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Energy, Environment and Development Programme Paper: 09/03

A Way Forward for GMO Cultivation in Europe?

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November 2009

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EXECUTIVE SUMMARY

- The Dutch and Austrian authorities have put forward proposals intended to help break the current deadlock in the European Union's decision-making on cultivation of genetically modified crops. There is general consensus amongst stakeholders that the *status quo* is not sustainable and the opportunity to explore innovative options has been welcomed.

- There are two basic elements to the outline proposals now on the table: (i) national self-determination on cultivation (within a European framework of a science-based assessment of safety); and (ii) explicit consideration of socio-economic factors as part of that process of national decision-making.

- These propositions have not yet been developed into detailed options. Whilst the self-determination principle and more explicit consideration of socio-economic factors have general appeal, there is more work to be done to determine how national opt-outs might be established, how to give these decisions a firm legal basis, how long it would take to deliver the changes, and what the wider implications might be of each option.

- In looking at potential models for national decision-making and socio-economic appraisal the issues to consider include:

    - Whether Member States would wish to evaluate the socio-economic impacts of each GMO on a case-by-case basis, or simply opt-out in all cases through declaration of a permanent 'GM-free' status for regions or whole nations;

    - Whether a common basket of socio-economic factors is determined at EU level, or each Member State develops its own;

    - The nature, strength and stability of evidence that would be included in the socio-economic assessments;

    - The timelines for decisions under a national opt-out model, allowing for preparation, consultation and decision on the socio-economic assessment;

  - The direct and indirect cost impacts and administrative burden of having to prepare a socio-economic assessment, especially if Member States each set their own methods.

- National self-determination would see discussions that are currently centred in Brussels move to Member State governments and devolved administrations, and ministers' decisions become more visible. For governments there will be challenges in defining and managing the process through which decisions are made. Some Member States have systems or structures that might be co-opted to this purpose; others do not.

- Citizens and consumers would see the debates about GM re-ignited as new decision-making frameworks were developed and introduced by Member States.

- If the changes resulted in more authorisations, farmers in Member States that did not opt out would ultimately have greater choice of products. Evidence would emerge on the strength of the market for GM-free production.

- For the industry the price for breaking the deadlock in this way would be new, challenging evidential requirements and greater complexity in the European market place, both in terms of obtaining authorisations and subsequent marketing.

- Finding a viable 'quick fix' may not be as easy as some initially hoped. Modifications that require changes to EU law or development of new national laws could commit Member States to many years of debate and due process in development of new systems for decision-making, with uncertain outcomes.

- At the same time, existing blockages to cultivation authorisations, such as differences of view among Member States about the scientific risk assessment, would not necessarily dissolve if national opt-outs and socio-economic appraisals were introduced.

- A legal review of opportunities and constraints is a priority. It should consider, at least, the:
  - External legal issues, with a focus on the EU's obligations under WTO;
  - EU legal issues, particularly the mechanism by which desired changes could be made;
  - Implications for national legislative frameworks, particular the point that Member States might need to put in place new primary legislation to provide a legal basis for national decisions.

- Industry, NGO and other stakeholders are concerned that if the EU legislation was opened up for 'minor' adjustment it would be very difficult to prevent the entire text being reappraised and revised. There is therefore interest in looking at what can be achieved within the scope of existing EU legislation rather than by reopening it, or forcing the creation of a new tier of laws at Member State level.

- A protracted reform process would have opportunity costs. Given the wide range of critical issues facing the EU's food system the time, energy and effort associated with a new review and reform of GMO legislation might well yield higher returns if spent elsewhere. So, before embarking on a formal change process, stakeholders would need to be convinced that there was a realistic prospect of achieving the stated goals.

1 INTRODUCTION

This paper considers the recent proposals for reform of the European Union's system for authorising the cultivation of genetically modified organisms (GMOs), specifically:

- That the authorisation process should include a more explicit consideration of socio-economic factors; and
- That Member States should be granted the right of self-determination in respect of cultivation (within a common EU risk assessment framework).

