IN THE MATTER OF THE PROPOSED REGULATION TO AMEND DIRECTIVE 2001/18/EC

ADVICE

Introduction

1. We are asked to advise Friends of the Earth Europe and Greenpeace in relation to specific questions posed in our instructions arising from the Commission's draft proposal for a Regulation modifying Directive 2001/18/EC as regards the possibility for the Member States to prohibit, restrict or impede the cultivation of GMOs in their territory. The proposal is to amend Directive 2001/18 in order to permit Member States to regulate the cultivation of GMOs, notwithstanding the harmonised authorisations process established under that Directive and Regulation (EC) 1829/2003, via a new provision:

> "Article 26b
> Authorisations granted under Part C and Regulation (EC) No 1829/2003 shall not affect the possibility for a Member State to adopt measures prohibiting, restricting or impeding the cultivation of all or particular GMOs, and including genetically modified varieties placed on the market in accordance with relevant EU legislation on the marketing of seed and plant propagating material, in all or part of its territory, ***provided that these measures are based on grounds other than those related to the assessment of the adverse effect on health and environment which might arise from the deliberate release or the placing on the market of GMOs or related to the need to avoid the unintended presence of GMOs in other products and that they are in conformity with the Treaties.***"

2. That provision therefore would follow the current Article 26a which provides that Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

3. It is in connection with that provision that the Commission issued Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming and intends to adopt revised

guidelines "for the development of national cultivation measures to avoid the unintended presence of GMOs in conventional and organic crops".

Summary of conclusions

4. Properly understood, the legal effect of the proposed Article 26b is either to clarify the limits to the legal effects of the authorisations granted under the EU regime or to redefine those legal effects (depending upon whether the true intention behind the proposed regulation is to restate what is already the position or to alter the existing position). The result in either case is to describe an area in which Member States have the power to act in accordance with the principle of subsidiarity but not confer a power to act. The Member States' power to prohibit, restrict or impede the cultivation of GMOs is inevitably open to challenge for breach of EU law in the same way as any other exercise by Member States of their powers. The proposed Article 26b does not afford the Member States any protection from challenge or any guarantees that the action that they take will be lawful. The proposed Article 26b is silent on both points.

5. We consider that a significant problem arises from the lack of any reference in the preamble to the Regulation (apart from a passing allusion in recital (6)) to the principle of subsidiarity and, more particularly, to the reasons leading to the conclusion that subsidiarity mandates action at EU level in relation to some issues (those covered by the authorisation regime) but action at national level in relation to others. Subsidiarity underlies and is absolutely crucial to the proposed provision, the purpose of which is essentially to permit Member States to "opt out" of cultivation of GMOs even where the latter have been authorised under the harmonised procedure. As matters currently stand, the Regulation refers only to Article 114 as its legal base and this inevitably introduces legal uncertainty and problems of construction. Moreover, although the stated intention of the proposed Article 26b is to restore freedom to Member States to regulate the cultivation of GMOs, the proper construction of that Article severely limits (or defines) that freedom and it is difficult to conceive of potential grounds for Member State action which are not related to a degree to the grounds of environmental and health protection or to the need to avoid the unintended presence of GMOs in

other products. There may perhaps be purely ethical motivations which are wholly unrelated to those grounds but we consider it strongly arguable that the scope of the Member State's competence is at best vague and renders the likelihood of there being any "legally solid" and invulnerable grounds limited.

Analysis

6. Before responding to the specific questions asked of us, we consider it useful to examine both the Explanatory Memorandum accompanying the draft Proposal and the draft "Commission Communication on the freedom for Member States to decide on the cultivation of genetically modified crops" in order to ascertain the apparent intentions underlying the Proposal. For ease of reference we reproduce the most salient paragraphs of each.

7. The proposed Regulation is clearly a response to various strongly held national positions on GMOs and the desire for subsidiarity in the field and refers to the political guidelines for the new Commission set out by President Barroso. The Memorandum states that "according to these guidelines it should be possible to combine a European Union authorisation system, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory" and that the "proposed Regulation aims at implementing these guidelines by providing a legal base in EU legal framework on GMOs to authorise Member States to restrict or prohibit the cultivation of GMOs in all or part of their territory which have been authorised at EU level": section 1 – Context of the Proposal.

8. Thus the stated intention of the Proposal is to provide freedom to Member States to reach their own decisions concerning cultivation of GMOs by way of an "opt out" from the normal consequences of the harmonised authorisation process.

