THE END OF ZERO-RISK REGULATION OF GM CROPS IN EUROPE: The Battle of Co-Existence Rules

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Introduction

GMOs involve three sorts of risks: environmental risks, sanitary risks and economic risks. While the first two are assessed and managed by a harmonized process involving National and European authorities, the last one depends only on the Member States' regulations. We will begin by introducing the current state of environmental and sanitary risk management of GM crops in Europe. Then, we will describe the main economic risks involving GM crops and the proposed co-existence measures. Finally we will analyze the main differences and similarities in co-existence measures applied in some European countries. In some countries farmers are sowing GM crops (Spain, France, Portugal and Germany), in others it is expected that GM will be on fields soon (UK and Denmark), but in others it is not likely that GM crops will be sown (Austria). In view of the complexity and size of the problem, this contribution is focused on GM maize, the only GMO that is grown commercially in Europe.

I. Environmental and sanitary risk management of GMs crops in Europe

Environmental and health risks arising from GMO are covered by the Deliberate Release Directive 2001/18/EC, completed by the GM Food and Feed Regulation 1829/2003, and the Traceability and Labelling of GMOs Regulation nº 1830/2003.

Directive 2001/18/EC has two procedures, one for the deliberate release of GMOs into the environment, i.e. the cultivation of GMO in European fields mainly for research purposes, and the other for the selling of GMOs, i.e. the consumption of GMO which have been either grown in the Community or imported. Both include the assessment of environmental and sanitary risks (Annex II of the Directive). However, the procedure of placing on the market is the only one that allows free circulation of GM goods (art. 22). The procedures for obtaining the authorisation to sell GMO are really

complicated, but in general terms a National Authority proposal is required, as well as a positive report from the EFSA (*European Food Safety Authority*) and the qualified majority voting in the European Council. The lack of this last requisite was the origin of *de facto* moratorium between 1999 and 2004[1].

Nevertheless, free circulation is not absolute. Art. 23 of the Directive 2001/18/EC permits Member States to restrict provisionally GMO circulation whenever new or additional information or the reassessment of existing information on the basis of new scientific knowledge suggests that GMO constitutes a risk to human health or the environment. Some Member States[2] have employed this safeguard clause with the support of arguments which have been systematically refused by the EFSA. However, the inability of European Commission to obtain a decision condemning these practices in the European Council allows the continuation of these prohibitions, generating a sort of limited *de facto* moratorium.

To sum up, to commercially cultivate a GM crop, the crop must be authorized for placing on the market under Directive 2001/18/CE and it must be registered in a national or common catalogue of varieties. As far as crop species are concerned, GMOs involving maize, oilseed rape, soybean and chicory have been authorized in the European market (mainly for importation purposes). However, only GM maize has been authorized for commercial cultivation, specifically T25 (Bayer CropScience), Bt-176 (Syngenta), MON 810 (Monsanto). Between 1998 and 2004 Spain was the only European country which included GM varieties in its national catalogue. In 2004, because of the end of *de facto* moratorium, 17 GM maize varieties were included in the Common Catalogue. At the moment only France (15.000 hectares), Germany (2.500 hectares), Portugal (4.200 hectares), and Spain (70.000 hectares) have commercial cultivation of GM crops.

[1] In 1999 five countries which constituted a blocking minority in the European Council declared that they would not vote for any new authorization of GMO until there were full draft rules ensuring labelling and traceability of GMOs and GMO-derived products. See Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorisations, 2194th Council Meeting - Environment-, Luxembourg, 24/25 June 1999.

[2] Austria, Hungary, Luxemburg and Greece have forbidden GM maize; France and Greece have prohibited GM rape/canola.

