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*Committee on the Environment, Public Health and Food Safety*

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**2010/0208(COD)**

27.1.2011

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## **DRAFT REPORT**

on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory (COM(2010)0375 – C7-0178/2010 – 2010/0208(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Corinne Lepage

### ***Symbols for procedures***

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

### ***Amendments to a draft act***

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory (COM(2010)0375 – C7-0178/2010 – 2010/0208(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2010)0375),
  - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0178/2010),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 9 December 2010<sup>1</sup>,
  - having regard to Rule 55 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A7-0000/2011),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

### **Amendment 1**

**Proposal for a regulation – amending act**  
**Citation 1**

*Text proposed by the Commission*

Having regard to the Treaty on the Functioning of the European Union, and in particular Article **114** [...] thereof,

*Amendment*

Having regard to the Treaty on the Functioning of the European Union, and in particular Article **192** thereof,

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<sup>1</sup> Not yet published in the Official Journal.

*Justification*

*The fact that Member States are responsible for factors relating to the conservation of fauna and flora, land use or town and country planning, on which they retain significant powers, justifies basing this Regulation on Article 192 of the Treaty.*

**Amendment 2****Proposal for a regulation – amending act  
Recital 2***Text proposed by the Commission*

(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.

*Amendment*

(2) Under this set of legislation, GMOs for cultivation shall undergo an individual assessment **of direct and indirect short-term and long-term risks** 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.

*Justification*

*Given the priority nature of the better enforcement of Directive 2001/18, it is necessary to reiterate the specific terms concerning the existing legislative requirements on assessing the environmental risks of GMOs.*

**Amendment 3****Proposal for a regulation – amending act  
Recital 2 a (new)***Text proposed by the Commission**Amendment*

**2a. In this connection, the Commission should accord priority to ensuring the correct enforcement of the legal requirements applicable to the GMO risk**

*assessment, as laid down by Directive 2001/18/EC and Annex II thereof in particular, including by the European agencies responsible for this assessment, in accordance with the conclusions of the 'Environment' Council meeting of 4 December 2008. All the Council's requests regarding the expertise procedure and the scope of the assessment should be enforced in order to ensure the implementation of Directive 2001/18/EC. Enforcement of these legal requirements is necessary in order to establish the necessary trust in the risk assessment and in the institutions responsible for this assessment. More specifically, the Commission should ensure that the new guidelines on GMO risk assessment are adopted. These guidelines should not be based primarily on the principle of substantial equivalence or on the concept of a comparative safety assessment, and should make it possible to clearly identify direct and indirect long-term effects, as well as scientific uncertainties. The Commission should also ensure that the assessment procedures guarantee the full involvement of the Member States, competent scientific bodies and other relevant stakeholders, and that changes in herbicide usage as a result of herbicide-tolerant GMOs are assessed, taking into account national policies aimed at reducing the use of pesticides.*

Or. fr

#### *Justification*

*Ce nouveau considérant reprend les demandes principales du Conseil exprimées dans les conclusions du 4 décembre 2008, adoptées à l'unanimité. Elles concernent l'amélioration de la mise en œuvre de l'évaluation du risque telle que prévue par la Directive 2001/18/EC sur la dissémination volontaire d'OGM dans l'environnement. Afin de restaurer la confiance de l'opinion publique dans les processus d'évaluation, il ne saurait être question de laisser croire qu'une plus grande flexibilité serait accordée aux Etats membres en échange d'un affaiblissement des exigences liées à l'évaluation du risque au niveau communautaire.*

## Amendment 4

### Proposal for a regulation – amending act Recital 7

#### *Text proposed by the Commission*

(7) Member States should therefore be authorised to adopt measures restricting or prohibiting 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 and plant propagating material which are placed on the market in accordance with relevant legislation on the marketing of seeds and plant propagating material and, in particular, in accordance with Directives 2002/53/EC and 2002/55/EC. Measures should refer to the cultivation of GMOs only and not to the free circulation and import of genetically modified seeds and plant propagating material, as or in products, and of the products of their harvest. Similarly they should not affect the cultivation of non genetically modified varieties of seed and plant propagating material in which adventitious or technically unavoidable traces of EU authorised GMOs are found.