9. The Memorandum refers to the series of conditions under which the proposed legislation permits Member States to take measures:

"1. As the assessment of the safety of GMOs for human/animal health and the environment is carried out at EU level, Member States have the possibility under the existing legal framework to invoke the special procedures of the safeguard clause of Directive 2001/18/EC (Article 23) or the emergency measure of Regulation (EC) No 1829/2003 (Article 34) in case they have serious grounds to consider that the authorised product is likely to constitute a serious risk to health and environment. Consequently, the proposal foresees that Member States cannot invoke protection of health and environment to justify a national ban of cultivation of GMOs outside these special procedures. This condition aims at preserving the authorisation system based on science set out in EU legislation.
2. The proposal also prohibits the Member States, when adopting national measures on cultivation, to invoke reasons related to the unintended presence of GMOs in other products, as they are already allowed to adopt such measures according to currently applicable Article 26a of Directive 2001/18/EC.
3. Finally the proposal establishes that the measures taken by the Member States have to be in conformity with the Treaty, in particular as regards the principle of non-discrimination between national and non-national products."

10. The Memorandum then goes on to discuss the conformity of the Proposal with the subsidiarity principle and states:

"According to Article 5(3) TUE, under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but rather, by reason of the scale of effects of the proposed action, be better achieved at Union level.

Following Article 2(2) TFEU, when the Treaties confer on the Union a competence shared with the Member States in a specific area, the Union and the Member States may legislate and adopt legally binding acts in that area. In accordance with the last sentence of this provision, Member States shall again exercise their competence to the extent that the Union decides to cease its competence.

The current EU legal framework fully harmonises cultivation of GMOs. Member States are thus allowed to adopt measures restricting, prohibiting or impeding the cultivation of GMOs only under the conditions set out in that legal framework (essentially the safeguard clauses and emergency measures provisions when a serious risk to health and environment is identified, and Article 26a of Directive 2001/18/EC to avoid the presence of authorised GMOs in other products).

Experience however has shown that cultivation of GMOs is an issue which is more thoroughly addressed by Member States, either at central level or at regional and local level. It is closely linked to land use and the requirements of local agricultural structures, separate production chains and consumers' perceptions. Contrary to the safety assessment of GMOs, whose aspects are common throughout the EU, or to issues related to the marketing of GMOs for food/feed/industrial processing and imports, which should remain regulated at EU level as an internal market affair, cultivation has been acknowledged as an issue with a strong local/regional dimension. As such, national, regional or local levels of decision making are considered to be the most appropriate frameworks to address the particularities linked to GMO cultivation.

In line with the principle of subsidiarity and by application of Article 5(3) last sentence TUE, Member States should therefore be entitled to conserve a possibility to adopt rules concerning the effective cultivation of GMOs in their territories after the GMO has been legally placed on the EU market, provided that these measures do not affect in particular the authorisation of GMOs and are in conformity with the Treaty."

11. The draft Commission Communication echoes some aspects of the Explanatory Memorandum. It concludes, *inter alia*:

> "The European Commission considers that the introduction of an 'opt-out clause' for Member States to decide on GMO cultivation, including through full prohibitions of all or particular GMOs, is necessary to fully deliver on the commitment to grant freedom to Member States in this area without changing the EU system of authorisations based on science. This is the only way to fulfil the requirement to grant freedom to Member States to decide on GMO cultivation using grounds that would go *beyond* co-existence (*but without invoking grounds linked to the environmental/health risk assessment carried out at EU level*)" (emphasis added).