It draws on a seminar held at Chatham House in October 2009 that was attended by officials from the UK, Dutch and Austrian governments, and invited interests from across the UK food system – farmers' representatives, biotech companies, non-governments organisations, academics and others. The objectives of the seminar were:

- To learn more about the nature of the new proposals from the key sponsoring Member States;
- To identify the questions that these proposals raise for the various stakeholders in the food chain, particularly here in the UK;
- To begin to explore the practical issues that these questions raise; and
- To foster a constructive dialogue about the proposals by raising awareness among UK stakeholders and helping to prompt further work and thinking here in the UK about it.

This document is structured as follows:

- Section 2 explains the background to the proposals and what those putting forward the proposals aim to achieve;
- Section 3 examines what the proposed changes might mean in practice;

- Section 4 briefly considers the implications of the proposed changes for different groups in the food chain; and

- Section 5 provides some concluding remarks.

2 THE CONTEXT

This section explains the background to this paper, specifically the proposals made in 2009 for reform to the EU's system for appraisal and authorisation of GMOs for cultivation.

2.1 Europe's current framework for assessment of GMOs for cultivation

The European Union (EU) has a common system for assessing the risks that GMOs might pose to human health and the environment on a case-by-case basis. Authorisation for 'use' of a GMO is conditional on the outcome of a risk assessment, and a complex set of risk management arrangements, labelling and traceability provisions set out in various Directives and Regulations.

In principle, if a GMO or derived product is not considered to present any risks over and above its conventional counterpart, it should be approved and released to the whole EU market. Various elements of the legislative framework provide for authorisation for cultivation, importation, processing, feed and food uses.

However, no new authorisations for cultivation of a GMO have been awarded since 1998. Despite positive safety opinions on various GMOs from the European Food Safety Authority or earlier assessment bodies, when cultivation dossiers have been put to a vote Member States have failed in official Committee or at Council to achieve a qualified majority for approval or rejection. In some cases old applications have yet to be put to a vote by the Commission. Some Member States are not content with the risk assessment process, and governments have also abstained or voted against authorisation on the basis of factors other than science.

In addition, some Member States have declared unilateral bans on the one type of GM seed that has already been approved under earlier legislation and is being marketed for cultivation. Under current legislation national bans on authorised GMOs can only be justified on scientific grounds. But Member States have retained those bans even in the face of opinions from the European Food Safety Authority that there is no scientific case for them to be upheld. The Council of Ministers has achieved a qualified majority against proposals from the European Commission to force the Member States concerned to repeal their bans.

In summary, decisions on market authorisation, whether positive or negative, are not being made. The authorisation procedures for cultivation are commonly regarded as slow and unpredictable. Member States decisions are influenced by factors beyond science.

2.2 The 2009 proposals

During 2009 Member States tabled suggestions for changes to the current system with the hope of 'unlocking' the paralysis that has afflicted the decision-making machinery for authorising GMO cultivation, or simply to provide what they would regard as a better regulatory system. These ideas are:

- That individual Member States should be given greater freedom to choose whether to allow the cultivation of GM crops, either on case-by-case basis or through declaration of GM-free areas, within the framework of a common European system of risk assessment and authorisation for deliberate release; and

- In taking that decision, Member States could factor into account socio-economic considerations that do not have a clear status within the existing regulatory framework.

The Dutch perspective

In March of this year the Netherlands delegation made a declaration to the Agriculture Council calling for Member States to have the right to decide for themselves on the cultivation of GMOs, and suggesting that such decisions could be based upon socio-economic criteria. The Dutch government's goals are to:

- Ease political pressure on GMO procedures;

- Give Member States more policy options at the national level;

- Speed up EU procedures for new authorisations.