#### *Amendment*

(7) Member States should therefore be authorised to adopt measures restricting or prohibiting 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. **Cultivation is in fact closely linked to land use and the conservation of fauna and flora, areas in which the Member States retain significant powers. The possibility of adopting these measures** should apply as well to genetically modified varieties of seed and plant propagating material which are placed on the market in accordance with relevant legislation on the marketing of seeds and plant propagating material and, in particular, in accordance with Directives 2002/53/EC and 2002/55/EC. Measures should refer to the cultivation of GMOs only and not to the free circulation and import of genetically modified seeds and plant propagating material, as or in products, and of the products of their harvest. Similarly they should not affect the cultivation of non genetically modified varieties of seed and plant propagating material in which adventitious or technically unavoidable traces of EU authorised GMOs are found.

Or. fr

#### *Justification*

*The Commission justifies the use of subsidiarity and recommendations on the issue of coexistence on the grounds of the diversity of agricultural practices among and within the Member States. Ecosystems and receiving environments are subject to comparable diversity. The cultivation of GMOs also touches on territorial matters over which the Member States*

*still have significant powers.*

## **Amendment 5**

### **Proposal for a regulation – amending act Recital 8**

#### *Text proposed by the Commission*

(8) According to the legal framework for the authorisation of GMOs, the level of protection of human/animal health and of the environment chosen in the *EU* cannot be revised by a Member State and this situation *must* not be altered. However Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs in all or part of their territory on the basis of grounds relating to the public interest *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 health and the environment*. Those measures should furthermore be in conformity with the Treaties, in particular as regards the principle of non discrimination between national and non national products and Articles 34 and 36 of the Treaty on the Functioning of the European Union, as well as with the relevant international obligations of the Union, notably in the context of the World Trade Organisation.

#### *Amendment*

(8) According to the legal framework for the authorisation of GMOs, the level of protection of human/animal health and of the environment chosen in the *Union* cannot be revised by a Member State and this situation *should* not be altered. However Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs in all or part of their territory on the basis of grounds relating to the public interest ***complementary to, or differing from,*** those already *assessed* by the harmonised set of *Union* rules. ***The grounds given by the Member States may include consideration of environmental impacts complementary to those already covered by the risk assessment provided for in Part C of Directive 2001/18/EC, and may thus, at least partially, include the consideration of scientific data relating to the central, local or regional environmental impact on receiving environments. These grounds may also depend on factors that are not directly connected with the risk assessment, but are linked to risk management or other national policies. The grounds given by the Member States may also include, inter alia, the risk of resistance development in weeds or in the target organisms, or the invasive potential of the plant. They may also include socio-economic considerations such as the practicality and cost of the measures laid down in Article 26a of Directive 2001/18/EC for avoiding the unintended presence of GMOs in other products, fragmentation of the territory, changes in***

***agricultural practices linked to intellectual property regimes, or social policy objectives such as the conservation of diversity or distinctive agricultural practices.*** Those measures should furthermore be in conformity with the Treaties, in particular as regards the principle of non discrimination between national and non national products and Articles 34 and 36 of the Treaty on the Functioning of the European Union, as well as with the relevant international obligations of the Union, notably in the context of the World Trade Organisation.

Or. fr

### *Justification*

*The examination of the national, regional or local impact of the cultivation of one or more GMOs with similar characteristics always requires at least some scientific data and touches on environmental aspects which may - or may not - already have been examined at Community level. The consideration of environmental grounds is consistent, but is also the aspect which gives the Member States the soundest legal bases for taking national measures.*

## **Amendment 6**

### **Proposal for a regulation – amending act Recital 9**

#### *Text proposed by the Commission*

(9) On the basis of the subsidiarity principle, the purpose of this Regulation is not to harmonize the conditions of cultivation in Member States but to grant freedom to Member States to invoke ***other*** grounds ***than*** scientific assessment of health and environmental risks to ban cultivation of GMOs on their territory. In addition, one of the purposes of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations which is to allow the Commission to consider the adoption

#### *Amendment*

(9) On the basis of the subsidiarity principle, the purpose of this Regulation is not to harmonize the conditions of cultivation in Member States but to grant freedom to Member States to invoke grounds ***complementary to, or differing from, the*** scientific assessment of health and environmental risks to ban cultivation of GMOs on their territory. In addition, one of the purposes of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations which is to allow the

of binding acts at *EU* level would not be served by the systematic notification of Member States' measures under that Directive. Moreover, since measures which Member States can adopt under this Regulation cannot have as a subject the placing of the market of GMOs and thus does not modify the conditions of placing on the market of GMOs authorised under the existing legislation, the notification procedure under Directive 98/34/EC does not appear the most appropriate information channel for the Commission. Therefore, by derogation, Directive 98/34/EC should not be applicable. A simpler notification system of the national measures prior to their adoption appears to be a more proportionate tool for the Commission to be aware of these measures. Measures which Member States intend to adopt should thus be communicated together with their reasons to the Commission and to the other Member States one month prior to their adoption for information purposes.