12. For the sake of completeness, we also set out below the most salient recitals to the Proposal:

> "(1) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed provide for a comprehensive legal framework for the authorisation of genetically modified organisms (GMOs), which is fully applicable to GMOs which may be used for cultivation purposes throughout the Union as seeds or other plant-propagating material (hereinafter 'GMOs for cultivation').
> (2) Under this set of legislation, GMOs for cultivation shall undergo an individual risk assessment before being authorised to be placed on the Union market. The aim of this authorisation procedure is to ensure a high level of protection of human life and health, animal health and welfare, the environment and consumer interests, whilst ensuring the effective functioning of the internal market.
> .....
>
> (4) Once a GMO is authorised for cultivation purposes in accordance with EU legislative framework on GMOs and complies, as regards the variety that is to be placed on the market, with the requirements of EU legislation on the marketing of seed and plant propagating material, Member States are not authorised to prohibit, restrict, or impede its free circulation within their territory, except under the conditions defined by EU legislation.
> (5) Increased emphasis has been put in the last years on the idea that the appropriate level of action to take decisions regarding the effective cultivation of GMOs is that of the Member States and that they should be entitled to conserve a possibility to adopt rules concerning the effective cultivation of GMOs in their territory after the GMO has been legally authorised to be placed on the EU market.
> (6) In this context, it appears appropriate to clarify EU legislation in order to grant, in accordance with the principle of subsidiarity, Member States more freedom to decide whether or not they wish to cultivate GMO crops on their territory without changing the system of Union authorisations of GMOs and independently of the measures that Member States are entitled to take by application of Article 26a of Directive 2001/18/EC to avoid the unintended presence of GMOs in other products.
> (7) Member States should thus be authorised to adopt measures prohibiting, restricting or impeding the cultivation of all or particular GMOs in all or part of their territory and respectively amend those measures as they deem appropriate, at all stages of the authorisation, re-authorisation or withdrawal from the market of the concerned GMOs. This should apply as well to genetically modified varieties of seed of agricultural plant species and vegetables which are placed on the market in accordance with Directives 2002/53/EC and 2002/55/EC.
> (8) To avoid that these measures undermine the EU system of authorisation, they shall be taken on grounds other than those already addressed by the harmonised set of EU rules which already

provide for procedures to take into account the risks that a GMO for cultivation may pose on environment and health. Moreover, given that Article 26a of Directive 2001/18/EC already provides a legal base for the Member States to adopt measures to avoid the unintended presence of GMOs in other products, measures taken on the basis of this Regulation should not be based on that ground as well. These measures shall also be in conformity with the Treaties, in particular as regards the principle of non discrimination between national and non national products. The other Member States and the Commission should be informed of the adoption of these measures by a Member State prior to their adoption....."

13. We turn now to the questions asked in our instructions.

Question 1. Would Member States be able to prohibit lawfully the cultivation of GM crops on their territories under the new proposal for Art 26b and the recommendations for new coexistence guidelines without the possibility of the ban being challenged?

14. Although the Explanatory Memorandum and the 6th recital to the Proposal would indicate that legal certainty was sought to be achieved in defining the scope of the Member States' freedom to prohibit or restrict GMO cultivation, we do not consider that that objective has been achieved by the proposed provision. To the contrary, the new provision not only potentially severely curtails the freedom of Member States but also renders the extent of that limited freedom wholly unclear. Moreover, as currently drafted, we consider there to be a significant incongruity between the stated intentions of the legislation to be found in the draft Explanatory Memorandum and Commission Communication and the potential construction of the provision proposed.

15. Before embarking on a more detailed explanation of those points, it should be observed that the proposed Article 26b is internally contradictory.

16. The first paragraph of the proposed Article 26b takes the legal form of a provision that is declaratory in nature: it states that the authorisations referred to do not "affect the possibility for a Member State to adopt measures..." (subject to qualifications that then appear later on in the paragraph). In other words, the first paragraph confirms that the authorisations *do* preclude action by the Member States that is taken for certain identified reasons but *do not* preclude action taken

on other grounds (not identified in the paragraph). The first paragraph is not, however, a power conferring provision. It merely states the limits to the legal effect of the authorisations referred to.

17. The second paragraph then refers to Member States adopting measures "under this Article", which implies that the proposed Article 26b *is* a power-conferring provision. The two paragraphs could be reconciled by reading "under" in the second paragraph as meaning "in accordance with": that would indicate that the second paragraph intends to refer to the situation contemplated in the first paragraph (which is one where Member States exercise a power derived from some other source - not the proposed Article 26b - without trespassing on the legal scope of the authorisations referred to in the first paragraph). However, it does not seem to be either possible or reasonable to use the word "under" in the second paragraph to override the clear wording of the first paragraph (in other words, one cannot use "under" to alter the legal meaning and effect of the first paragraph).

18. The same confusion between defining the limits of a measure and conferring a power is evident in the preamble to the proposed regulation. Recital (5) says that Member States "should be entitled to *conserve* a possibility to adopt rules" (which implies that they have it already). Recital (6) says that "it appears appropriate to *clarify* EU legislation *in order to grant*...Member States *more* freedom" (which is obviously a contradiction because clarifying something means explaining what it already says, not saying something different). Recital (7) pursues the idea of empowering Member States ("Member States should thus be authorised to adopt measures..." - we observe in passing that "thus" is inappropriate in that phrase).

