Reports

This part of the EJRR hosts reports in which our correspondents keep readers up to date on the most recent developments in different areas of risk regulation. Our aim is to fuel the debate and trigger future research on cutting-edge risk subjects. The Reports are organised under different policy sections. Further sections will be added at regular intervals. If you are interested in contributing to any of the existing sections, please contact the Reports Editor at e.bonadio@abertay.ac.uk

Biotechnology

This section aims to update readers on decisions related to marketing products of modern biotechnology (e.g., GMOs, animal clones) at EU level and on national measures concerning their production. Special attention is devoted to problems of competence between Member States and the EU in regulating biotechnology issues; the institutional dynamics of decision making regarding products derived from modern biotechnology; the relationship between the EFSA and the EU institutions on green biotech-related issues; the evolution of EU regulatory framework and of national attitudes towards the risks and benefits of biotechnology derived products and their production. This section will also delve into the interaction between the EU legislation and WTO law regarding advances in the application of biotechnology within the agri-food value chain.

Coexistence of Genetically Modified, Conventional and Organic Products in the European Market: State of the Art Report

I. Introduction

Genetically Modified Organisms (GMOs) are plants or animals whose genetic material has been altered by using *genetic engineering techniques*[1]. Even though some people believe that GMOs are just alike any other *genetic improvements*[2] and are thus equivalent to conventional (i.e. non-biotech) products, for others they are completely new products that have to be assessed in detail and must be specifically regulated before their introduction on the market. This is the position of the EU regulation.

Generally speaking, GMOs involve three sorts of risks: environmental, health and economic. While the first two are assessed and managed by a European harmonised authorisation procedure, the third is regulated mainly at Member State level through the so-call "coexistence" rules.

In this paper, we will begin by introducing the legal framework of environmental and sanitary risk management of GM crops in Europe and the rise of the "coexistence" policy as a consensus agreement of technological pluralism. Then we will describe the economic risks involving GM crops and the proposed co-existence measures. Finally, we will conclude with some reflections on the co-existence measures proposed by the Member States and the EU, and their consequences for the placing of GM products on the single market.

II. Environmental and sanitary risk management of GMs in Europe and the rise of the "coexistence" policy

Environmental and health risks arising from GMOs are covered by the Deliberate Release Directive

1 For a more detailed definition see OECD "OECD's Glossary of Terms of Biosecurity Codes", available on the Internet at http://www.biosecuritycodes.org/gloss.htm (last accessed on 15 January 2009): "GMOs are organisms wherein the genetic material (ADN) has been artificially altered, usually by replacing some of the host organism's genes with those of another related or unrelated species".

2 *Genetic improvements* are traditional laboratory activities (selection, controlled crosspollination or hybridization) either geared to avoid weakness, or to improve the quality and profitability of agricultural products. Even though these necessary activities produce modifications in the genetic material, unlike biotech manipulation, they do not act directly on the DNA but by a trial-and-error methodology. Consequently, they take long time to achieve expected results and they never cross species barriers.

2001/18/EC[3], completed by the GM Food and Feed Regulation EC 1829/2003[4] and the Traceability and Labelling of GMOs Regulation EC 1830/2003[5].

Directive 2001/18/EC has two procedures, one for the deliberate release of GMOs into the environment (i.e. the cultivation of GMOs in European fields mainly for research purposes) and the other for the placing of GMOs on the market (i.e. the consumption of GMOs which have been either grown in the Community or imported). While both procedures include the assessment of environmental and sanitary risks (Annex II of the Directive), the procedure for placing on the market is the only one that permits the free circulation of GM goods (Article 22). In general terms, a national authority proposal is required, as well as a positive report from the EFSA (*European Food Safety Authority*) and a Decision according to the comitology system if there is opposition. The strong opposition of some Member States during these proceedings was the origin of a *de facto* moratorium between 1999 and 2004[6].

Nevertheless, a Directive 2001/18/EC authorisation for placing on the market does not automatically allow the cultivation of GM crops. Firstly, Article 23 of the Directive 2001/18/EC permits Member States to restrict GMO circulation provisionally whenever either new or additional information (or the reassessment of existing information on the basis of new scientific knowledge) suggests that GMOs constitute a risk for human health or the environment. Some Member States[7] have employed this safeguard clause with supporting arguments deemed scientifically unjustified by the EFSA[8]. However, the inability of the European Commission[9] to obtain a Decision of condemnation from the Council has meant that these prohibitions continue, generating a sort of limited *de facto* moratorium.