Commission to consider the adoption of binding acts at *Union* level would not be served by the systematic notification of Member States' measures under that Directive. Moreover, since measures which Member States can adopt under this Regulation cannot have as a subject the placing of the market of GMOs and thus does not modify the conditions of placing on the market of GMOs authorised under the existing legislation, the notification procedure under Directive 98/34/EC does not appear the most appropriate information channel for the Commission. Therefore, by derogation, Directive 98/34/EC should not be applicable. A simpler notification system of the national measures prior to their adoption appears to be a more proportionate tool for the Commission to be aware of these measures. Measures which Member States intend to adopt should thus be communicated together with their reasons to the Commission and to the other Member States one month prior to their adoption for information purposes.

Or. fr

### *Justification*

*The Community risk assessment cannot examine the impact of a GMO within all ecosystems or receiving environments concerned, and certain environmental or agri-environmental aspects are not examined during the Community assessment. Member States should thus be allowed to invoke environmental grounds, without these grounds necessarily challenging the assessment conducted at Community level, which cannot be exhaustive.*

### **Amendment 7**

#### **Proposal for a regulation – amending act**

#### **Article 1 – point -1 (new)**

Directive 2001/18/EC

Article 26 a – paragraph 1

*Text proposed by the Commission*

*Amendment*

***Directive 2001/18/EC shall be amended as***

*follows:*

*-1) Article 26a(1) shall be replaced by the following:*

**"1. Member States shall take appropriate measures to avoid the unintended presence of GMOs in other products.";**

Or. fr

*Justification*

*The possible cultivation of GMOs should not result in additional costs for farmers working in conventional or organic farming. It should thus be compulsory for Member States to take measures to avoid the presence of GMOs in other products, measures which are at the moment optional under the current wording of Article 26a. Specific attention should be paid to any possible cross-border contamination.*

**Amendment 8**

**Proposal for a regulation – amending act**

**Article 1 – point 1**

Directive 2001/18/CE

Article 26 b

*Text proposed by the Commission*

***In Directive 2001/18/EC, the following Article shall be inserted with effect from the date of entry into force of this Regulation:***

'Article 26b

Cultivation

Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of 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 their territory, provided that:

a) those measures are based on grounds ***other than those related to the assessment***

*Amendment*

***1) The following Article shall be inserted:***

'Article 26b

Cultivation

Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties placed on the market in accordance with relevant *Union* legislation on the marketing of seed and plant propagating material, in all or part of their territory, provided that:

a) those measures are based on

***of the adverse effect on health and environment*** which might arise from the deliberate release or the placing on the market of GMOs;

***i) grounds relating to environmental impacts*** which might arise from the deliberate release or the placing on the market of GMOs, ***and which are complementary to the environmental impacts examined during the assessment of the negative impacts on the environment conducted under Part C of this Directive; or***

***ii) the absence or lack of data on the potential negative impacts of the release of GMOs on the territory or biodiversity of the Member State; or***

***iii) other grounds that may include, inter alia, changes in agricultural practices, land use, town and country planning, socio-economic impacts, or other legitimate factors;***

and

b) that they are in conformity with the Treaties.

By way of derogation to Directive 98/34/EC, Member States that intend to adopt reasoned measures under this Article shall communicate them to the other Member States and to the Commission, one month prior to their adoption for information purposes'.

and

b) that they are in conformity with the Treaties.

By way of derogation to Directive 98/34/EC, Member States that intend to adopt reasoned measures under this Article shall communicate them to the other Member States and to the Commission, one month prior to their adoption for information purposes'.