19. Strictly speaking, the proposed Article 26b is not a power-conferring provision but an attempt either to clarify or to limit the legal effect of authorisations in accordance with the principle of subsidiarity. In accordance with that principle (and so far as is here relevant), the EU acts if and insofar as the objectives served by its action cannot be sufficiently achieved by the Member States: see Article 5(3) of the TEU. Where that is not the case, the use made by the EU of its competence infringes the principle of subsidiarity. There is no need for the EU to confer power of action on the Member States where, properly understood, the

EU's action is consistent with the principle of subsidiarity and the problem is merely one of making the position clear. Where, on the other hand, the EU's action is inconsistent with subsidiarity, it is also unnecessary for the EU to confer power of action on the Member States in order to remedy the breach of the principle; instead, the EU simply reduces the use of its competence so as to bring it into conformity with the principle of subsidiarity.

20. Having said that, since (properly understood) the legal effect of the proposed Article 26b is either to clarify the limits to the legal effects of the authorisations granted under the EU regime or to redefine them (depending upon whether the true intention behind the proposed regulation is to restate what is already the position or to alter the existing position), the result in either case is to describe an area in which Member States have the power to act. However, the Member States' power to prohibit, restrict or impede the cultivation of GMOs is inevitably open to challenge for breach of EU law in the same way as any other exercise by Member States of their powers. The proposed Article 26b does not afford the Member States any protection from challenge or any guarantees that the action that they take will be lawful. The proposed Article 26b is silent on both points.

21. We consider that a significant problem arises from the lack of any reference in the preamble to the Regulation (apart from a passing allusion in recital (6)) to the principle of subsidiarity and, more particularly, to the reasons leading to the conclusion that subsidiarity mandates action at EU level in relation to some issues (those covered by the authorisation regime) but action at national level in relation to others. Subsidiarity underlies and is absolutely crucial to the proposed provision, the purpose of which is essentially to permit Member States to "opt out" of cultivation of GMOs even where the latter have been authorised under the harmonised procedure.

22. The position is all the more difficult because of the different signals sent out by the proposed regulation and the accompanying documents as to whether the proposed regulation is a clarification of the existing situation or an amendment of it that is justified by application of the principle of subsidiarity.

23. The preamble to the Proposed Regulation appears to treat Article 114 as its sole legal basis, undoubtedly because that provision forms the legal basis of the Directive which it seeks to amend; but, in the absence of any properly articulated reference to subsidiarity, the proposed provision does not sit happily at all with that Article. Article 2(2) TFEU provides that:

> "When the Treaties confer on the Union a competence shared with the Member States in a specific area, the Union and the Member States may legislate and adopt legally binding acts in that area. The Member States shall exercise their competence to the extent that the Union has not exercised its competence. The Member States shall again exercise their competence to the extent that the Union has decided to cease exercising its competence".

24. It is clear from the Explanatory Memorandum to the Proposal (and we refer to the extracts above which refer to subsidiarity) that here the Union has indeed decided to cease exercising exclusive competence over the cultivation of GMOs, or to declare that its competence is not exclusive, or in any event has decided that the principle of subsidiarity ought now to apply to such cultivation. Thus, Article 26b seeks to define the extent to which Member States may (now) exercise their competence in that area and the extent to which Member States may not interfere with harmonised measures. Where Member States may (now) exercise competence, such exercise is not constrained by a need to demonstrate that a proposed measure is proportional to any Community objective.

25. Article 296 TFEU requires that legal acts shall state the reasons on which they are based and shall refer to any proposals, initiatives, recommendations, requests or opinions required by the Treaties. The Court of Justice has held in many cases that the obligation to give reasons requires that the measures concerned should contain a statement of the reasons which led the institution to adopt them, so that the Court can exercise its power of review and so that the Member States and the nationals concerned may learn of the conditions under which the Community institutions have applied the Treaty (see, inter alia, Case C-41/93 *France v Commission* [1994] ECR I-1829, paragraph 34).

26. We consider that, unless the proposed regulation simply declares what the position is and always has been, the absence of any reference to the crucial "re-allocation" of powers underlying the proposed regulation would be in clear breach of Article

296 TFEU. Moreover, the absence of such reference and the reference only to Article 114 as the legal base for the proposed regulation create additional legal uncertainty since, on the face it, the proposed Article 26b does not and cannot sit happily with Article 114 at all. Article 114, after all, is applicable only to the *approximation* of laws and it provides Member States with the power to "opt out" of or go beyond those harmonised measures in the narrow circumstances specified in that Article, namely where it is *necessary* to do so on grounds referred to in Article 36 (namely grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property) and on grounds relating to the protection of the environment or the working environment.