Its intention is to address the perceived problems of the authorisation procedure being seen as inefficient, slow and unpredictable, and discussions on technical issues being entwined with discussion of political issues.

A high level task force has been established in the Netherlands to work on the further development of these proposals and has commissioned supporting work on issues such as socio-economic criteria and sustainability. The proposals fit into wider context of interest in the Dutch government in the use of GMOs in sustainable agriculture and food production.

The Austrian perspective

The Austrian government has long-standing objections to the risk assessments prepared under the existing authorisation process, seeing them as not compliant with the requirements of the Directive 2001/18/EC. Austria has been arguing for changes to the guidelines for environmental risk assessment and:

- More explicit consideration in the environmental risk assessment of regional agricultural, ecological and geographical conditions;
- Recognition of socio-economic impacts as legitimate factors in the decision; and
- The right for regions to restrict or prohibit the cultivation of GMOs.

The Austrian public does not, in general, support GM cultivation. All provinces (Länder) have joined the Alliance of GMO free regions in Europe and all political parties in the Austrian national parliament have adopted common resolutions (the latest in July 2009) to work for a 'GMO-free Austrian Region'. Parties also expressed an intention not to vote in favour of applications for GM food and feed.

In general Austrian farmers do not support GM cultivation. Austria has a large number of small farms, many of them managed organically, and many areas protected for nature conservation purposes. Cooperatives for the production of GM-free food and feed have been established.

In June the Austrian government submitted a note to the Environment Council (with the support of twelve other Member States) recommending changes to the legislative framework that could put the Dutch proposals into effect (Annex 1). It has suggested that the current deadlock could be addressed by providing:

- A right of self-determination not to cultivate GMOs that is founded directly on the Treaty (specifically Article 5, paragraph 2 on subsidiarity and Article 175, paragraph 2 on unanimity for decisions on land use); and

- A means for a Member State to be able to justify prohibition of GMO cultivation on its territory based on socio-economic criteria relevant to that Member State.

Austria has proposed specific amendments to Directive 2001/18/EC, specifically

- To amend Article 22 to exclude GMO cultivation from the principle of free circulation;

- To add text to Article 26 that provides for Member States to notify the Commission that GMOs are not allowed to be cultivated in their entire territory or in designed parts of their territory, and that any EU approvals of GMOs for cultivation should recognise these exclusions.

The Austrian government has commissioned a number of studies intended to support the further development of its proposals.

3 THE PROPOSALS IN PRACTICE

This chapter considers the translation of the outline proposals into practice and the issues that it raises, covering:

- How the approval process might work under the reforms suggested by the Netherlands and Austria;
- The definition and use of socio-economic factors within that process;
- The implications for marketing of GMOs for cultivation; and
- The legal framework required to support the modified system.

3.1 Definition of the process by which devolved decisions on cultivation would be taken and given formal recognition is a key issue

As envisaged, the EU-wide safety assessment would continue to be based on a scientific appraisal of risk. Member State decisions could then draw upon a broader set of socio-economic factors in making their own decisions on whether to opt-out of the authorisation for cultivation.

The process of Member States choosing whether to notify the EU of its decision to opt out of cultivation (fully or in certain named regions within the country) would presumably be triggered by release of a positive Opinion from EFSA on the risk assessment. There appear to be two options for this next step:

- That Member States vote on a draft decision by the Commission for authorisation, as now, but that this authorisation would be qualified where Member States had notified a wish to opt-out in part (i.e. some regions) or in full; or
- That the EU Decision is qualified retrospectively by Member State opt-outs.

Whether it would be practical to suspend a final EU authorisation decision until 27 Member State processes have been completed, and notified to Brussels, is not clear. But retrospective qualification of an EU authorisation is

likely to require further changes to the existing legislation, and introduce further uncertainty.

