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EUROPEAN COMMISSION



Brussels, 13.7.2010 C(2010) 4822 final

COMMISSION RECOMMENDATION

on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops

{COM(2010) 375 final} {COM(2010) 380 final}

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COMMISSION RECOMMENDATION

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union (EU), and in particular Article 292 thereof.

Having regard to Article 26a, second paragraph, of 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 repealing Council Directive 90/220/EC¹,

Whereas:

- (1) Article 26a of Directive 2001/18/EC provides that Member States may take appropriate measures to avoid the unintended presence of genetically modified organisms (GMOs) in other products. This applies in particular to avoiding the presence of GMOs in other crops, such as conventional or organic.
- (2) Farm structures and farming systems, and the economic and natural conditions under which farmers in the European Union operate, are extremely diverse. The diversity of farming systems and natural and economic conditions in the EU needs to be taken into consideration when designing measures to avoid the unintended presence of GM crops in other crops.
- (3) It may be necessary for Member States' public authorities to define, in the areas where GMOs are cultivated, appropriate measures to allow consumers and producers a choice between conventional, organic and GM production (hereinafter referred to as "co-existence measures").
- (4) The objective of co-existence measures in areas where GMOs are cultivated is to avoid unintended presence of GMOs in other products, preventing the potential economic loss and impact of the admixture of GM and non-GM crops (including organic crops).
- (5) In some cases, depending on economic and natural conditions, it may be necessary to exclude GMO cultivation from large areas. This possibility should rest on the demonstration by the 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 needs to be proportionate to the objective (i.e. protection of particular needs of conventional or organic farmers).

OJ L 106, 17.4.2001, p. 1.

- (6) In the context of combining the 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 Commission considers that measures to avoid the unintended presence of GMOs in conventional and organic crops should be established at Member State level.
- (7) It is necessary to replace Recommendation 2003/556/EC² to better reflect the possibility provided by Article 26a for Member States to establish measures to avoid the unintended presence of GMOs in conventional and organic crops. Accordingly, the current guidelines limit their content to the main general principles for the development of co-existence measures, recognising that Member States need sufficient flexibility to take into account their regional and national specificities and the particular local needs of conventional, organic and other types of crops and products.
- (8) The European Coexistence Bureau (ECoB) will continue to develop together with Member States best practices for co-existence as well as technical guidelines on related issues,

HAS ADOPTED THIS RECOMMENDATION:

- 1. In developing national measures to avoid the unintended presence of GMOs in conventional and organic crops Member States should follow the guidelines provided in the Annex to this Recommendation.
- 2. Recommendation 2003/556/EC is repealed.
- 3. This Recommendation is addressed to the Member States.

Done at Brussels,

For the Commission John DALLI Member of the Commission

² Commission Recommendation 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 (OJ L 189/36).

ANNEX

1. Introduction

1.1. National co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops

The cultivation of GMOs in the EU has implications for the organisation of agricultural production. On the one hand, the possibility of the unintended presence of genetically modified (GM) crops in non-GM crops (conventional and organic), raises the question as to how producer choice for the different production types can be ensured. In principle, farmers should be able to cultivate the types of agricultural crops they choose - be it GM crops, conventional or organic crops. This possibility should be combined with the wish of some farmers and operators to ensure that their crops have the lowest possible presence of GMOs.

On the other hand, the issue is also linked to consumer choice. To provide European consumers with a choice between GM food and non-GM food, there should not only be a traceability and labelling system that functions properly, but also an agricultural sector that can provide the different types of products. The ability of the food industry to deliver a high degree of consumer choice goes hand in hand with the ability of the agricultural sector to maintain different production systems.

The adventitious presence of GMOs above the tolerance threshold set out in EU legislation triggers the need for a crop that was intended to be a non-GMO crop, to be labelled as containing GMOs³. This could cause a loss of income, due to a lower market price of the GM crop or difficulties in selling it. Moreover, additional costs might incur to farmers if they have to adopt monitoring systems and measures to minimise the admixture of GM and non-GM crops.

However, the potential loss of income for producers of particular agriculture products such as organic products is not necessarily limited to exceeding the labelling threshold set out in EU legislation at 0.9%. In certain cases, and depending on market demand and on the respective provisions of national legislations (e.g. some Member States have developed national standards for different types of "GM-free" labelling), the presence of traces of GMOs in particular food crops —even at a level below 0.9%- may cause economic damages to operators who would wish to market them as non containing GMOs.