27. If Article 26b were to be construed as a deviation from harmonised measures and subject to the provisions of Article 114 TFEU, rather than reserving to Member States full competence in relation to GMO cultivation, the result would be that the residual power in Member States conferred (or recognised) by Article 26b would arguably be nothing more than an expression of the existing residual power in Article 114 which is itself severely curtailed by the strict requirements of necessity and proportionality and is subject to approval on the part of the Commission.

28. Therefore, without explaining that the proposed Article 26b is aimed at restoring or at the very least confirming Member State's competence in relation to cultivation of GMOs, it is easy to see how significant confusion and problems of interpretation could arise.

29. To say the least, the Proposed Regulation introducing Article 26b is in its current form riddled with legal uncertainty and lack of reasoning. Since the legislative act itself, if maintained in its current state, is vulnerable to challenge on these grounds, this potentially renders any national measure taken on the basis of it, pursuant to it, or in accordance with it, similarly vulnerable to challenge.

Question 2: On what (legally solid) grounds could Member States prohibit GM cultivation in their territory, if health and environmental concerns as well as measures to avoid the unintended presence of GMOs in other products of GM contamination are explicitly excluded by this new Art. 26b?

30. The following analysis is based on the assumption that the legal basis and reasoning of the new Article 26b is made clear.

31. The current proposal is not intended to render lawful bans on the prohibition of the cultivation of GMOs in order to preserve or protect organic markets, non-GM markets, biodiversity, geographic designations of origins etc. It simply deals with the legal scope and effect of authorisations.

32. Article 26b must be construed in the light of the legislative context into which it is to be placed. It is perhaps easier to start with determining what Article 26b does *not* permit.

33. According to the Commission, the assessment of safety for human health and the environment is carried out as part of the authorisation process under Directive 2001/18. According to it, the only means of exercising a prohibition or restriction on GMO cultivation on grounds of environmental or health protection are by means of invoking the safeguard clause in Article 23 (or the emergency provisions of Regulation 1829/2003). Article 23 permits however only *provisional* measures restricting or prohibiting the use of a GMO where new or additional information available after authorisation of that GMO gives rise to grounds for considering that the latter is a risk to human health or the environment. Article 34 provides that where it is *evident* that authorised GMOs are likely to constitute a serious risk to human health or the environment, certain specified emergency procedures may be followed to prohibit or restrict the use of that GMO. Those Articles therefore impose a high evidential burden on Member States and, in relation to each GMO for which a restriction or prohibition is sought, limit any action to provisional or emergency measures.

34. There is no mechanism in either Directive 2001/18 or Regulation 1989/2003 which would enable a Member State to implement a permanent and comprehensive prohibition on GMO cultivation on grounds associated with risk to the environment or human health.

35. Article 26b does not permit Member States to take account of considerations which are related to the assessment undertaken as part of the authorisation process and does not permit them to go beyond their limited powers in the exceptional circumstances envisaged by Article 23 (and Article 34 of Regulation 1829/2003). Member States are not therefore free to base any prohibition or restriction on cultivation on grounds of risk to the environment or human health under this Article. Their only competence in this respect is therefore confined to Article 114(4) and (5) TFEU.

36. Article 26a provides that Member States may take appropriate measures to avoid the unintended presence of GMOs in other products. It is wholly unclear to what extent this Article permits, if at all, a *prohibition* on the cultivation of GMOs. In view of the fact that the measure purports to enable measures to be taken which on the one hand provide protection for non-GM and organic operators whilst on the other hand accepting the legitimacy of authorised GM production, it is difficult to see how it may be used to promulgate a total ban on GMO cultivation. Indeed, the entire premise of the Article appears to be that the Member State has permitted GM cultivation (particularly in view of the fact that it was introduced at a time when both authorisation and cultivation were the subject of harmonisation). Article 26a might however provide the basis for local or regional bans or "zoning" provisions aimed at preventing GM contamination. Even the Commission appears to accept in its proposed new Guidelines that measures taken under that Article may, exceptionally, entail regional or local prohibitions on GMO cultivation.

37. Given that Article 26b does not permit Member States to take account of grounds related to the need to avoid the unintended presence of GMOs in other products, it appears that it would not enable Member States to introduce a national prohibition on GMO cultivation where, for example, it considered that co-existence could not be achieved without cross-contamination and that prohibition was the only

appropriate means of avoiding the unintended presence of GMOs in conventional and organic crops.

