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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

on the freedom for Member States to decide on the cultivation of genetically modified crops

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1. INTRODUCTION

The European Union (EU) has adopted a comprehensive legal framework for the authorisation of products consisting of or derived from Genetically Modified Organisms (GMOs). The authorisation procedure covers the use of GMOs and their derived products for food and feed, industrial processing and cultivation.

The EU authorisation system aims at ensuring the safety of authorised GMOs while establishing an internal market for those products. Two pieces of legislation, namely Directive 2001/18/EC on the environmental release of GMOs[1] and Regulation (EC) No 1829/2003 on GM food and feed[2], provide for the pre-marketing authorisation of GMOs. Both set science based standards in terms of human health, animal health and environmental risk assessment. In addition, Regulation (EC) No 1830/2003[3] provides rules on the traceability and labelling of GMOs and the traceability of food and feed produced from GMOs.

The responsibility for the scientific assessment is assigned to the European Food Safety Authority (EFSA), but also to the scientific authorities of the Member States. The role of the Member States is particularly important in the authorisation of GMOs for cultivation, where they carry out the initial risk assessment of environmental aspects.

Since the adoption of the legal framework six years ago, seven Member States have prohibited or restricted cultivation on their territories through safeguard measures on individual authorized GMOs[4] or through general prohibitions of GM seeds[5]. In four different occasions[6], the Council has rejected by qualified majority all Commission proposals to repeal national safeguard measures on GMO cultivation even though in

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1 OJ L 106, 17.4.2001, p. 1.

2 OJ L 268, 18.10.2003, p. 1.

3 OJ L 268, 18.10.2003, p. 24.

4 Maize MON 810 has been prohibited by AT, HU and LU on the basis of Article 23 of Directive 2001/18/EC, EL on the basis of Article 23 of Directive 2001/18/EC and Article 18 of Directive 2002/53/EC, FR and DE on the basis of Article 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No1829/2003. Maize T 25 has been prohibited by AT on the basis of Article 23 of Directive 2001/18/EC. Amflora Potato has been banned by AT, HU and LU on the basis of Article 23 of Directive 2001/18/EC.

5 PL has also adopted a legislation prohibiting in general the marketing of GM seeds which was not based on the safeguard clauses set out in EU legislation. On 16 July 2009 the Court of Justice of the EU issued a judgement whereby it considered that legislation contrary to EU law and condemned Poland for failure to fulfil its obligations (case C-165/08).

6 June 2005, December 2006, February 2007 and March 2009.

all cases EU scientific assessments had concluded that these measures were not based on new or additional scientific information since the authorisations were granted and therefore such measures were not justified from a legal point of view.

The Council Conclusions of December 2008 considered the legislative framework on GMOs comprehensive and underlined the need to better implement the existing provisions, notably as concerns cultivation, while noting the necessity of continuing processing applications without undue delays. The Council conclusions identified particular areas for improvement of the implementation of the GMO legislation, on which work by the Commission and EFSA, in co-operation with the Member States, is currently ongoing.

Commission and EFSA, together with the Member States, are working on the particular areas for improvement of the implementation of the GMO legislation, identified by the 2008 Environment Council conclusions. The update of the EFSA guidelines for the environmental risk assessment is ongoing and covers the specific areas requested by the Council. EFSA is expected to finish the guidelines in the last quarter of 2010. The Commission will then discuss these updated guidelines with Member States to give them normative value with the Member States' endorsement.

Furthermore, the Commission is analysing how to further reinforce the post-market environmental monitoring of GMO crops, in line with the provisions of the current legislation and the 2008 Environment Council conclusions.

In December 2008, the Council requested the Commission as well to provide a report on the socio-economic implications of GMOs. This report should be based on information provided by Member States, which have made an important effort to compile information on the socio-economic implications of GMOs and, notably, of their cultivation. The Commission will finalize its report by the end of 2010. This report will then be submitted to the European Parliament and to the Council for consideration and further discussion.

As part of broader regular exercises of revision of EU legislation, the Commission has launched two evaluations in order to assess the EU legislative framework on GMOs: one on GM food and feed, the other on the cultivation of GMOs. The scope of these evaluations covers the major aspects of the legislative framework. The two evaluations will be finalised in the last quarter of 2010 and will be followed by an analysis of possible policy changes by mid-2012.

The 2008 Conclusions discussed as well at some length regional aspects of GMO cultivation, both in the context of the scientific risk assessment and of particular socio-economic implications. Some Member States have since called on the Commission to prepare proposals to give freedom to Member States to decide on cultivation of GMOs.

Against this background, the political guidelines for the new Commission set out by President Barroso in September 2009 and endorsed by the Commission in March 2010, indicated that 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.