It is reasonable to expect that Member States would vary in the speed of their response. Those Member States that had made strategic choices not to accept GMO cultivation without reservation, might be expected to respond more quickly than Member States that wanted to review each GMO on a case-by-case basis. In the latter cases the complexity and timescale of the national process would determine the rate at which opt-out decisions could be notified.

The logic of the proposed change is that an individual Member State could, in theory, vote in favour of the EU-wide authorisation Decision (thus implicitly accepting the safety case set out in the appraisal of the risk assessment) but decide to opt-out of cultivation itself. Whether the objections that some Member States have to the risk assessment would be sustained in an environment where those States can exclude themselves from direct impacts of cultivation is unclear.

3.2 Determination of the basket(s) of socio-economic factors that might be used in decision-making is not straightforward

The Dutch and Austrian outline proposals do not define 'socio-economic' factors in detail but discussions show that countries could interpret this term very broadly, and differently.

Single basket vs. multiple baskets

The basket of socio-economic factors could potentially contain a wide range of issues and impacts, including:

- The economic benefit of the GMO to farmers;
- The economic impact on society more generally;
- Public attitudes to GMOs in general, or the GMO in question;
- Ethical considerations;
- 'Sustainability', howsoever defined.

The factors that individual Member States might wish to take into account might vary depending on environmental conditions, agronomic practice, crops planted, consumer choice, cultural preferences, etc.

An EU-wide information-gathering exercise on socio-economic factors, managed by the European Commission, will report in June 2010. This should reveal the extent to which there is variation in the issues of concern across the EU.

Obtaining unanimity on a single basket of factors and on a common set of guidelines for interpretation and use of those factors at EU level is unlikely to be a straightforward or speedy process. But if Member States determined their own baskets of socio-economic factors on the basis of national priorities and public opinion there would be significant practical consequences:

- The process of researching, defining and consulting on their socio-economic factors and then codifying them into law would take time;

- The use of, potentially, 27 different baskets around the EU could create a significant new barrier to authorisation of GMOs.

Administrative burdens

The Austrian model, by which GMO-free areas (regions or nations) are recognised, would be straightforward to administer once the mechanisms were established but it does not, by definition, discriminate among GMO products. The alternative model of case-by-case evaluation, as per the Dutch proposals, prompts questions about the costs and administrative burdens of compiling and defining a socio-economic dossier, and who would bear these burdens. Some measures could be data-intensive and costly to estimate.

The total administrative burden and cost of developing a socio-economic dossier for a given GMO will be greater if the basket of socio-economic factors on which opt-out decisions are made varied among Member States. It is not hard to imagine that companies (if they were responsible for the dossier) would not develop dossiers for small markets, potentially impacting on the Single Market, and perhaps resulting in Member States being unable to notify the Commission of whether or not they wished to opt out.

The extent to which individual socio-economic factors are considered on a case-by-case basis for each authorisation, or subject to generic strategic policy guidance at Member State or EU level would need to be determined. It

may be that Member States would want to set general guidance on some factors in the basket but examine others on a case-by-case basis. This could potentially reduce time and effort required for case-by-case appraisals.

Evidence

There is concern, particularly with the industry, about how robust and defensible *ex ante* assessments of the socio-economic impacts of a given GMO could be prepared. Issues include:

- ***Robustness:*** The future success of a new product in the market, in terms of uptake by farmers, is uncertain. The net economic impact on the farming sector of a given product is generally hard to determine retrospectively and very difficult to project in advance – the assumptions used in ex ante projections would be open to legitimate challenge. The industry prefers the current legislation's focus on a science-based risk assessment and authorisation of products deemed safe.

- ***Stability***: There may be issues of the stability of socio-economic evidence over time if, for instance, measures of public opinion were incorporated into the basket as some have suggested. If measures on key indicators change (shifting the composition of the basket), would Member States seek to (or be allowed to) review their opt-out decision?

- ***Reach:*** A decision would be needed on whether evidence gathered outside the EU would be admissible as evidence in the socio-economic dossier (e.g. economic impact on farm enterprises cultivating the GMO in North America), and on what terms.

