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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

on the coexistence of genetically modified crops with conventional and organic farming

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1. Introduction

The coexistence of genetically modified organisms (GMOs) with conventional and organic agricultural production is directly related to the practical choice of consumers and agricultural producers to respect individual preferences and economic opportunities, in compliance with the legal obligations regarding the labelling of GMOs. According to Directive 2001/18/EC on the deliberate release into the environment of GMOs¹, Regulation (EC) No 1829/2003 on GM food and feed² and Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs³, GMOs as well as food and feed containing, consisting of or produced from GMOs have to be labelled accordingly in order to guarantee an informed choice. This implies that products requiring labelling as GM have to be segregated from non-labelled products.

Since the environmental and health aspects of GM crop cultivation are fully covered during their authorisation procedure, the issues to be addressed in the context of coexistence concern technical segregation measures and the possible economic consequences of admixing GM and non-GM crops.

According to Article 26a of Directive 2001/18/EC, Member States may take appropriate national measures on coexistence in order to avoid the unintended presence of GMOs in other products. Commission Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming⁴ is intended to help Member States develop national legislative or other strategies for coexistence.

In March 2006, the Commission adopted a first report on the implementation of national measures on the coexistence of GM crops with conventional and organic farming⁵.

On 22 May 2006 the Council of Agricultural Ministers adopted Conclusions on Coexistence in which it invites the Commission to undertake the following activities:

(1) Come forward, as soon as possible, with Community labelling thresholds for seeds.

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OJ L 106, 17.4.2001, p. 1, as amended by Regulation (EC) No 1829/2003 and Regulation (EC) 1830/2003.

² OJ L 268, 18.10.2003, p. 1.

³ OJ L 268, 18.10.2003, p. 24.

⁴ OJ L 189, 29.7.2003, p. 36.

COM(2006) 104 final and Commission staff working document: http://ec.europa.eu/agriculture/co-existence/sec313_en.pdf

- (2) Identify, in close cooperation with the Member States and stakeholders, best practice for technical segregation measures and, on the basis of this work, develop guidelines for crop-specific measures.
- (3) Intensify the use of COEX-NET⁶ to exchange information regarding crop segregation and liability measures, including cross-border problems in relation to coexistence, and to discuss possible solutions should such problems be observed.
- (4) Explore with Member States possible ways of minimising potential cross-border problems related to coexistence.
- (5) Explore sustainable solutions, which are in line with EU law, for areas where agricultural structures and farming conditions are such that farm-level coexistence is difficult to achieve for a given crop.
- (6) Strengthen European research on coexistence in order to fill current knowledge gaps and make existing research results available to the Member States.
- (7) Study the different national civil liability systems relating to their application in case of economic damage from the admixture of GMOs in non-GM crops, including in cross-border situations. In this context, examine also specific compensation and insurance schemes developed in the Member States.
- (8) Continue to explore, together with the Member States, whether further steps towards common principles regarding coexistence should be taken.

This report provides an overview of the Commission's activities in relation to the mandate provided by the Council Conclusions. It also provides an overview of the state of implementation of national and regional coexistence measures, based on information provided by the Member States.

2. COMMUNITY LABELLING THRESHOLDS FOR SEEDS

Directive 2001/18/EC provides for the possibility to exempt seed lots from labelling if they contain traces of GM seeds authorised for cultivation in the EU that are below a certain threshold. The Commission is currently carrying out an impact assessment for the establishment of such labelling thresholds for seeds which will form the basis for a forthcoming Commission legislative text. When drafting its proposal, the Commission will also take into account the Council Conclusions on GMOs of 5 December 2008 that such thresholds should be set at the lowest practicable, proportionate and functional levels for all economic operators, and contribute to ensuring freedom of choice for producers and consumers of conventional, organic and GM products alike.

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The Network Group for the Exchange and Coordination of Information concerning Coexistence.

