatives. Notwithstanding this, the Commission does not even attempt to find a remedy but only offers an opportunity to the Member States to walk out. This is startling – if it was following the same logic in other areas, the internal market would have collapsed before it was established. Still, as a most extraordinary exception this opt-out policy could be a partial solution – of the illegitimacy if not of the illegality problem – if it were legally or materially possible. The third section of this part will return to the latter issues to show that it is not.

The other welcome recognition in the GM Review is that 'other legitimate factors' are routinely not taken into account, despite the explicit requirements to the contrary of the Food and Feed Regulation and the Deliberative Release Directive. Essentially, the Commission identifies two problems which have led to the current controversy and impasse – the need for decisions to be reasoned and the need to consider all relevant factors. It correctly notes that Art. 41 of the Charter of Fundamental Rights requires that the administration gives reasons for its decisions, including those for authorisation of GMOs. However, nothing in the Charter, or elsewhere in the primary law, requires these reasons to be limited to those prompted by the EFSA opinion. On the contrary (as was shown in Part II, section 2), the secondary law explicitly calls upon the administration – and the Commission in particular – to take

other reasons into account. The obligations to justify its decisions and to take other factors into account are, in fact, complementary. If the Commission fails to respect both of them – as it recognises it does – it is necessary for the regime to be amended and the administration enabled to do so, rather than provide a margin of flexibility which we shall see that the Member States would have to struggle to make use of. If it is difficult for the Commission to justify a rejection of a GMO, how can the Member States be expected to do so when they will have the extra trouble of the apparent violation of Art. 34 TFEU?
To sum up, the present author agrees with the Commission that "it is important to maintain a single risk-management system, based on independent risk assessment". All that is needed is to make it really independent and adequate to the actual concerns that are being raised about GMOs.

2) Proposed opt-outs

The operative part of the GM Proposal consists of a single article which would allow the Member States to restrict or prohibit the *use* of authorised GMOs for food and feed on their territories. Pursuant to the first paragraph of the proposed Art. 34a, a Member State which chose to do so would be still bound by the centralised risk assessments it is unconvinced by, and which is the result of a process which is now admitted to be flawed.

Before embarking on the analysis of the legal problems of that proposal it is worth being reminded that during the decade since the current regime was set in place, a number of Member States, hostile to GMOs, have introduced bans on cultivation but never a ban on their use. The obvious reason is that in an integrated market such bans cannot be enforced in practice, even if they were legal. Thus, the only remedy of the flawed regime that the Commission has proposed cannot be expected to work in practice. There is no need to list the obvious difficulties for a Member State if it were to restrict on its territory the use of a particular GMO variety that has been authorised in the single market, and especially the costs of enforcing such ban. The legality of the proposed ban has already been questioned in a number of academic publications[84] so this report will briefly list only three problems which are related to the debate about the role of the 'other factors' in the risk analysis initiated above. The first one is the grounds on which such restrictive measures would be allowed by the amended Food and Feed Regulation. Secondly, even if a prohibition of the use of an authorised GMO is explicitly allowed by the secondary legislation, it would almost certainly run foul of the primary law of the EU. Finally, even if it can be made compatible with the free movement rules of the EU, it still runs the risk of violating the WTO rules. The following subsections will discuss these issues in turn.

a) Vanishing grounds for restrictive measures

In its current form, the GM Proposal makes it all but impossible to justify the restrictive measures that it seeks to allow. According to its Recital 7, they must be adopted on the basis of compelling grounds not related to human and animal health and the environment. According to Art. 34a (1)(a) and Recital 10, for all issues related to these areas, the Member

States would remain bound by the centralised risk assessment. Thus, the statements contained in EFSA's opinions will pre-empt any conclusions of the national authorities to the contrary. This renders unacceptable as justification almost all of the concerns a Member State may have – indeed, few issues do not have implications for human or animal health or the environment in any way. For example, the anticipated adverse effects on consumption patterns or farming practices that a Member State may be worried about would not be valid grounds for restriction as they would be "related" to health and the environment accordingly. On the other hand, EFSA will continue to discount such factors as being outside of *its* remit. **Thus, such concerns will remain unaccounted for at any level; instead of allowing the Member States to attend to such concerns, the GM proposal, if adopted, will officially entrench their exclusion.** As argued throughout this report the factors relevant for the safety of a new technology are interrelated so if some of them are reserved for the Union administration to consider, and others are the domain of the states, neither will be able to carry out an adequate risk analysis. Further to this, any national measure which survives the Scylla of justification will have to face the Charybdis of proportionality and non-discrimination review (Recital 8).