38. Article 26b therefore does not create or recognise a broad freedom of Member State to prohibit or restrict GM cultivation and potentially leaves a relatively narrow sphere of Member State competence. Although, in principle, Member States may base a prohibition on *any* grounds other than those relating to potential adverse effects on health and environment which might arise from the deliberate release or the placing on the market of GMOs and other than those related to the need to avoid the unintended presence of GMOs in other products, we consider that the circumstances in which a prohibition is not in some way linked to those excluded grounds may well be practically limited.

39. For example, to what extent is an economic choice to ban GM cultivation in preference for the creation of a GM-free or organic market in order to meet consumer demand distinct and dissociable from the need to avoid the unintended presence of GMOs in conventional or organic crops when the need necessarily arises from that economic choice? To what extent can it be said that a ban based on the desire to protect biodiversity involves trespassing on environmental protection considerations *capable* of being considered but not necessarily considered under the authorisation procedure? To what extent are political and ethical grounds for action permissible where the political and ethical opposition to GM cultivation is underpinned by consumer perceptions of environmental risks?

40. The Commission Communication appears to consider a number of grounds as falling outside the harmonised provisions and within the competence of Member States. It states:

> "The reasons for banning GMOs in a country or declaring a region GM-free appears to be diverse. *These reasons vary from agronomic justifications related to difficulties of ensuring co-existence to economic motivations such as meeting the demand of GM-free markets. In other cases, Member States want to preserve certain areas in line with national policies on biodiversity or other nature protection goals. Such considerations setting protection goals of a more political nature go beyond the environmental risk assessment provisions set out in the legislation and assessed by Member States and EFSA.*
>
> In this context it appears appropriate to change EU legislation in order to provide in the EU legislative framework on GMOs an explicit legal base to authorise Member States to restrict or

prohibit the cultivation of all or particular authorised GMO in part or all of their territories provided that measures so adopted are based on grounds other than those related to the assessment of the adverse effect on health and environment which might arise from the deliberate release or the placing on the market of GMOs or related to the need to avoid the unintended presences of GMOs in other products and that they are in conformity with the Treaties." (emphasis added)

41. That position, even if correct, is not adequately reflected in the language proposed for Article 26b.

42. In conclusion, therefore, we consider that although the stated intention of the proposed Article 26b is to restore freedom to Member States to regulate the cultivation of GMOs, the proper construction of that Article severely limits that freedom and it is difficult to conceive of potential grounds for Member State action which are not related to a degree to the grounds of environmental and health protection or to the need to avoid the unintended presence of GMOs in other products. There may perhaps be purely ethical motivations which are wholly unrelated to those grounds but we consider it strongly arguable that the scope of the Member State's competence is at best vague and renders the likelihood of there being any "legally solid" and invulnerable grounds limited.

Question 3: How should the proposed article 1 (new 26b) be drafted in order to provide Member States with a (legally solid) right to prohibit GMOs in their territory and therefore to make sure that the Commission promises are maintained?

43. We do not propose to proffer a form of wording but we consider that, in view of the fact that the proposed provision is intended either to clarify the existence of, or to restore, a Member State competence in accordance with the principle of subsidiarity, it would be difficult to convert the proposed regulation into one that provided Member States with a "legally solid" right to prohibit GMOs.

44. However, for the reasons we have explained above, we consider it imperative and in any event a requirement pursuant to Article 296 TFEU that the reasoning underlying the provision and in particular the principle of subsidiarity is set out

and made clear in the preamble and recitals to the Regulation and, further, that the relevance of Article 114 is clarified. For the same reasons, the reference in the preamble to Article 114 as the sole legal base ought be removed. Further and in any event, the Explanatory Memorandum appears to confirm that the reference to grounds relating to the unintended presence of GMOs in Article 26b is intended to ensure that measures which can be taken under Article 26a are not also taken under Article 26b. The desire appears to be to avoid duplication. It is important therefore for the language to reflect the position that Article 26a does not in fact confer a power to impose a national ban on GMO cultivation for the reasons we have identified. It ought therefore to preserve the ability of Member States to impose a prohibition on the cultivation of GMOs precisely in order to avoid the unintended presence of GM in other products thus preserving the ability of a Member State to remain a GM free or organic market.

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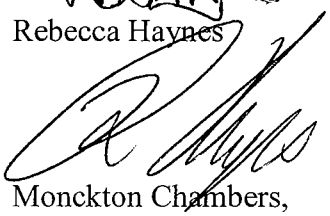

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