II. Economic risks and co-existence measures among GM, conventional and biological crops.

The existence of different markets for GM, conventional and biological grains[3] implies the risk of economic losses in the case of involuntary presence of GMO traces in non-GM products. Art. 26.a of Directive 2001/18/EC allows Member States to establish *"measures to avoid the unintended presence of GMOs in other products"*. These measures are necessary to ensure the viability of conventional and organic farming and their sustainable *coexistence* with genetically modified crops (European Commission – 2002). The aim of co-existence rules is to avoid GM "pollution" of conventional and organic crops. Crops are seen to be "GM polluted" whenever they contain GMO traces over 0.9 % (the labelling threshold established in Regulation EC 1829/2003, applicable also to ecological products by Regulation 834/2007). The main economic damages resulting from this "pollution" are a reduction in the sale price of the crops (because of the labelling as transgenic) and loss of ecological status.

As far as maize is concerned, there are three main sources of "pollution": seed impurities, cross-pollination, and pre-sowing, sowing, harvest and post-harvest mixtures (see Annex I).

Seed impurities:

From farmers' point of view, seed impurities can easily be prevented by buying certified seeds which guarantee reduced levels of impurities. However, this co-existence measure has important socio-economic consequences. It fortifies the seed companies' position, which will have a captive market. It particularly affects biological farmers, who are used to sowing their own seeds, since they will be obliged to buy certified seeds every year.

From the regulators and seeds companies' point of view, seed impurity risks are not a new problem. OECD standards allow up to 1% of impurities in certified maize seed (OECD 2007, pp 220). In Europe, the average level of impurities in hybrid maize varieties over the past years has been around 0.7% (ESA-EuropaBio - 2007). However, this initial level of impurities would not necessarily guarantee a final product below the

[3] This market segmentation is produced by segregation, traceability, and labelling rules.

0.9% threshold. Consequently, European authorities proposed reducing this seed impurity level to 0.5%[4] in the case of adventitious presence of GM maize seeds in conventional and organic seeds (European Commission – 2003a; European Commission 2004), in accordance with the 0.3%-0.5% recommendations of scientific studies on co-existence done by EU experts (Scientific Committee on Plants-2001, Bock A-K *et al.*-2002 and Messean A. *et al.*-2006). However this proposal was severely criticized by environmental organizations which wanted a zero risk limit, and in the end it was not approved[5].

Some Member States have developed "purity requirements". For example Austria, after the Pionner scandal in 2001[6], introduced a technical zero impurity tolerance[7] policy enforced by expensive testing programmes (Greenpeace – 2004). Nevertheless, the majority of States tolerate at least a 0.3 % of impurities, taking into account EU scientific reports (DEFRA-2006).

Cross-pollination:

In midsummer, maize produces its male flowers (tassels) and releases pollen into the air. The pollen reaches the female flowers (the ears) primarily by wind, and secondarily by insects visiting the tassels to collect pollen. Maize pollen is very heavy, so almost 90% fall to the ground within a 2 meter perimeter. To avoid cross-pollination, coexistence practices recommend isolation distances, border crops barriers, coordination in sowing to prevent simultaneous flowering dates, and the use of hybrid seeds which produce less pollen.

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[4] In the proposal, seed impurity tolerance was up to 0.3 % for oilseed rape, 0.5 % for maize, sugar beet, potato, tomato, chicory and 0.7 % for soybean.

[5] Representatives of Poland, Germany, Italy, Denmark, Austria, and Greece rejected the proposals in the European Council of 19 October 2004. Arguments against the projects are well explained in the Foundation on Future Farming report (Haerlin B. - 2003).

[6] In May 2001 Greenpeace Austria published test results showing that maize seeds of the variety PR39D81 by Pioneer were polluted by GMO which were not authorised for release in Austria. Gradually it emerged that almost 180 tons of GE contaminated seeds, affecting an area under cultivation of around 6,000 hectares, had been released into the environment. About 2,000 hectares of it were eventually destroyed, the Austrian State paid € 2.67 million in compensation (see Greenpeace report "Austrian 'Purity Requirement' successful for past three years" available at http://www.gmo-free-regions.org/Downloads/WS_B5_austrianseedpurity.pdf)

[7] In practice it corresponds to 0.1% of impurities, which is the test detectable boundary.