3. GUIDELINES FOR CROP-SPECIFIC COEXISTENCE MEASURES, CROSS-BORDER PROBLEMS AND REGIONS WHERE COEXISTENCE IS DIFFICULT TO ACHIEVE

The Commission has created the European Coexistence Bureau (ECoB⁷), which is aimed at developing crop-specific Best Practice Documents for technical coexistence measures. The ECoB will also address possible ways of minimising potential cross-border problems related to coexistence and develop recommendations for areas where agricultural structures and farming conditions are such that farm-level coexistence is difficult to achieve for a given crop.

The ECoB consists of a Secretariat and crop-specific Technical Working Groups comprised of technical representatives of Member States. Stakeholders are consulted, in particular, via the relevant Advisory Groups established by the Commission.

The first ECoB Technical Working Group deals with the development of coexistence measures in maize crop production. It is assumed that it will develop a Best Practice Document for maize crop production by 2010.

4. NETWORK GROUP FOR THE EXCHANGE AND COORDINATION OF INFORMATION CONCERNING COEXISTENCE (COEX-NET)

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 regarding coexistence. Two meetings of this group were held in 2006, one in 2007, and one in 2008.

5. RESEARCH ACTIVITIES AT COMMUNITY LEVEL IN RELATION TO COEXISTENCE

Three research projects related to coexistence were supported under the 6th Framework Programme for Community Research. The SIGMEA project ended in November 2008. It studied temporal and spatial gene flow from GMOs across Europe in both seed and crop production systems in order to determine appropriate coexistence measures. The TRANSCONTAINER and CO-EXTRA projects are still ongoing and will finish in the course of 2009.

In February 2006, the Commission's Joint Research Centre published a report⁸, which analyses the need and feasibility of changes in agricultural practices to ensure coexistence.

6. NATIONAL LIABILITY AND COMPENSATION SCHEMES FOR DAMAGE RESULTING FROM GMO ADMIXTURE

Admixture of GMOs may lead to the devaluation of non-GM products, which would entail an economic damage to their producers. For instance, the affected product may require to be labelled as GM according to EU legislation, which might result in lower market returns.

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http://ecob.jrc.ec.europa.eu/

ftp://ftp.jrc.es/pub/EURdoc/eur22102en.pdf

The admixture of GMOs may also have specific implications for organic products. Regulation (EC) No 834/2007 on organic production and labelling of organic products stipulates that products, which require labelling according to Community legislation due to the admixture of GMOs, can no longer be marketed with an organic label.

Liability in the event of economic damage to non-GM crops resulting from GMO admixture is a matter for civil law, which is the responsibility of Member States. A study¹⁰ ordered by the Commission has shown that all national jurisdictions provide a minimum of protection in cases of such damage under the regular conditions of tort law. The majority of Member States have not changed the conditions for application of general tort law to the specific case posed by GMO admixture.

Nevertheless, there are differences between the general tort laws of Member States, which imply differences in the way that potential claims in relation to GMO admixture would be handled and resolved. For instance, under fault-based systems, proof of wrongdoing or negligence by the defendant is required, whereas under strict liability systems, the judgement does not depend upon a value judgement of the defendant's behaviour. Some Member States have introduced strict liability regimes which apply specifically to damage resulting from GMO admixture.

Furthermore, almost all legal systems have specific rules on neighbours' disputes, which may also apply in the event of economic damage resulting from GMO admixture.

Up to now, there have been no court cases in any Member State that would illustrate the actual application of the different rules in place by the national courts.

At present, insurance products covering risks of GMO admixture seem not to be available on EU markets. In four Member States, however, insurance cover or alternative types of financial guarantee for potential economic damage are legally required, or may be required following case-by-case assessment, in order for GM crops to be cultivated.

Some Member States have established compensation funds for economic damage resulting from GMO admixture. Where the conditions for the payments into the scheme are defined, the funds are financed by a levy for GM crop cultivation. As, so far, no compensation has been paid out from any of these funds, it cannot be judged whether the levies raised are appropriate so as to avoid either an under-supply of funds and, thus, the risk that certain damage may not be fully compensated, or over-financing, which would entail an unnecessary economic burden for GM crop farming.