In accordance with Articles 12 and 24 of Regulation (EC) No 1829/2003, the labelling obligation does not apply to foods/feed containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9% of: (i) the food ingredients considered individually; or (ii) food consisting of a single ingredient; or (iii) the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.

Moreover, the admixture of GMOs has specific implications for producers of particular products such as organic farmers⁴, impacting also the final consumer⁵. Since such production is often more costly, stricter segregation efforts to avoid GMO presence may be necessary to guarantee the associated price premium In addition, local constraints and characteristics may render these particular segregation needs very difficult and costly to be met efficiently in some geographical areas.

It is therefore necessary to recognise that Member States need sufficient flexibility to take into consideration their particular regional and local needs with regard to GMO cultivation in order to achieve the lowest possible presence of GMOs in organic and other crops, when sufficient levels of purity cannot be achieved by other means.

1.2. Distinction between economic aspects of GMO cultivation and scientific aspects covered by the environmental risk assessment

It is important to make a clear distinction between the economic aspects of GMO cultivation and the environmental risk assessment aspects dealt with under the authorisation procedures of Directive 2001/18/EC and of Regulation (EC) No 1829/2003 on GM food and feed.

According to the procedure laid down in Directive 2001/18/EC and in Regulation (EC) No 1829/2003, the authorisation to release GMOs into the environment is subject to a comprehensive health and environmental risk assessment. The outcome of the risk assessment can be one of the following:

- a risk of an adverse effect to the environment or health that cannot be managed is identified, in which case authorisation is refused;
- no risk of adverse effects on the environment or health is identified, in which
 case authorisation is granted without requiring any additional management
 measures other than those specifically prescribed in the legislation;
- risks are identified, but they can be managed with appropriate measures (e.g. physical separation and/or monitoring); in this case the authorisation will carry the obligation to implement environmental risk management measures.

If a risk to the environment or health is identified *after* the authorisation has been granted, a procedure for the termination or modification of the EU consent or authorisation is provided respectively by Directive 2001/18/EC (Article 20.3) and Regulation (EC) No 1829/2003 (Articles 10 and 22). Moreover, Member States may invoke the special safeguard clause of Directive 2001/18/EC (Article 23) or the emergency measure of Regulation (EC) No 1829/2003 (Article 34) to provisionally restrict or prohibit the cultivation of GMOs on the basis of new or additional information concerning risks for health or the environment.

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In accordance with Article 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).

⁵ COM(2009) 153 - Report from the Commission to the Council and the European Parliament on the coexistence of genetically modified crops with conventional and organic farming.

Since only authorised GMOs can be cultivated in the EU⁶ and the environmental and health aspects are already covered by the environmental risk assessment of the EU authorisation process, the pending issues still to be addressed in the context of coexistence concern the economic aspects associated with the admixture of GM and non-GM crops.

1.3. Recognition of diverse farming conditions in the EU

European farmers work under extremely diverse conditions. Farm and field sizes, production systems, crop rotations and cropping patterns, as well as natural conditions, vary across Europe. This variability needs to be taken into account when devising, implementing, and monitoring national measures to avoid the unintended presence of GMOs in conventional and organic crops. The measures that are applied must be specific to the farm structures, farming systems, cropping patterns and natural conditions in a region.

Strategies and best practices for GMO cultivation may need to be developed and implemented at national or regional level, with the participation of farmers and other stakeholders and taking account of national, regional and local factors.

Therefore it is appropriate that measures to avoid the unintended presence of GMOs in conventional and organic crops should be developed at national and sometimes regional or local level.

1.4. Purpose and scope of the guidelines

The present guidelines take the form of non-binding recommendations addressed to the Member States. They are intended to provide general principles for the development of national measures to avoid the unintended presence of GMOs in conventional and organic crops. It is recognised that many of the factors that are important in this context are specific to national, regional and local conditions.