b) Incompatibility with the primary EU law

As the Commission itself notes, any measures adopted by the Member States pursuant to its GM Proposal will have to be reasoned, proportionate and indistinctly applicable. Even if the secondary legislation explicitly empowers the Member States to introduce them, they may be still found by the Union courts to constitute obstacles to trade, prohibited by Art. 34 TFEU (free movement of goods). It should be noted that even though Art. 36 allows a number of exceptions, and the Court has expanded the list of permissible grounds considerably, some of the legitimate concerns of the Member States, such as the protection of conventional or organic farming, are clearly *not* among the permissible exceptions. In the light of well-known cases of the Court of Justice,[85] it is clear that the Court will subject any such measures – by definition antithetical to the single market – to very rigorous scrutiny. The need to adopt bans on a case-by-case basis compounds the difficulties further. As the Court is likely to review rigorously a broad spectrum of national policies to find inherently contradictory justifications[86] it would be difficult for a Member State to convince it that the grounds invoked to prohibit the marketing of one GMO variety are genuine, if it has not already prohibited all other GMOs on the same grounds. On the other hand, it may have failed to prohibit the other GMOs simply because the government did not have the resources to defend a challenge of the prohibition.

Anticipating such difficulties, Member States which have concerns about the GMO in question are likely to abstain from introducing restrictions and will continue to oppose the proposals for authorisation as intensely as they do now. Thus the opt-outs will fail to resolve the problems which the Commission identifies and will certainly fail to address the concerns of the Member States and of the citizens of Europe. In the view of the present author, the only palpable effect if such opt-outs are allowed would be to enable the Commission to exert

pressure on certain Member States to reduce their opposition to authorisations *ex ante*, with the vain promise that they will be able to limit the damage done thereafter. Thus, the proposed opt-out will at best be redundant and at worst will render the GM regime even more undemocratic.

c) Incompatibility with the WTO rules

Finally, the GM Proposal sets the Member States who wish to make use of the proposed opt-out on a collision course with their WTO obligations. As they are not allowed to use any health and environment related grounds anyway, the compliance with the Agreements on the Technical Barriers to Trade (TBT) and on the Application of Sanitary and Phytosanitary Measures (SPS) is unlikely to become an issue. However, it is quite likely that such measures will be found to be in violation of Art. III para 4 of the GATT Agreement, which stipulates "products … shall be accorded treatment no less favourable than that accorded to *like products* of national origin in respect of all laws…" (emphasis added). Thus, the question arises whether the WTO dispute settlement panels will find, say, a GMO maize which is prohibited in compliance with the proposed Art. 34a of the Food and Feed Regulation, to be sufficiently like a non-GMO maize which is not prohibited. While most European citizens – even those who have no qualms about the technology – find GM varieties profoundly different from conventional crops, the WTO panels may think the opposite.
As far as the law is concerned, for the time being the question of similarity has not been decided definitively. The GMO technology was an issue in *EC-Biotech*[87] but the Dispute Settlement Panel left open the matter of likeness of GMO and their conventional counterparts. However, in *EC-Asbestos,*[88] the Appellate Body identified the following criteria for likeness: (i) the properties, nature and quality of the products; (ii) the end-uses of the products; (iii) consumers' tastes and habits — more comprehensively termed consumers' perceptions and behaviour — in respect of the products; and (iv) the tariff classification of the products. On this understanding, even if the widespread consumption of GMOs has demonstrably different effects along the whole food chain – on farming practices, pesticide use, bio-diversity and social structures – all of these will have to be discounted. All that would matter is whether the consumers perceive the end product to be just like the conventional one.[89] In any event, Member States wishing to make use of the proposed opt-out will be forced into an uphill battle to prove the opposite. Their efforts will be further undermined by the fact of authorisation itself and also by EFSA, which opines, inter alia, *on the similarity with conventional counterparts*, essentially disregarding the factors which make them different. The fact that other Member States have not banned the same GMO will not help either, even if they have refrained from doing so only because they did not have the nerve to pursue such battles themselves. Thus, in all likelihood, the restrictive measures adopted in pursuance of the GM proposal will be found in violation of Art. III (4) GATT Agreement.