So far, no instance of economic damage resulting from cross-border admixture of GMOs has been reported by the Member States. Generally, questions of jurisdiction in cross-border cases are addressed by the Rome II Regulation¹¹.

⁹ OJ L 189, 20.7.2007, p. 1.

http://ec.europa.eu/agriculture/analysis/external/liability_gmo/index_en.htm

Regulation (EC) No 864/2007 on the law applicable to non-contractual obligations (Rome II). OJ L 199, 31.7.2007, p. 40.

7. OVERVIEW OF NATIONAL COEXISTENCE MEASURES

At the present stage, 15 Member States have adopted specific legislation on coexistence¹². Draft legislation of three further Member States has been notified to the Commission. The Commission examines the compatibility of national coexistence measures with the internal market in accordance with Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations¹³.

No Member States reported addressing coexistence by means of non-legislative instruments, but in some Member States the development of a regulatory framework is not envisaged in the near future as the cultivation of GM crops on their territory has been deemed unlikely to take place.

In some Member States, competence for coexistence lies at regional level.

In the absence of GM crop cultivation in most Member States, programmes monitoring the application and effectiveness of the coexistence legislation have not yet been practically implemented. Existing monitoring programmes in some Member States did not reveal any negative results as regards non-compliance with compulsory coexistence or labelling rules.

No Member State indicated that the coexistence rules in place would be insufficient to ensure appropriate levels of segregation of GM and non-GM crops. Member States did not refer to any court cases in relation to GMO admixture to non-GM crops, but one case was reported in relation to bee keeping.

Apart from some Member States that have not yet started to develop an approach on coexistence, all Member States conducted stakeholder consultations for the development of coexistence measures.

7.1. Information, registration and training procedures

The national provisions on informing public authorities, third parties and the general public on GM crop cultivation differ in detail. Some Member States require a case-by-case approval procedure for the cultivation of GM crops, whereas others only require farmers to notify GM crop cultivation to the competent authorities. One Member State does not stipulate individual registration of GM crop cultivation by farmers.

In the majority of Member States, GM crop growers have to inform their immediate neighbours, operators with whom they share agricultural machinery, the owners of the property on which cultivation is intended, and in three Member States, bee keepers within a certain perimeter around a GM crop field.

The public is generally informed about the cultivation of GM crops via a public register, which may either include extensive information about cultivation plots, including personal data of growers and the exact location of plots, or only information at an aggregate level, e.g. total cultivation surface per region or local authority area.

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AT, BE, CZ, DE, DK, FR, HU, LT, LU, LV, NL, PT, RO, SE, SK.

OJ L 204, 21.7.1998, p. 37. Draft measures can be obtained from a public database at: http://ec.europa.eu/enterprise/tris/pisa/app/search/

In some Member States, seed distributors have to report the amount of GM seeds sold and/or inform farmers about the coexistence rules in place. Operators dealing with transport, storage and packing of GM crops sometimes have to be registered.

Some Member States require GM crop growers to undergo mandatory training or to demonstrate sufficient knowledge in order to implement the required segregation measures.

7.2. Technical segregation measures

The majority of Member States have designed the coexistence measures in such a manner that they prevent the labelling threshold for GMOs in food and feed set at a level of 0.9% from being exceeded. However, some Member States indicated that they strove for GMO admixture levels to be as low as possible. Some Member States take into account possible future seeds thresholds at values different from zero, which limits the scope for admixture from other, non-seed sources and requires stricter segregation measures in the field.

Twelve Member States adopted segregation measures for at least one crop. The spatial segregation is generally based on isolation distances between GM crop fields and neighbouring non-GM fields with sexually compatible crops. The isolation distances can sometimes be partially or fully replaced by buffer zones between GM and non-GM fields in which sexually compatible non-GM crops are grown that are harvested and treated as GM plants. In other Member States, buffer zones are mandatory supplements to isolation distances. The possible use of different flowering times is permitted by two Member States.