Without anti-cross-pollination measures, GM pollution could reach 1.5% (Bock A-K *et al.*-2002). Each anti-cross-pollination measure can be used alone or in conjunction with others. Although there are different approaches, co-existence regulations aim to keep cross-pollination below 0.20% (see Annex II). There are many disagreements regarding the most suitable anti-cross-pollination system. Recommended isolation distances range from 25 meters (French and German seed companies guidelines) to 300 meters (Portugal Decree). With an isolation distance of 100 meters, cross-pollination would be just 0.01% (see Annex II), and it seems clear that an isolation distance of more than 50 meters could only be founded in precautionary principles. However, it would be very difficult to coordinate 100 or 200 meter isolation distances in small fields.

Border rows and coordination among neighbours to avoid simultaneous flowering dates are not as effective as isolation distances, but they are very useful in conjunction with them for reducing the necessary distance of separation without increasing the risk. For example, the scientific report of the Spanish Bio-Vigilance Commission established that 0.9 cross-pollination risks could be achieved either by 4 meters of isolation plus 4 border rows plus a 3 week gap in sowing dates; or by 16 metres of isolation distance plus a 1 week gap in sowing dates (Comisión Nacional de Biovigilancia – 2006).

Isolation distances presuppose some amount of coordination among neighbours. Coordination can be direct (through notification) or indirect (through a public register office which individualizes fields where GMOs are grown [8]). All countries include one or both of these information duties.

Pre-sowing, sowing, harvest, and post-harvest mixtures

Training in good agricultural practices is the simplest way for guaranteeing segregation during pre-sowing, sowing, harvest, and post-harvest activities. In some countries training courses are compulsory (see Annex III, fourth column). Consequently, the problem is not the training but the high cost of segregation. Segregation demands duplication of facilities, which can be very expensive. Cleaning

[8] In fact, art. 31 of Directive 2001/18/EC includes the obligation of creating registry offices ("...Member States shall also establish registers for recording the location of GMOs...")

the sowing and harvest machinery demands plenty of time and also money. Double facilities are not affordable for small farmers. Moreover, in small field regions those activities are not done by farmers but by third parties (specialised sowing or harvest professionals) who want to finish their work as soon as possible and who consider cleaning recommendations a wasting of time. Messean A. *et al.* (2006) have fixed an economic advantage of 43€ *per hectare* for GM maize compared to its conventional counterpart. This scholar affirms that cleaning machinery brings additional costs exceeding 55€ *per cleaning*. So, in regions where maize fields are smaller than 1 hectare, the cleaning costs would outweigh the economic advantages of GMO.

Apart from co-existence regulations *strictu sensu*, there are other important rules which could affect the development of GM crops. Specific ***liability regimes*** can determine farmers' attitudes toward GM crops. Some countries have established specific rules for liability in relation to GMO, but others regulate biotechnological damages through general tort laws. Germany and Austria have a specific strict liability regime. Denmark, Portugal and DEFRA proposal prefer a specific fault liability regime completed by a Public Compensation Fund. If farmers fulfill co-existence recommendations but there is still cross-pollination pollution, a Public Fund would compensate the sale price reduction, costs for sampling and analysis, and any losses in organic areas caused by the presence of genetically modified material. Finally in Spain and the UK there are no specific rules for economic damages arising from GM crops[9]

III. Main differences and similarities in co-existence measures in some European countries

It is evident that national co-existence rules and guidelines are very different and they determine the locations of GM crops (strict prohibition in Austria versus 70,000 hectares in Spain). The European Commission tried to find points in common through soft-law techniques. The "Recommendation of 23 July 2003..." (European

[9] In Continental Law, economic damages arising from GM crops may be included in the Civil Code liability. In Common Law, claims would seem to be in the law of nuisance or under the principle in *Rylands v. Fletcher*.

Commission – 2003b) is a complete catalogue of co-existence risks and measures but it does not "recommend" any specific distance of isolation, number of border rows, etc. In 2006 the European Commission wrote a "Report on the implementation of national measures on the coexistence..." (European Commission – 2006a). We have prepared a comparative table based on the information included in this report and additional data from other sources (see Annex III). We have chosen seven representative countries (Austria, Germany, Denmark, Portugal, United Kingdom, France, and Spain) and we have arranged them according the strictness of their co-existence regimes (from the strictest to the weakest). This classification corresponds reasonably well with the index of optimism for biotechnology of the Eurobarometer (European Commission – 2006b), which is included in the second column of the scheme.