To summarise: in its GM Review, the Commission admits that the risk management system is broken – as is, in our view, also the risk assessment – yet instead of proposing a way to fix the problem, it proposes to keep the system intact and only provides to

those who care a largely ineffective possibility of opting out of it. In the view of the present author, the GM Proposal, if ever adopted, would neither improve the existing centralised authorisation regime, nor provide an effective and legally sound way out of it. Instead of making the process more democratic and risk assessments more adequate to the real world, the Commission proposes an avenue of fragmentation of the single market without clear benefits to anyone. All in all, it acknowledges that the current regime is flawed, but fails to notice most of the problems identified in Part II of this report; does not propose any measure to fix them as suggested in Part III; and proposes a route out of the single market which is not viable, as demonstrated in Part IV.

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Endnotes

[1] Communication from the Commission Reviewing the decision-making process on GMOs, COM (2015) 176 final, from 22.4.2015.
[2] Proposal for a 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.
[4] *Euractiv,* 'EU proposal on GMO food criticised by Greenpeace, industry', 22 April 2015.
[5] *European Parliament (press release),* 'Parliament rejects national GMO bans proposal', 28 October 2015.
[6] See the full story in Vesco Paskalev, 'Can Science Tame Politics: The Collapse of the New GMO Regime in the EU' (2012) 3 (2) European Journal of Risk Regulation 190–201.
[7] T-240/10 *Hungary v. Commission* [2013].
[8] For a recent review of the literature see Hilbeck, A et al, 'There Is No Scientific Consensus on GMO Safety' 27 (4) Environmental Sciences Europe and a summary in *The Ecologist* from 23 February 2015. It is worth noting that Kvakkestad and colleagues find a strong correlation between experts' disciplinary background and their position, with microbiologists usually in favour and ecologists sceptical: see Valborg Kvakkestad et al, 'Scientists' Perspectives on the Deliberate Release of GM Crops' (2007) 16 Environmental Values 79.
[9] 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." This is in line with the philosophy of food regulation in Europe, where the "risk management must be left to an institutional framework with full political accountability", see White Paper on Food Safety, COM/99/0719 final.
[10] For a good account of the pressures behind the Commission's approach, see François Randour, Cédric Janssens and Tom Delreux, 'The Cultivation of Genetically Modified Organisms in the European Union: A Necessary Trade-Off?' (2014) 52 Journal of Common Market Studies 1307. While Randour and colleagues identify the constraints on the Commission, they seem to take for granted the legality of the existing regime, which is questioned in this report.
[11] These culminated in the resignation of the head of EFSA in 2012, see Declan Butler, 'EU agencies accused of conflicts of interest' in *Nature* 495 (17 May 2012), 282.
[12] The regime was established in the early 2000s by two legislative acts - *Directive 2001/18/EC on the deliberate release into the environment of GMOs*, hereinafter Deliberate Release Directive and *Regulation (EC) 1829/2003 on GM Food and Feed*, hereinafter 'Food and Feed Regulation.'
[13] 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'.
[14] Under the old comitology rules, the committee could raise the issue to the Council (which routinely failed to reach any decision too) but now stalemates are referred to an Appeal committee, which also consists of national experts. Hereafter 'committees' refers to any of the comitology committees that may become relevant.
[15] For example in 2008, of 2185 proposals subject to comitology only 7 failed to gain support, see Renaud Dehousse, A Fernández Pasarín and J Plaza, 'How Consensual Is Comitology' (2014) 21 Journal of European Public Policy 842.
[16] EFSA's de facto authority has been recognised and criticised before, see for example Christoph Klika, Jinhee Kim and Esther Versluis, 'Why Science Cannot Tame Politics: The New EU Comitology Rules and the Centralised Authorisation Procedure of GMOs' (2013) 3 European Journal of Risk Regulation 327.
[17] See Anne Chapman, 'Regulating Chemicals - from Risks to Riskiness' (2006) 26 Risk Analysis 603, 605.
[18] Chapman suggests an alternative approach to estimate 'riskiness', which is more adequate to novel technologies where by definition we cannot have sufficient data to make an adequate risk analysis even for the known effects, let alone know the impacts which are possible but still unknown. Most importantly, this would include assessment also of the benefits of the technology. See ibid.
[19] GMOs are a prime example of the latter – not only because they may propagate themselves globally, but also as Read notes, they *create* man-made dependencies on a global scale which did not exist before. See Rupert Read, 'How to End Our Love Affair with Evidence', The Philosopher's Magazine Online, 1 July 2015, available at http://www.philosophersmag.com/index.php/reflections/49-how-to-end-our-love-affair-with-evidence.
[20] See Nassim Nicholas Taleb et al, 'The Precautionary Principle (with Application to the Genetic Modification of Organisms)' (NYU School of Engineering Working Paper Series, 2014). Taleb and