Some Member States require obligatory consultation of neighbours, and in some cases their written agreement to the cultivation of GM crops if their own land is used to implement the isolation distances.

Species so far addressed by national segregation measures include maize, and in some Member States also potato, sugar beet, fodder beet, wheat and oilseed rape.

In six Member States segregation measures between GM crop fields and organic fields are more stringent when compared to those applying between GM crop fields and conventional fields. In six other Member States identical segregation measures apply. Different segregation measures are defined by some Member States regarding fields used for the production of seeds.

Segregation measures vary among Member States: for instance, isolation distances for maize production range between 25m and 600m with respect to conventional maize and between 50m and 600m regarding organic maize.

One Member State requires GM crop growers to observe isolation distances with regard to sites of established bee keeping.

In all Member States the segregation measures have to be applied by GM crop growers and operators dealing with GM seeds or harvests. Only where neighbouring non-GM crop growers voluntarily agree to joint implementation of segregation measures would they be required to adopt some responsibility. For coexistence in seed production, some Member States assign this responsibility to the seed producers and others to the GM crop growers.

Some Member States allow operators to agree amongst themselves not to implement segregation measures between their fields, whereas in other Member States segregation is obligatory in all cases.

Some Member States regulate segregation during different specific agricultural operations (e.g. seeding cultivation, harvest, post-harvest operations, transport, storage), whereas others only address segregation from neighbouring fields.

7.3. Restrictions on the cultivation of GM crops

Many Member States require specific procedures for, or prohibit, the cultivation of GM crops in areas under environmental protection (e.g. Natura 2000 areas). These measures are not related to coexistence and need to be assessed against existing Community legislation.

Even though some Member States provide for the possibility of defining regions in which GM crop cultivation could be prohibited for socio-economic reasons, such regions have not yet been set up. The establishment of such regions would need to be notified to the Commission. In the absence of notification, the measures may not be applicable and therefore not be enforceable against individuals. Certain regions in some Member States declared themselves to be GMO-free, but such declarations are of a political nature and do not constitute legally binding prohibitions.

Some Member States provide for the possibility of designating regions in which either only GM varieties of a given crop or, alternatively, only non-GM varieties can be cultivated on the basis of voluntary decisions by all farmers within the zone.

Four Member States prohibit the cultivation of the GM maize MON810 under the safeguard measures laid down by EU legislation in cases of new scientific evidence in relation to the safety assessment of GMOs. In those Member States, GM crop cultivation is currently not possible as MON810 is for the time being the only GM crop available for commercial cultivation in the EU. These measures are not related to coexistence and are being addressed in accordance with the procedure under EU legislation.

7.4. Administrative provisions

Rules on the enforcement and monitoring of coexistence measures were put in place by the majority of Member States that established legislation on coexistence. However, practical application of the procedures were started only in those Member States where GM crops are actually cultivated.

Infringement of coexistence legislation is punishable in some, but not all Member States.

7.5. Commercial experience with GM maize cultivation

The only GM crop currently cultivated in the EU is the GM maize MON810, which is resistant to certain lepidopteran pests. In 2008, based on information provided by the Member States, MON810 was cultivated in six Member States (CZ, DE, ES, PT, RO, SK) on a cultivation surface of about 100 000 hectares, which equals 1.2 percent of the total maize acreage in EU27 this year. However, in certain Member States, GM maize cultivation represents a larger share of maize production (e.g. more than 20% in ES).

In general, the Member States consider their national coexistence legislation not to have a strong impact regarding the introduction of GM crops by farmers, but this issue deserves further investigation. Generally, the trend is that cultivation surfaces are expanding in the seven abovementioned Member States, five of which have set up mandatory coexistence rules.

7.6. Cross-border issues

So far, only a few Member States have started collaboration with other Member States to develop possible measures for addressing cross-border coexistence issues. There have been no documented cases of cross-border admixture of GMOs.

7.7. National research activities on coexistence

Many Member States reported national research activities in order to substantiate the development of coexistence measures. Research activities in this area are still ongoing in thirteen Member States.