3.3 The reforms would add complexity to the marketing of authorised GM products

The Dutch and Austrian proposals both, in effect, separate the authorisation for placing the GMO on the European market from the authorisation to cultivate (it being the cultivation stage that gives rise to the potential for environmental risk).

As noted above, a system of national socio-economic assessments (rather than a centralised EU socio-economic appraisal) could result in companies (if it was their responsibility) only compiling dossiers for the largest markets.

This could potentially leave some markets under-served, in a situation analogous to that seen in the EU veterinary medicines market (though there it is the hurdle of national safety, rather than socio-economic, approvals that discourages marketing).

Exactly how the constraint on cultivation would be applied and enforced, and the integrity of the Single Market in purchase and sale of seed protected, is the matter of some debate. There are systems in similar markets (e.g. for pesticide) by which products can only be marketed in some countries following specific national approval. As with these systems, it would be farmers, rather than the seed marketer, who would be held liable for planting a GMO seed in a jurisdiction that had opted-out of cultivating that product.

Labelling requirements are potentially an issue if seed has to be labelled with details of those locations in which it is not authorised for cultivation:

- In practical terms (if/when Member State decisions change);
- In the context of WTO rules; and
- As an additional cost burden on companies.

3.4 An appraisal of the legal opportunities and constraints at international, EU and national levels is a high priority

Opt-out decisions taken at Member State level would need to have a firm basis in national and EU law, and be consistent with the EU's international legal obligations.

The extent to which the changes being discussed would create additional difficulties for the EU at the World Trade Organisation has not yet been determined and is a matter of some uncertainty. This is a factor that needs further investigation.

Under a reformed system built on self-determination there would need to be a mechanism by which Member States' national and sub-national decisions were recognised and recorded at EU level. It is presumed that the decisions would be that of the Member State, recognised by the European Union.

Legislation would need to define who had the responsibility to compile the socio-economic dossier (e.g. Member State institutions or the organisation seeking authorisation for cultivation), its composition and how it should be processed. There may be questions of how that data gathering and analysis work is funded.

These considerations might mean amendment of the current EU legislation. There is widespread nervousness about any opening up of the legislation. This stems from a belief that this cannot in reality be done in a 'controlled' and 'limited' fashion because of the potential for the European Parliament and others to open up and propose changes in other areas. There is the potential for unanticipated changes and outcomes.

Provision of a firm legal foundation for national decisions might well require primary legislation in some Member States. Where this is the case there would be a significant delay before the revised system could come into effect: development of the various national proposals, consultation, their passage through parliament and entry into force would take a number of years.

A legal appraisal is needed to determine opportunities, constraints and options in the context of international, EU and national law. This is a high priority in order to avoid time being spent on development of options that subsequently prove not to be viable by virtue of their direct or indirect legal consequences (e.g. that they would entail a multitude of 5-10 year legislative processes across the Member States).

As a general case there is more interest in looking at what can be achieved within the scope of existing EU legislation than in reopening it, or of forcing the creation of a new tier of laws at Member State level.

4 PERSPECTIVES

This section briefly examines the outline proposals from the perspective of different actors: farmers, consumers, biotech/seed companies and Member States.

4.1 Farmers

The proposed reforms might result in a situation in which a given GMO crop can be cultivated in one Member State but not in another. There is concern amongst some in the EU agricultural system that it would create new competitive tensions between farmers in different countries and erode the pan-EU agricultural market. On the other hand it would allow farmers to exercise choice and pursue their own market strategies. It could, for instance, demonstrate the strength of the market for GM-free provenance.

The changes to the authorisation system discussed here would not change the portfolio of GMO products in the authorisation or research pipeline. Those products currently awaiting approval would only ever be cultivated in a subset of Member States for agronomic reasons.