colleagues argue that only ordinary risks – where probabilities are well-defined and gains and losses are bounded – can be 'managed'; in any case of non-zero probability of catastrophe precautionary action *must* be taken. Notwithstanding this, this report sticks to the orthodox approach where the precautionary principle is part of risk analysis, not an alternative to it.

[21] David A Quist et al, 'Hungry for Innovation: Pathways from GM Crops to Agroecology' in EEA (ed), *Late Lessons from Early Warnings: Science, Precaution, Innovation* (2nd edn, 2013).

[22] 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).

[23] Marjolein BA van Asselt and Ellen Vos, 'Wrestling with Uncertain Risks: EU Regulation of GMOs and the Uncertainty Paradox' (2010) 11 Journal of Risk Research 281. As Quist and colleagues aptly put it, making this leap is assumption-based rather than evidence-based reasoning, see 'Late Lessons' (n 21), 468.

[24] For an excellent primer on 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.

[25] As numerical probabilities of risk from novel substances are by definition impossible to determine, Chapman suggests that assessments should be less demanding in terms of precision, but more demanding in their scope, addressing a much wider set of possible impacts: see Chapman, 'Regulating Chemicals', 608.

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

[27] See n 12 above.

[28] 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.'

29 The problem of unlawful delegation has been exposed in more detail in Vesco Paskalev, 'GMO Regulation in Europe: Undue Delegation, Abdication or Design Flaw?' (2015) 6 European Journal of Risk Regulation 573. This subsection is a non-technical summary of the discussion and uses a few paragraphs from this publication.

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

[31] Before Pfizer was decided, there were cases when the Commission took a decision against the advice of the relevant advisory body. Chapman points to the example of the banning of phthalates in baby pacifiers, see Anne Chapman, 'Greens and Science: Why the Green Movement Is Not Anti-Science' (Greenhouse Reports, 2012), available at www.greenhousethinktank.org/files/greenhouse/home/Science_inside_2.pdf), 10. While this is not outlawed by Pfizer, the judgement set such a high standard for justifying such moves that they are not taken any more.

[32] In my view, the correct reading of Pfizer as well as the case law quoted in the GM Review do *not* oblige the Commission to defer to its advisor, yet this is how the Commission sees its role in the process. See Paskalev, 'GMO Regulation in Europe' (n 28).

[33] See the GM Proposal, recital 4.

[34] A step in that direction has already been made with the new Comitology Regulation adopted in 2011. In a notable departure from the earlier rules, its Art 6 (3) provides that where the Appeal committee fails to deliver an opinion, the Commission *may* adopt the act as proposed so it is no longer *required* to do so. Notwithstanding this change, the Commission still feels compelled to adopt the initial proposal.

[35] The Commission is already required to do the former by recital 14 of Regulation 182/2011. This text can be strengthened to make it clear that the failure of the Appeal committee to take a decision by qualified majority vote (QMV) cannot be interpreted as lack of predominant position of the Member States.

[36] Anderson severely criticises this 'agenda for narrowing avenues of meaningful public participation', see Paul Anderson, 'What Rights Are Eclipsed When Risk Is Defined by Corporatism? Governance and GM Food' (2004) 21 Theory, Culture & Society 155. The present report takes a somewhat more moderate position, and does not contest the heavy reliance on science in GMO regulation; it only argues against the particular way the science is employed by the current regulation.

[37] The explanations vary greatly with the position of the participants: according to the environmentalists EFSA is too close to the industry, according to the industry stubbornness of the opponents is the sole reason. A systematic investigation of the causes of this failure is beyond the scope of this report but the position defended here is that the problem is not in any of the parties but in the

flawed understanding of the role of science on which the regime is built. See more in Vesco Paskalev, 'May Science Be with You: Can Scientific Expertise Confer Legitimacy to Transnational Authority?' (2016 forthcomming), available at http://ssrn.com/abstract=2695240.