Or. fr

#### *Justification*

*The risk assessment conducted at Community level cannot be exhaustive. In addition, the absence or lack of data relating to the potential negative impacts of GMOs on specific national ecosystems or receiving environments should be a sufficient reason to allow Member States to ban the cultivation of the GMO(s) concerned. It should also be possible for Member States to invoke other factors which may or may not be linked to environmental impacts.*

## Amendment 9

### Proposal for a regulation – amending act Article 2

#### *Text proposed by the Commission*

This Regulation shall enter into force on the *[...]* day following that of its publication in the Official Journal of the European Union.

#### *Amendment*

This Regulation shall enter into force on the ***twentieth*** day following that of its publication in the Official Journal of the European Union.

Or. fr

## EXPLANATORY STATEMENT

### 1 - Background

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 (GMOs) and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed establish a very tight framework which, if correctly enforced, should offer 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. The Directive only allows GMOs to be placed on the market if a specific environmental risk assessment has been carried out in accordance with the principles set out in Annex II and on the basis of information provided by the notifier and specified in Annex III. Annex II, which establishes the principles applicable to the environmental risk assessment, requires that direct and indirect immediate and delayed effects be taken into account, as well as an analysis of the cumulative long-term effects relevant to the release and the placing on the market of the GMO. These cumulative long-term effects refer to the accumulated effects of consents on human health and the environment, including on flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

Annexes II and III of the Directive specify the need to conduct studies on the conditions of release and the receiving environment, involving an in-depth study of the receiving environments in which cultivation is foreseen, as well as information on the interactions between the GMOs and the environment.

Annexes III to VII call for information on monitoring, control, waste treatment and emergency response plans, covering monitoring techniques, control of the release, waste treatment and especially emergency response plans to allow the introduction of methods for decontamination of the areas affected, isolation of the affected areas, and the protection of human health and the environment should undesirable effects occur.

Directive 2001/18 also states in Article 19 entitled 'Consent' that when a consent has been given for the placing on the market of a GMO, it can be used without further notification in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

### 2 – Objectives of the Commission proposal

This proposal is made against the backdrop of persistent opposition within European public opinion to the release of GMOs and their use in agriculture. According to the latest Eurobarometer survey on this issue published in October 2010, 61% of Europeans consider that GM food makes them feel uneasy and the same proportion (61%) disagree with the idea that the development of GM food should be encouraged. Only 21% agree (as opposed to the 58% who disagree) with the statement that 'GM food is safe for future generations'. Less than a quarter of European citizens (23%) agree with the idea that 'GM food does no harm to the

environment', whilst over 53% disagree with this statement (and a quarter 'don't know'). Finally, in no country was there a majority of respondents who agreed with the statement that GM food is good for the national economy.

The lack of trust placed by European public opinion in agricultural GMOs is first and foremost related to the fact that Directive 2001/18 has not been seriously enforced. The studies envisaged are not in fact conducted by the parties requesting authorisation, be they the studies on long-term effects, the prior studies on receiving environments, or the consideration of socio-economic impacts.

The requirements in the Directive regarding risk assessment are not being observed, and these shortcomings in its implementation explain the opposition encountered in several Member States to the cultivation of GMOs on their territory. It should be emphasised here that the cultivation and release of GM plants on the national territory is a separate issue from those of authorisations for marketing and consumption and the freedom of movement of goods and products, which are not covered by this text.

In its conclusions which it adopted unanimously on 4 December 2008, the Council called for the strengthening of environmental assessment and of monitoring arrangements; it noted that the mandate given by the Commission to EFSA included a detailed assessment of the long-term environmental effects of GM plants (GMPs), and development of the detailed risk assessment.

In accordance with the legislation, the Council asks in particular that consideration be given to the potential ecological effects of the GMPs in receiving environments, identification of the EU geographic regions where the GMPs may be released, and selection of appropriate techniques to assess the potential long-term effects including experimental methodologies. The Council also called for a stricter definition of the criteria and requirements for assessing GMPs, with the need to ensure coherence between risk assessments of GMPs which produce active substances covered by directive 91/414/EEC and those of the corresponding plant protection products.

The Council also demanded that regular and in-depth monitoring be performed and disclosed by authorisation holders in order to detect any potentially adverse effects foreseen by the Directive. The monitoring activities should be developed, and the findings forwarded to the Commission and made available to the general public. No serious monitoring study has, however, been carried out to date, and the control systems are not in place.

The Council also asked for the submission of a report on the implementation of the Directive, including an assessment, inter alia, of socio-economic implications of deliberate releases and placing on the market of GMOs, so that a report could be submitted by June 2010.