However, in so far as the changes would lead to more authorisations and the cultivation of GMOs in more locations in the EU, they would increase the use of existing rules for managing co-existence and, for instance, the interface between organic and GM farming.

4.2 Citizens and consumers

As a general case, GMO cultivation is not a front-of-mind public issue at present. With no new authorisations for cultivation for more than 10 years, the debates have less energy than they once did. However, the process of defining national socio-economic criteria (if that happened) would be expected to increase the level of public interest and participation.

Even if GMO cultivation became more extensive that would not necessarily result in any immediate changes to consumer exposure to GMO-derived food products at the supermarket. Maize and soya bean products are generally channelled into animal feed and processing. The EU is now reliant on imported supplies of animal feed, including approved GM varieties. There appear to be differences in consumer attitudes to GMOs in the supply chain (including animal feed), as opposed to for personal consumption.

4.3 Biotechnology and seed companies

The biotechnology and seed industry in Europe wants to see an end to the current impasse. But changes could create worse problems by, for instance, building in requirements for assessments that result in additional delays, uncertainties and added cost. Measures that create new barriers within the Single Market are likely to be problematic.

The industry's general view is that the first-best solution would be for the existing legislative framework to be operated 'as intended', with products being authorised to be placed on the market once they have received a favourable appraisal in a science-based risk assessment.

4.3 Member States

The support for the Austrian note to Council shows that there is general, in-principle, interest, among Member States in exploring new options and breaking the current deadlock. But decisions about changes will be made on the merits of the proposals put forward.

For Member State politicians, the proposed reforms would put decisions that are currently taken behind closed doors in Brussels into the hands of ministers and administrations of national government. Lines of accountability would change.

Options that involved a case-by-case approach and high level of decentralisation - e.g. the development and implementation of new national laws, the definition of Member State-specific baskets of socio-economic factors – would result in an additional administrative burden. There could also be additional duties in assembly and/or scrutiny of the socio-economic dossier on individual GMOs, depending on how the system was designed and where reporting obligations fell.

Member States would need to develop systems for determination of the opt-out decision. It is generally agreed that this would need to be open to public engagement and scrutiny, and seen to be legitimate and fair. Some Member States have established institutions that could take on this task, but for others it might require new arrangements.

Stakeholders suggested that, at least in some instances, Member States laws would need to be able to provide regional autonomy and recognise decisions by devolved administrations. In that context, different parts of a given Member State may make different choices about whether to accept cultivation of a GMO.

5 IN CONCLUSION

Despite the attractions of the Member State opt-out concept and more explicit consideration of socio-economic factors, an administrative 'quick fix' to the deadlock in EU decision-making on GMO cultivation may prove elusive.

To be viable the proposals that emerge from the current reviews need to define a system that will:

- Have a firm international, EU, and national legal basis;
- Be achievable within a reasonable period of time;
- Plausibly address the issues that are blocking decision-making now whilst avoiding creating new barriers to timely EU decisions.

Without those guarantees in place there is concern that the EU could embark on a protracted process of legislative review, definition of new systems and formulation of new guidance but end up with a system less workable and no faster or more certain that that which it started with.

The opt-out facility does not, itself, provide a guarantee that the disputes over the appraisal of the risk assessment, its scope and detail, will end. Member States would still have the freedom to pursue existing lines of argument and, if so minded, vote against Commission Decisions on the basis that the EFSA Opinion was flawed[1].

Preliminary analysis suggests that blanket opt-outs (i.e. the formal recognition by the EU of self-declared GM-free regions or GM-free nations) would probably be less cumbersome to administer than case-by-case socio-economic evaluations, assuming the former could be accommodated within EU law. But further development of options is required, set in the context of the appraisal of the legal opportunities and constraints. There is interest in what could be achieved within the existing EU legislative framework among those who are unwilling to embark upon changes to the current laws.