[38] While there is no way to measure the trust of Member States in EFSA empirically, this paradox is a clear sign that it is very low, at least with regard to GMO matters.

[39] On the relationship of the GM opponents with science see Chapman, 'Greens and Science' (n 30).

[40] See also the criticism of the established risk assessment/risk management approach in Part I above.

[41] Mihail Kritikos, 'Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-Scientific Factors?' (2009) 34 European Law Review 405, 418, references omitted. While he calls all of these factors – in line with the established practice – non-scientific, in my view their inclusion is actually necessary for the assessment to be based on really *sound science*.

[42] Anderson also argues that the exclusion of factors which cannot be easily quantified from the risk analysis has similar effect. See Anderson (n 35).

[43] See Kritikos (n 12) for a full account of the references to the other legitimate factors in the legislation in force.

[44] *Monsanto's Newest GM Crops May Create More Problems Than They Solve*, Wired, 2 February 2015. According to another study, 10,000 ha in Argentina are now covered by glyphosate-resistant weeds and the farmers have entered a treadmill where overuse of a single product leads to tolerance and tolerance is overcome with more product, see Binimelis, R et al. '''Transgenic treadmill": Responses to the emergence and spread of glyphosate-resistant johnsongrass in Argentina' in (2009) 40 *Geoforum* 623-633. See also Natasha Gilbert, 'Case studies: A hard look at GM crops', *Nature*, 01.05.2013.

[45] It is amazing how innocent of this issue the scientists can be. While the danger of falling into the treadmill has always been one of the major reasons for opposition to GMOs, a recent opinion piece in *Nature* calls for development of indigenous Indian GMOs, *because* the existing varieties have become obsolete and do not work against the new bugs they bred. See Anurag Chaurasia, 'India needs home-grown GM food to stop starvation', *Nature*, 28.01.2016, vol. 529, 439.

[46] As a matter of fact, one study showed that in states which resist GM technology (Germany and Austria) there is a greater variety of maize than in states which adopt it (i.e. Spain). See Angelika Hilbeck et al, 'Farmer's choice of seeds in four EU countries under different levels of GM crop adoption, (2013) *Environment Sciences Europe* 25 (12).

[47] EFSA has been persistently under fire for conflicts of interests, and according to one report more than half of its experts are too close to industry, see Corporate Europe Observatory, 'Unhappy meal: The European Food Safety Authority's independence problem', 2013 available at http://corporateeurope.org/sites/default/files/attachments/unhappy_meal_report_23_10_2013.pdf. The present report does not need to take a position in this debate, as the argument defended here is that EFSA's credibility suffers from the design of the regime and cannot be remedied by any personal changes.

[48] According to the dissenter "given the magnitude and multitude of exposures from the foreseen use of GM plants … it appears the cumulative probability of transfer could range from unlikely to high", see in Paskalev, 'Can Science Tame Politics' (n 6), 198.

[49] In the case of the Amflora authorisation it was concluded that potential spread of resistance to kanamycin is not a problem as the latter was considered not important for human or animal health. As it happened, this conclusion was proven preposterous by a report of the World Health Organisation, which classified kanamycin as important. Still it remains unclear whether anyone can make an assessment of the potential consequences of such resistance – they can vary from zero to infinity.

[50] See Taleb et al (n 20).

[51] Taleb and colleagues also point to the "extremely poor" track record of experts in assessing the magnitude of the adverse impacts of the products they are evaluating, citing a number of notorious failures – Thalidomide, Fen-Phen, Tylenol and Vioxx; ibid.

[52] European Environment Agency, 'Late Lessons from Early Warnings: The Precautionary Principle 1896-2000' (Environmental Issue Report 22, 2002), 177. The report also notes that the other benefit from lay knowledge is the "independence from the narrow professional perspectives that can be a downside of specialist expertise".

[53] This is a requirement of Art. 25(1) of the General Food Law.

[54] See Anderson (n 35) and Kritikos (n 12), 425.

[55] Kritikos, ibid.