2. GENERAL PRINCIPLES FOR THE DEVELOPMENT OF NATIONAL CO-EXISTENCE MEASURES TO AVOID THE UNINTENDED PRESENCE OF GMOS IN CONVENTIONAL AND ORGANIC CROPS

2.1. Transparency, cross-border co-operation and stakeholder involvement

National measures to avoid the unintended presence of GMOs in conventional and organic crops should be developed in cooperation with all relevant stakeholders and in a transparent manner. Member States should ensure cross-border co-operation with neighbouring countries to guarantee the effective functioning of co-existence measures in border areas. In this respect they should provide and ensure adequate and timely information about the measures that they decide to put in place.

In order to be cultivated in the EU, the GMO must have been authorised *for cultivation* under the Directive 2001/18/EC or under Regulation (EC) No 1829/2003.

2.2. Proportionality

Measures to avoid unintended presence of GMOs in other crops should be proportionate to the objective which is pursued (protection of the particular needs of conventional or organic farmers). Co-existence measures should avoid any unnecessary burden for farmers, seed producers, cooperatives and other operators associated with any production type. The choice of measures should take into account the regional and local constraints and characteristics, such as the shape and size of the fields in a region, the fragmentation and geographical dispersion of fields belonging to individual farms and regional farm management practices.

2.3. Levels of admixture to be attained through national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops

National measures to avoid the unintended presence of GMOs in conventional and organic crops should take into account available knowledge on the probability and sources of admixture between GM and non-GM crops. These measures should be proportionate to the level of admixture to be pursued, which will depend on regional and national specificities and the particular local needs of conventional, organic and other types of crops and production.

- 2.3.1. In some cases, the presence of GMO traces in food and feed has an economic effect only when they exceed the 0.9% labelling threshold. In these cases, Member States should consider that measures to ensure compliance with the 0.9% labelling threshold would be sufficient.
- 2.3.2. Member States should consider that there may be no need to pursue specific levels of admixture where labelling a crop as GM has no economic implications.
- 2.3.3. In several other cases, the potential loss of income for organic and some conventional producers (e.g. certain food producers) may be due to the presence of GMO traces at levels lower than 0.9%. In those cases, and in the interest of protecting particular types of production, concerned Member States may define measures that aim at reaching levels of presence of GMOs in other crops lower than 0.9%.

Regardless of the level of admixture to be pursued through co-existence measures, the thresholds established in the EU legislation⁷ will continue to apply for the labelling of GMO presence in food, feed and products intended for direct processing.

2.4. Measures to exclude GMO cultivation from large areas ("GM-free areas")

Differences in regional aspects, such as climatic conditions (that influence the activity of pollinators and the transport of airborne pollen), topography, cropping patterns and crop rotation systems or farm structures (including surrounding structures, such as hedges, forests, uncultivated areas and the spatial arrangement of fields) may influence the degree of admixture between GM and conventional and organic crops and the measures necessary to avoid unintended presence of GMOs in other crops.

Articles 12 and 24 of Regulation (EC) No 1829/2003 and 21.3 of Directive 2001/18/EC.

Under certain economic and natural conditions, Member States should consider the possibility to exclude GMO cultivation from large areas of their territory to avoid the unintended presence of GMOs in conventional and organic crops. Such exclusion should rest on the demonstration by Member States that, for those areas, other measures are not enough to achieve sufficient levels of purity. Moreover, the restriction measures should be proportionate to the objective pursued (i.e. protection of particular needs of conventional and/or organic farming).

2.5. Liability rules

Matters concerning financial compensation or liability for economic damage are the exclusive competence of Member States.

3. EXCHANGE OF INFORMATION AT EU LEVEL

The Commission will continue gathering and coordinating relevant information based on on-going studies at EU and national level and offering technical advice to assist interested Member States in establishing national approaches to co-existence.

The ongoing coordination through COEX-NET⁸ and technical advice by the European Coexistence Bureau (ECoB)⁹ will continue. ECoB will keep up to date an indicative catalogue of measures as well as a list of agronomic, natural and cropspecific factors to be considered when developing national measures to avoid the unintended presence of GMOs in conventional and organic crops. Member States should continue to contribute to the technical work of ECoB.

The Network Group for the Exchange and Coordination of Information concerning Coexistence of Genetically Modified, Conventional and Organic Crops (COEX-NET) is aimed at facilitating the exchange of information among the Member States and the Commission.

The ECoB develops crop-specific Best Practice Documents for technical coexistence measures. The ECoB consists of a Secretariat and crop-specific Technical Working Groups comprised of technical representatives of Member States.