Finally, the Council sought improvements in how EFSA worked. At the time, it was stated that the Member States could have more opportunity to provide their views on the additional information provided by the notifier, that an extensive network of scientific organisations should be formed, that it was essential that any potential divergence between scientific opinions be identified and discussed, that it was essential that systematic and independent research be conducted on the risks, and that independent researchers should be given access to

all relevant material. Few independent studies have, however, been conducted into the risks. Furthermore, even though clear conflicts of interest have been discovered, a reform of the expertise procedures at EFSA seems to be on the agenda but has not yet been undertaken.

As a result, the reluctance shown by some Member States seem to be fully justified by these inconsistencies and shortcomings in the effective enforcement of Directive 2001/18, and thus of Regulation 1829/2003.

The primary objective is therefore to progress towards the effective application of the existing legislation on risk assessment.

### 3 – Legal elements of the proposal

In this context, the objective of the Commission proposal for a regulation to give Member States competence on the use of their territory to grow GMOs is welcome. It should be coupled with the drafting of new guidelines on the assessment of health and environmental risks which must finally allow for the effective application of the rules laid down by Directive 2001/18 and Annex II thereof. This proposal should also be read in the light of Article 19(1) of the Directive that defines the specific conditions of use on which the Member States should be more demanding.

First of all, the wording of the proposal should not be limited to a negative definition of the grounds that may be invoked by the Member States. The respective opinions issued by Council and Parliament's legal services both expressed strong reservations about the legality of national measures that could be taken by Member States on the basis of reasons that had very little to do with environmental considerations, such as public morality, public order or ethics. It was also time to recognise that the environmental risk assessment conducted at Community level could not be exhaustive given the diversity of European ecosystems and the diversity of possible direct or indirect impacts.

In order to comply with the internal market and the Community assessments – provided that the necessary reforms are able to restore the credibility of EFSA's GMO panel – the grounds invoked by the Member States should be supplementary to those assessed by EFSA. The grounds invoked by the Member States may not then exclude environmental or agri-environmental grounds, particularly those of a local and/or regional nature, which have not been covered by a Community assessment. The grounds invoked by the Member States will inevitably be based at least partly on scientific data if they concern some form of environmental impact .

The distinction made by the Commission in its explanatory memorandum between a 'scientific' assessment conducted at Community level on the one hand, and grounds that have nothing to do with the scientific debate on the environmental impact on the other, is simplistic and takes no account of the complexity of the link between risk assessment and risk management. This distinction also ignores the fact that the failure to consider scientific uncertainties, although provision is made for this in the texts, may make it difficult to reach appropriate risk management decisions, or indeed to apply the precautionary principle. Whether it be the impact of using a herbicide associated with a herbicide-tolerant GM plant,

the impact of changes in agricultural practices caused by the use of a GMO, or the risk of harmful insects developing resistance to Bt toxins in a given region, all these aspects involve an assessment of scientific data - or the lack thereof - relating to the environmental impact.

On the issue of the contamination of conventional or organic farming by GMOs, also known as 'coexistence', the Commission has always justified its refusal to legislate at Community level by the diversity of agricultural practices, climates and geography among and within Member States. This same diversity exists for ecosystems and receiving environments, and justifies the application of subsidiarity to the cultivation of GMOs, following the same logic.

Finally, in order to put an end to the current situation regarding the absence of studies, even though these are required by the existing legislation, the Member States should be given greater powers where there is a lack of relevant information about the impact on the national, regional and/or local territory. It is necessary to respect the rights of the Member States when it comes to the use of their own territory, an area which is covered by subsidiarity and which in no way calls into question the rules governing the internal market and the free movement of goods and products throughout the territory of the Union.

The high level of protection in the field of health and the environment targeted by Directive 2001/18 and other Community texts can only be achieved if all the necessary studies on the receiving environment and the conditions in the monitoring plans are effectively at the disposal of the Member States, and take account of the specific characteristics of their territory, their agricultural methods and their spatial planning choices.

Finally, the measures taken by Member States should apply to a given GMO or, as the case may be, a group of GMOs with similar characteristics, rather than to all GMOs. These measures should be substantiated. The possible cultivation of a GMO should also not result in additional costs for farmers working in conventional or organic farming. It should thus be compulsory for Member States to take measures to avoid the presence of GMOs in other products, and particular attention should be paid to any possible cross-border contamination.