[56] According to one study, the assessments conducted by EFSA are *de facto* meta-reviews of the assessment provided by the applicant, and it often fails to exercise even an adequate 'peer review', let alone independent inquiry. See van Asselt and Vos (n 23), 284.
[57] For example, the use of Roundup in US has more than doubled since 2002 as a result of the adoption of Monsanto's Roundup-Ready™ crops (note how this raises competition issues alongside the other factors). See in *The Wired* article quoted above.
[58] Marjolein BA van Asselt and Ortwin Renn, 'Risk Governance' (2011) 14 Journal of Risk Research 431, 443.
[59] See n 12 above.
[60] van Asselt and Renn, ibid.
[61] See more in Kritikos (n 12), 420.
[62] N Thayyil, *Biotechnology Regulation and GMOs: Law, Technology and Public Contestations in Europe* (Edward Elgar 2014), 119. Earlier Kritikos observed no traceable effect of the web-consultations on the formulation of EFSA's opinions. See Kritikos (n 12), 420.
[63] Marion Dreyer and Ortwin Renn, 'EFSA's Involvement Policy: Moving towards an Analytic-Deliberative Process in EU Food Safety Governance?' in Cathrine Holst (ed), *Expertise and Democracy* (ARENA Reports 2014), 341, references omitted, emphasis added.
[64] Jasanoff (n 22).
[65] Chapman, 'Regulating Chemicals' (n 17), 609. See also Taleb and colleagues (n 20) who also note that the controlled ex ante tests that are used to assess innovations cannot produce sufficient evidence because they cannot replicate the great variety of conditions in which these will interact in the real world, ibid, 14.
[66] This accusation is misguided. As Anderson aptly puts it, "it is precisely the need for 'scientific assurance' that is cause for public alarm", ibid (n 35), 157. See also Damian Chalmers, 'Risk, Anxiety and the European Mediation of the Politics of Life' (2005) 30 European Law Review 649.
[67] Christian Joerges and Jurgen Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology' (1997) 3 European Law Journal 273.
[68] Actually, as elaborated in section 1), the Commission feels constrained to follow EFSA's recommendations. Even if this were a legally valid constraint, it works the wrong way – making the Commission controlled by its advisor, rather than by the Parliament and the Council.
[69] The old comitology rules provided a 'regulatory procedure with scrutiny', which involved the EP, but it has now been abandoned. It can be restored in this connection to remedy the problem.
[70] See Elizabeth Fisher, 'Precaution, Precaution Everywhere: Developing a "Common Understanding" of the Precautionary Principle in the European Community' (2002) 9 Maastricht Journal of European and Comparative Law 21 and Maria Weimer, 'Applying Precaution in EU Authorisation of Genetically Modified Products—Challenges and Suggestions for Reform' (2010) 16 European Law Journal 624.
[71] Communication from the Commission of 2 February 2000 on the precautionary principle [COM(2000) 1 final].
[72] Thayyil, (n 58), 123.
[73] Ibid, 123.
[74] Ibid.
[75] Note that this is a separate reason for the illegality of the existing GMO regime, apart from the problems with the non-delegation doctrine elaborated in the first section.
[76] Quist et al in 'Late Lessons from Early Warnings' (n 21), 470, references omitted.
[77] In this case, the data from the very same study of mice was interpreted in three different ways – it was reinterpreted by EPA itself over a period of time and was once again interpreted differently by the WHO recently.
[78] See details in Paskalev, 'Can Science Tame Politics' (n 6).
[79] AG Sharpston, Opinion in C-439/05 *Land Oberosterreich and Austria v. Commission*, para 124.
[80] The term is borrowed from Kritikos (n 12).
[81] See n 13 above.
[82] Commission Work Programme 2015, COM(2014) 910 final, Annex I, Item 23.
[83] European Ombudsman own initiative inquiry, OI/6/2014/NF, letter to Commission President from 27/01/2015.
[84] See Sara Poli, 'The Reform of the EU Legislation on Genetically Modified Organisms: A Journey to an Unknown Destination' (2015) 4 European Journal of Risk Regulation 559 and Nicolas de Sadeleer, 'The Uncertain Balance between Centrifugal and Centripetal Forces in the Marketing and Cultivation of GMOs in the EU' (2015) 4 European Journal of Risk Regulation 532.

[85] C 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)* and its progeny.
[86] Case C-316/07 *Markus Stoß.*
[87] WT/DS291/R.
[88] WT/DS135/AB/R
[89] In the case of feed, the consumers themselves would be often large farming companies.