Austria has the strictest regime. In fact, Austrian authorities do not want GM crops. There are certain "coexistence measures" but their real aim is to avoid GMO instead of promoting co-existence among GM, conventional and ecological crops. Zero risk seed purity regulation, compulsory training courses and strict liability are proofs of that policy. However, the requirement of a pre-sowing administrative authorization is the main guarantee of GMO national moratorium. Although the European Court of First Instance has said that Austria must not legally forbid GM cultivation[10], it is hardly probable that European authorities will pursue strict co-existence rules, especially considering the strong development of biological agriculture in Austria and the strong opposition of the public.

Germany is other country where biotechnology is not welcome. Apart from some controversies about isolation distances[11] and the requirement of an exam after training courses in good agricultural practices, the main tool for keeping out GMO is the special strict liability regime. The German liability regime for GMO is stricter than the Austrian one because it does not allow general exceptions like *force majeure* or acts of a third party. If there were diffuse pollution, all neighbours sowing GMO would be

[10] Judgment of the Court of First Instance (Fourth Chamber) of 5 October 2005 *Land Oberösterreich and Republic of Austria v Commission of the European Communities*, joined cases T-366/03 and T-235/04, European Court reports 2005 Page II-04005. The trial was appealed to the European Court of Justice but no decision has yet been reached. However, the Opinion of Advocate General is against appellants. See Opinion of Advocate General Sharpston of 15 May 2007 *Land Oberösterreich and Republic of Austria v Commission of the European Communities*, joined cases C-439/05 P and C-454/05 P, not published yet.

[11] Current agriculture guidelines recommend 25 meters of isolation but it is expected that 150/300 meters of separation will be compulsory next year.

responsible, even if some of them had fulfilled good agricultural practices. That is why only big breeding farms are sowing GM maize for their own livestock consumption (Coextra – 2007a). Moreover, the largest German farmer association (DBV) recommends that its members to be wary of planting GM crops because of liability consequences (Coextra – 2007b)

Denmark is the first country which has tackled the problem of no-fault pollution using a Public Compensation Fund. It is built up by 100DKK (9GBP) tax for each GM hectare. Apart from the liability regime, the main co-existence measure is a 200 meter isolation distance. However there are no GM crops in Denmark. One reason could be that maize is not suitable for Danish weather (there is very little cultivation of corn in Denmark). However, the decision of Danish government not to allow region-by-region segregation does not help to reduce segregation costs.

Portugal seems to have a well-balanced regime. It has a complete system of regulation (established before commercial planting) with compulsory training courses, strict anti-cross-pollination measures, and a Public Compensation Fund. However, isolation measures can be replaced by voluntary agreements among neighbours with the aim of creating either GM planting areas or GM-free areas. This kind of collective initiative avoids complicated anti-cross-pollination measures and expensive double farm facilities.

The UK DEFRA proposal includes also a Public Compensation Fund for no-fault pollution. However, anti-cross-pollination measures are limited to an 80/110 meter isolation distance. The proposal excludes other coordination measures and the promotion of region-by-region segregation. The fact that the weather in the UK is not suitable for maize will reduce the quantitative impact of this quite weak co-existence regime, which could be in force in 2008.

France and Spain, the biggest GM growers in Europe, have similar situations. They allow GM cultivation without a complete regulation regime. In both cases, the establishment of co-existence rules has been prevented by disputes between the Ministry of Agriculture (pressured by farmers' lobbies) and the Ministry of Environment (pressured by ecological lobbies). Nowadays, co-existence is ruled by seed company guidelines together with some specific regulations (APROSE – 2007). No

compulsory training courses, no specific liability rules, and 50 meters of isolation are the main characteristics of those regimes.