8. CONCLUSIONS

Since 2006, Member States have made significant progress in developing coexistence legislation. This development of the legislative framework went hand in hand with a moderate expansion of the cultivation surface involving GM crops. However, GM crop production is still a niche production in the EU, with currently only a single GM product being in commercial use and with cultivation on a very limited scale.

Even though there is ongoing controversy about the cultivation of GM crops in the EU within society at large, there is no concrete indication that there have been practical difficulties in introducing GM crops into EU agriculture. This assessment is, however, based on the limited commercial experience gained so far. More extensive practical experience resulting from cultivation over several years is confined to some regions within a few Member States.

There have been no reports of economic damage resulting from either non-compliance with the national coexistence rules or from the rules themselves being inappropriate in terms of achieving sufficient levels of segregation between GM and non-GM crop production. Monitoring programmes set up by Member States have not revealed any shortcomings in the rules in place.

The coexistence approaches applied in Member States differ with respect to the administrative procedures and technical segregation measures. There is no compelling evidence, however, that differences in the legislative framework are a determining factor in the choice of farmers whether to grow GM crops or not. Other aspects that seem to play an at least equally important role are the existence of suitable market outlets for GM products, regional variation as regards the possible advantages or disadvantages of GM crops over their conventional or organic counterparts, and societal drivers such as neighbours' disputes and destruction of fields. The importance of these aspects is demonstrated by the heterogeneous spatial distribution of GMO cultivation even within Member States under identical coexistence regimes.

The differences observed among the national measures can, at least to some extent, be attributed to the regional variation of agronomic, climatic and other factors determining the

likelihood of GMO admixture to other crops. Further experience needs to be gained in order to fully assess the efficiency of national coexistence measures. The European Coexistence Bureau will develop guidance in this regard.

Even though different coexistence approaches between neighbouring Member States have the potential to create cross-border problems, such difficulties have not been observed in practice. Therefore, for the time being there seems to be no need to develop specific measures on cross-border issues in relation to coexistence.

The Commission does not consider it appropriate to initiate the development of Community legal instruments that could interfere with the national liability provisions in relation to damage caused by GMO admixture. As explained above, much of the diversity in this regard results from differences in existing national liability and compensation systems, which also apply in relation to other economic activities. These differences have not yet led to the need for harmonisation. Furthermore, the different jurisdictions of Member States have developed individual claims cultures and a distinct compensation cultures. Creating uniform rules for the narrow scenario posed by GMO admixture may lead to parallel application of different tort law regimes within a single Member State.

Given the apparent absence of insurance solutions for such damage, Member States are encouraged to explore steps aimed at facilitating the development of appropriate products by insurers.

Research activities concerning various aspects of coexistence are still ongoing in many Member States, illustrating the need to further develop the knowledge base concerning coexistence. Further research activities will be required in the medium term to address segregation of GM and non-GM production chains beyond the farm gate.

An assessment of the best way forward to address coexistence must take into account commercial experience in Member States. It must include a solid assessment of the effectiveness and efficiency of the measures put in place, and an analysis of the impact of national measures on the competitiveness of farmers and the freedom of choice of both farmers and consumers. At the present time there is no indication of the need to deviate from the subsidiarity-based approach on coexistence and to develop further harmonisation on this matter.

The Commission sees a need to undertake the following actions in relation to coexistence:

- The Commission will, at the earliest possibility, conclude an economic impact assessment concerning the establishment of potential future seeds thresholds. The Commission will propose appropriate legislative follow-up on the basis of that assessment.
- The Commission will continue the activity of COEX-NET to foster an exchange of information on coexistence with Member States as regards practical experience, research and monitoring results.
- Jointly with the Member States, and following consultations of relevant stakeholder groups, the Commission will develop technical guidance on crop-specific coexistence measures through the European Coexistence Bureau.

- Under the Framework Programme for Community Research, the Commission will support further research based upon clearly established needs identified within ongoing or future initiatives.
- In 2012, the Commission will report on the coexistence situation in Member States, based on information provided by the Member States.