The objective of this Communication is to clarify how to implement the freedom for Member States through an approach that combines a revision of the existing recommendation on coexistence, recognising that Member States need more flexibility, with a modification of the existing legislative framework.

2. A MORE FLEXIBLE APPROACH UNDER THE EXISTING LEGISLATION

2.1. The way forward: increase of flexibility for Member States on GMO cultivation

In line with Article 26a of Directive 2001/18/EC, Member States are entitled to take appropriate measures to avoid the unintended presence of GMOs in other products. Given the diversity of national, regional and local conditions under which European farmers work, the Commission has always considered that measures to avoid the unintended presence of GMOs in conventional and organic crops should be developed and implemented by the Member States.

In an attempt to support Member States in the process of developing national measures to avoid that presence, the Commission published in 2003 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[7]. The purpose of such national measures is to avoid the potential economic impact of the admixture of GM and non-GM crops (conventional and organic).

Experience gained over the last years shows that the approach applied on the basis of Recommendation 2003/556/EC does not exhaust the provisions of Article 26a of Directive 2001/18/EC, notably as concerns the Member States' entitlement to set measures to avoid the unintended presence of GMOs in other products. This is supported by the observation of the developments regarding GMO cultivation in the Member States. At present some Member States have adopted national co-existence measures that aim at reaching levels of presence of GMOs in other crops lower than 0.9%. Other Member States have provided different isolation requirements for organic production. In concrete terms, experience with the implementation of the 2003 Recommendation shows that the potential loss of income for organic and (sometimes) conventional producers is not limited to exceeding 0.9%.

Since certain types of agriculture production such as organic production[8] are often more costly, the possibility of losing the associated price premium due to unintended presence of GMOs may entail important economic damages to these types of production. Therefore such production may require stricter segregation efforts. In addition, local constraints and characteristics may render these particular segregation needs very difficult and costly to be met efficiently in some regions.

Furthermore, in certain cases, and depending on market demand and on the respective provisions of national legislations (e.g. some Member States have

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7 OJ L 189, 29.07.2003, p. 36.

8 In accordance with Regulation (EC) No 834/2007 on organic production and labelling of organic products, GMOs shall not be used in organic production, including as seeds, food or feed (Article 9(1)). The aim is to have the lowest possible presence of GMOs in organic products (see Recital 10).

developed national standards for different types of "GM-free" labelling), the presence of traces of GMOs in particular food products –even at a level close to 0.9%- may cause economic damages to operators who would wish to market them as non containing GMOs.

From the above, it appears that it is appropriate to revise the 2003 Recommendation on co-existence and replace it with a new one to reflect the experience gained with national measures on GMO cultivation so far and make it more flexible.

The new Recommendation further refers to the possibility for Member States to restrict GMO cultivation from large areas of their territory to avoid the unintended presence of GMOs on conventional and organic crops ("GM-free areas"). However, this possibility has to rest on the demonstration by Member States that for those areas other measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops. Moreover, the restriction measures need to be proportionate to the objective pursued (i.e. protection of particular needs of conventional or organic farming).

To these ends, the new Recommendation on guidelines for the development of national co-existence measures (annexed) limits its content to the main general principles for the development of measures to avoid GMO admixture thereby recognising the flexibility for Member States to take into account their regional and national specificities and the particular local needs of organic, conventional and other types of crops. This Recommendation is adopted by the Commission together with this Communication. The Commission will continue to develop together with Member States best practices for co-existence (work of the European Coexistence Bureau).

2.2. Other elements linked to the EU framework of GMO authorisation

It should also be noted that the existing legislative framework on GMOs consists of a clear European Union wide authorisation system, based on a scientific risk assessment. It is possible in principle to differentiate between regions in the risk assessment, on the basis of scientific arguments[9]. If the risk assessment concludes that the cultivation of a GMO raises particular regional concerns, these concerns must be addressed in the EU authorisation through specific conditions or risk management measures. Such measures may include restriction or prohibition measures, if scientifically justified.

Regulation (EC) No 1829/2003 also provides for the possibility for the Commission to take into account legitimate factors other than science in the context of the procedure of authorisation of GMOs to restrict or prohibit their placing on the market However, justifications for such restrictions need to be specific to each GMO and can only be taken into account at the moment of the adoption of the decision of authorisation of the GMO in question. In addition this possibility does not exist under Directive 2001/18/EC and would thus not be applicable to GMOs authorised under this Directive.

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[9] In line with Article 19(3)(c) and Annex II of Directive 2001/18/EC and Article 6 and Article 18 of Regulation (EC) No 1829/2003.