Region-by-region segregation seems to be the only affordable and convenient co-existence regime. European Law allows region-by-region segregation whenever it is founded on voluntary private agreements. Mediterranean countries are trying to develop this sort of segregation through their co-existence regulations. Thus, Portugal's coexistence decree and the 2005 Spanish proposal encourage authorities to promote this solution. However, North European countries are not very concerned about region-by-region segregation. The DEFRA 2006 proposal found it impracticable to achieve this sort of agreements in the UK (DEFRA – 2006). NGOs and some local authorities in France and Germany promote anti-GMO commitments, but exclusively with the aim of declaring GM-free areas.

Agricultural traditions (intensive or extensive agriculture), the high cost of segregation facilities, and difficulties in the coordination of isolation distances in small field regions are all factors which favor region-by-region segregation.

In fact, after 9 years of sowing GM crops in Spain, market forces have created region-by-region segregation there. In Aragon, a productive agricultural region, almost 50% of the maize is transgenic. Biological crops are being "expelled" from this region where ecological maize production has dropped 70% in only 4 years (El Pais – 2006). The main reason for this reduction is the fact that the ecological certification authority has detected GM pollution in 40% of tests (Assemblea Pagesa - Plataforam Transgenics Fora - Greenpeace - 2006). In contrast, Asturias and the Basque Country have declared themselves "GM-Free regions" with the support of regional governments and farmers' associations, and their biological maize production is growing.

IV Concluding remarks concerning sociological causes of co-existence regimes

Public opinion about biotechnology seems to affect co-existence regimes. The strictness of the regimes is indirectly proportional to the social acceptance of biotechnology. Member States seem to apply their "acceptable level of risk" in their co-

existence regulations. However, there are other links between co-existence rules and the sociological contexts apart from the strictness of the regimes.

Co-existence measures can be very difficult to carry out in small field regions. Moreover, segregation costs can outweigh the economic advantages of GM crops. Consequently, region-by-region segregation could be a good solution for these difficulties. However, because of European exigencies, region-by-region segregation only can be achieved through individual agreements among farmers. Cooperative and farmers' associations are very important in this concentration process. It is not the first time that European farmers worked together to fix common production methods with the support of regional authorities (see for example Geographical Indication rules). Taking into account those experiences, the Spanish and Portuguese co-existence regulations promote region-by-region segregation.

However, the well developed co-existence regimes of North European countries (like Denmark, Germany or UK DEFRA proposal) do not promote coordination methodology among farmers. Some local French authorities and some German NGOs are promoting farmers agreements for building GM-free regions, but there is no general official policy for region-by-region segregation in those countries. Are Spanish or Portuguese farmers more open to coordinating regional production models than English or German farmers? I do not think so. The big question is: Do certain authorities refuse promoting region-by-region segregation because they think that it would be socially impracticable for their farmers, or because they are afraid of being seen as promoters of GM regions?

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Annex I: Classification of co-existence measures taking into account risk sources

<table>
<tr><th>Source of “pollution”</th><th>Field by field
co-existence measure</th><th>Region by region
co-existence measure</th></tr>
<tr><td>Seed impurities</td><td colspan="2">Certified Seeds</td></tr>
<tr><td rowspan="3">Cross-pollination</td><td>Isolation distances</td><td rowspan="4">Voluntary agreements among neighbours</td></tr>
<tr><td>Border rows</td></tr>
<tr><td>Coordination among neighbours to avoid simultaneous flowering dates</td></tr>
<tr><td rowspan="3">Pre-sowing, sowing, harvest and post-harvest activities</td><td>Segregation facilities</td></tr>
<tr><td colspan="2">Training in good agricultural practices
(e.g. cleaning of machinery)</td></tr>
<tr><td colspan="2">Notification addressed to government and neighbours</td></tr>
</table>

Annex II: Quantification of "pollution" risks taking into account sources and co-existence measures