Changing current arrangements for GMO cultivation would consume time and energy of the Member States, Commission, industry, NGOs and others. There is an opportunity cost associated with dedicating this effort to reform of GMO cultivation authorisations and some stakeholders would prefer to see that effort spent on other issues that they regard as more critical to rebuilding the sustainability of the EU's food system and its broader food security.

ANNEX 1 THE AUSTRIAN NOTE TO THE JUNE 2009 ENVIRONMENT COUNCIL

23 June 2009[2]

Note from: General Secretariat to: Delegations

Subject: Genetically Modified Organisms - A Way Forward

Information from the Austrian delegation

Note submitted by the Austrian delegation, supported by Bulgaria, Ireland, Greece, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland and Slovenia

Background

The authorisation of GMOs is one of those rare subjects of EU legislation where no qualified majority has been achieved in recent years. In accordance with Council Decision 1999/468/EC on Committee Procedure and in the absence of a qualified majority, it has primarily been the European Commission which has adopted decisions for the authorisation of GMOs.

On four occasions, a qualified majority in Council voted against EC proposals to lift the safeguard clauses invoked with regard to certain GMOs by several Member States: in June 2005, in December 2006, in February 2007 and most recently in March 2009. These safeguard clauses concerned in particular GMOs approved for cultivation.

The French EU Presidency showed great initiative by establishing the Ad hoc Council Working Party on GMOs in the second half of 2008, which resulted in unanimous Council conclusions on 4 December 2008. These Council conclusions called inter alia for a strengthening of environmental risk assessment, more freedom for Member States to decide upon GMO-free zones on their national territory and the appraisal of socio-economic benefits and risks.

The Netherlands delegation came up with a declaration at the last Environment Council on 2 March 2009 calling for Member States to have the right to decide for themselves on the cultivation of GMOs. The delegations

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[1] Since 2005 all cultivation applications have been made under Regulation 1829/2003, under which EFSA issued an Opinion.

[2] http://register.consilium.europa.eu/pdf/en/09/st11/st11226-re02.en09.pdf

cited above appreciate this initiative and are willing to develop it further in order to find a satisfactory long-term solution.

The Way Forward

Given the unsatisfactory situation and the negative attitude towards GMOs of large parts of the population in many Member States, the time has come to find a new approach to deal with the authorisation and use of GMOs in agriculture.

In addition to reasons of nature conservation and biodiversity, the delegations supporting this initiative are of the opinion that relevant socio-economic aspects could form a basis for individual Member States to prohibit or regulate the cultivation of GMOs on the whole territory, or certain defined areas, of individual Member States. However, there is currently no methodology available for defining and evaluating socio-economic criteria. Such criteria could be discussed and agreed upon during the process of discussion on socio-economic aspects that started with the adoption of the Council conclusions of 2008.

In anticipation of the development of socio-economic criteria, we believe that options should be considered which could allow Member States to decide for themselves as regards cultivation, without changing the general authorisation procedure for placing GMOs and products thereof on the market. In this context it should be noted that the Commission has started a process to re-evaluate the respective Regulations on GMOs, i.e. Directive 2001/18/EC and Regulation (EC) No 1829/2003.

The legally soundest solution we envisage is a set of minor amendments to relevant EU legislation, which should introduce the right of an individual Member State to restrict or prohibit indefinitely the cultivation of authorised GMOs on its territory. The amendments could be based on the subsidiarity principle (Article 5 TEC) and the principle of unanimity for decisions on land use (Article 175 TEC). Such an “opt-out” clause could be formulated in quite straightforward legal terms and could easily be integrated into the existing legislation.

The Member States supporting this initiative urge the Commission to put forward a proposal on the basis of this discussion on GMOs and possible additional options, with the common goal of finding a solution acceptable to all Member States as soon as possible.

All Member States supporting this note are willing to discuss any further options and proposals which might arise.

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Citations

Title: *A Way Forward for GMO Cultivation in Europe?*

A Chatham House Programme Paper, November 2009.

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