Therefore, it appears that the existing framework within which scientific arguments or other legitimate factors may be applied to justify restrictions or prohibitions of GMO cultivation, does not provide the necessary freedom for Member States to decide whether or not they wish to cultivate GMOs in their territory on the basis of their specific conditions.

3. LEGISLATIVE AMENDMENT TO INTRODUCE AN "OPT-OUT CLAUSE"

A certain number of Member States want to have the possibility to opt-out from GM cultivation. So far, several of these Member States have banned the cultivation of GMOs on the basis of the safeguard clause set out in Article 23 of Directive 2001/18/EC or the emergency measures referred to in Article 34 of Regulation (EC) No 1829/2003, which are solely intended to address new risks emerging after an authorisation has been granted. As a result, these measures were not considered to be scientifically justified by the European Food Safety Authority (EFSA). Similarly a certain number of regions have declared themselves to be "GM-free".

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 political or 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 broad nature conservation goals.

The Netherlands submitted a declaration to the 23 March 2009 Agriculture and Environment Councils[10] asking the Commission to come forward with a solution on cultivation while taking into account the socio-economic dimension of GMO cultivation and keeping the internal market for GM food and feed products. Austria, supported by twelve Member States[11], presented in the Environment Council of 25 June 2009 a paper[12] that underlined the subsidiarity issue linked to cultivation and suggested an opt-out clause for cultivation to be introduced in the legislation.

In this context it appears appropriate to amend 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 on the basis of their specific conditions. This amendment can be done through the inclusion of a new Article 26b in Directive 2001/18/EC and would be applicable to all GMOs which have been authorised for cultivation in the EU, being under Directive 2001/18/EC or under Regulation (EC) No 1829/2003.

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, with the new legal base, Member States will be able to adopt measures restricting or prohibiting the cultivation of all or particular GMOs in all or part of their territory on

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10 Note with ref. 7581/09 of the Council of the European Union.

11 BG, IE, EL, CY, LV, LT, HU, LU, MT, NL, PL and SI.

12 Note with ref. 11226/2/09 REV 2 of the Council of the European Union.

the basis of 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 health and the environment.

Moreover, these national measures will have to be in conformity with the Treaties in particular 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 concerning the free circulation of goods. 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 and the products of their harvest. These measures shall also be consistent with EU international obligations, notably those in the context of the World Trade Organisation. To ensure transparency, Member States which intend to adopt measures will have to communicate them, together with their reasons, to the Commission and to the other Member States one month prior to their adoption.

Member States would be further free to amend these measures as they deem appropriate at all stages of the authorisation or re-authorisation of the concerned GMOs.

In summary, this new legal basis does not change the system of EU authorisations of GMOs but it would allow Member States to adopt measures which would be applicable to GMOs which have been authorised under the existing legislation. It is thus a further option for Member States to adopt measures in relation to authorised GMOs, in addition to the measures that they are already entitled to take by application of Article 26a of Directive 2001/18/EC to avoid the unintended presence of GMOs in other crops.

Therefore, and on the basis of the above principles, the Commission has decided to submit to the European Parliament and the Council a legislative proposal which takes the form of a Regulation amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

4. CONCLUSIONS

The Commission considers that this new approach is necessary to achieve the right balance between maintaining the EU system of authorisations based on scientific assessment of health and environmental risks and the need to grant freedom to Member States to address specific national, regional or local issues raised by the cultivation of GMOs.

As a first step a revision of the existing Recommendation on co-existence (2003/556/EC) will better reflect the possibilities offered to Member States to adopt measures to avoid unintended presence of GMOs in conventional and organic crops in accordance with the existing legislative framework.

In a second step, the adoption of the legislative proposal providing the possibility for Member States to restrict or prohibit, under certain conditions, the cultivation of all or particular GMOs in part or all their territory by the European Parliament and the

Council will offer the possibility to Member States to address specific national or local issues raised by the cultivation of GMOs independently of the authorisation process. This approach on GMO cultivation, while preserving the European Union authorisation system of GMOs, which will continue to apply, as well as the free circulation and import of GM food, feed and seeds, is expected to address the demands of several Member States, and receive stakeholders and public support. It is also in line with the observation of the reality of Member States' practice on GMO cultivation so far and the principle of subsidiarity and proportionality. Meanwhile, the Commission will continue to apply the existing EU legislative framework on GMOs. In this context, and in line with Article 31 of Directive 2001/18/EC, the reports on the implementation of the Directive will pay particular attention to experience acquired with regard to Article 26a and 26b.

The new Recommendation on guidelines for the development of national cultivation measures to avoid the unintended presence of GMOs in conventional and organic crops and a legislative proposal modifying Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, are annexed to this Communication.