<table>
<tr><th rowspan="2">Source</th><th rowspan="2">Rate of "pollution" without co-existence</th><th rowspan="2" colspan="2">Co-existence measure</th><th colspan="2">Rate of "pollution" expected</th></tr>
<tr><th>By measure</th><th>By source</th></tr>
<tr><td>Seeds impurities</td><td>0.70%</td><td colspan="2">Certified Seeds</td><td colspan="2">0.50-0.30%</td></tr>
<tr><td rowspan="6">Cross-pollination</td><td rowspan="6">1.50%</td><td rowspan="4">Isolation distances</td><td>20m</td><td>0.90%</td><td rowspan="6">0.20%</td></tr>
<tr><td>50m</td><td>0.30%</td></tr>
<tr><td>100m</td><td>0.01%</td></tr>
<tr><td>200m</td><td>0,01%</td></tr>
<tr><td colspan="2">Border rows</td><td>0.90%</td></tr>
<tr><td colspan="2">Change flowering times or use hybrid seeds</td><td>0.60%</td></tr>
<tr><td>Pre-sowing, sowing, harvest and post-harvest activities</td><td>0.50%</td><td colspan="2">Training in good agricultural practices</td><td colspan="2">0.10%</td></tr>
<tr><td>TOTAL</td><td>2.70-1.50%</td><td colspan="2"></td><td colspan="2">0.60%</td></tr>
</table>

This is a simplified scheme. "Pollution" rates and the effectiveness of measures depend on several factors, like field sizes, prevailing winds, and climatic and geographical conditions
Data Source: Bock A-K *et al.* (2002); DEFRA (2005) and Messean A. *et al.* (2006)

Annex III: Main differences in co-existence measures in some European countries

Country	Optimism for Biotech (Euro-barometer 2005)	GM plantings in 2007[a]	Training courses in Good Agricultural Practices	Field by field segregation			Region by region segregation
				Coordination in sowing or use of seeds with different flowering dates	Isolation distances & Border rows	Liability Regime in case of "pollution"	
Austria (Gene Technology Act)	22%	No commercial crops	Compulsory	Since Austria prohibits the importation and sale of GMO, it does not need anti-cross-pollination measures		Strict Liability	All *länder* (regions) have declared themselves "GM-Free"
Germany (Gene Technology Act)	33%	2.500 hectares (mostly sowed in breeding farms for their own livestock consumption)	Compulsory (with exam)	No specific rules	2007 Proposal: 150 meters of isolation for conventional maize, and 300 meters for organic maize Current guidelines of seed companies: 20 meters of isolation + 20 meters of border rows	Strict Liability (fulfilling good agricultural practices is not a valid defense)	There are more than 100 small GM-Free regions promoted by environmental organizations. They encourage farmers to sign legally binding obligations not to grow GMOs.
Denmark (Act Nº 436/2004)	56%	No commercial crops	Compulsory	No specific rules	200 meters of isolation	Fault Liability + Compensation Fund	The government does not allow GM-free regions
Portugal (Decree Nº 160/2005)	71%	4200 hectares	Compulsory	Optional (depends on farmer agreements)	Conventional maize: 200 meters of isolation or 24 border rows. Biological maize: 300 meters of isolation or 50 meters of isolation plus 28 border rows.	Fault Liability + Compensation Fund	Agricultural associations and NGO can create GM/non-GM production areas with the agreement of farmers
UK (2006 DEFRA proposal)	50%	No commercial crops	Optional	From DEFRA point of view, coordination is unviable in UK	Forage maize: 80 meters of isolation Grain maize: 110 meters of isolation	Fault Liability + Compensation Fund	DEFRA will offer guidance for creating GM-free areas, but it will not promote them.
France (no general regulation)	49%	15.000 hectares	Optional	No specific rules	Decree of March 2007: 50 meters of isolation	No specific rules	Many local authorities have promoted voluntary agreements for creating GM-free areas.
Spain (2005 regulation proposal)	75%	70.000 hectares	Optional	Local Authorities can coordinate sowing dates to allow different flowering times	Last draft: 220 meters of isolation + 4 border rows (except in case of agreement among neighbours) Current guidelines of seed companies: 50 meters of isolation + 4 border rows	No specific rules	Authorities may promote and coordinate voluntary agreements concerning region by region segregation.

[a] Total grain maize production: Austria 200.000 hectares, France 1.808.000, Germany 395.000 hectares, UK 2.500 hectares Portugal 132.000 hectares, Spain 453.600 hectares.