Secondly, if a crop is cultivated for commercial purposes, the seed must be registered in a national or common catalogue of varieties. Consequently, even if GMOs involving maize, oilseed rape, soybean, and cotton have been authorised in the European market[10], only GM maize has been included in catalogues of varieties and therefore it is the only crop authorised for commercial cultivation. Moreover, between 1998 and 2004, Spain was the only European country which included GM varieties in its national catalogue. It was not until 2004, with the end of *de facto* moratorium, that 17 GM maize varieties were included in the Common Catalogue which in theory permitted their free cultivation in any EU country.

Finally, Article 26a of Directive 2001/18/EC allows Member States to establish "measures to avoid the unintended presence of GMOs in other products". These measures are supposed to be necessary to ensure the viability of conventional and organic farming and their "coexistence" with genetically modified crops. They were the price to be paid for

3 European Parliament and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, OJ L 106, pp. 1–39.

4 European Parliament and Council Regulation (EC) No 1829/2003 on genetically modified food and feed (Text with EEA relevance), OJ L 268, pp. 1–23.

5 European Parliament and Council Regulation (EC) No. 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ L 268, pp. 24–28.

6 In 1999 five countries (Denmark, Greece, France, Italy and Luxembourg) constituted a blocking minority in the European Council by declaring that they would not vote for any new authorisation of GMO until it "put in place a tighter, more transparent framework, in particular for risk assessment, having regard to the specifics of European ecosystems, monitoring and labelling …". The European Commission, aware of the sensitivity of the issue, never took a Decision to unfreeze the proceedings until the Directive 2001/18/EC and Regulations EC 1829/2003 and 1830/2003 were passed. See Europa Press Release "2194th Council Meeting – Environment, Luxembourg, 24/25 June 1999", PRES/99/203, at p. 22.

7 Austria (14 February 1997 for Bt176 maize; 8 May 2000 for T25 and MON810 maize – submitting additional information on February 2004 and November 2007 –; 27 July 2007 for oilseed rape GT73; 15 July 2008 for oilseed rape MS8, RF3 and MS8xRF3; 16 July 2008 for MON863 maize); France (20 November 1998 for GM canola – renewed on 26 July 2001, 6 October 2003 and 27 August 2004 –, and 9 February 2008 for MON810 maize); Germany (28 February, 2 March and 4 April 2000 for GM maize); Greece (3 November 1998 for GM canola; 29 March 2006 – extended on 13 September 2007 – for MON810 maize); Hungary (20 January 2005 for MON810 maize –submitting additional information on April 2008 –); and Luxemburg (17 March 1997 for Bt176 maize).

8 Questions EFSA-Q-2005-294, EFSA-Q-2004-062, EFSA-Q-2004-062, EFSA-Q-2005-055, EFSA-Q-2006-048, EFSA-Q-2006-048, Question EFSA-Q-2008-077, EFSA-Q-2008-313, EFSA-Q-2008-316, EFSA-Q-2008-314, EFSA-Q-2008-315, EFSA-Q-2008-742, EFSA-Q-2008-743; all of them available on the Internet at http://www.efsa.europa.eu/en/scdocs.htm.

9 European Commission Proposals COM(1998)340, COM(2005)161, COM(2005)162, COM(2005)164, COM(2005)165, COM(2005)166, COM(2005)167, COM(2005)169, COM(2006)509, COM(2006)510, COM(2006)713, COM(2007)586, COM(2007)589, COM(2009)12, COM(2009)51, COM(2009)56; all of them available on the Internet at http://eur-lex.europa.eu/.

10 The complete list of authorized GMOs can be consulted on the Internet at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

resolving the conflict of the *de facto* moratorium[11]; in practice, they implied the establishment of a new policy for GMOs in the EU.

According to the definition provided by a Commission Recommendation of 2003, "coexistence refers to the ability of farmers to make a practical choice between conventional, organic and GM-crop production, in compliance with the legal obligations for labelling and/or purity standards"[12]. To guarantee this right of choice, it is necessary not only to isolate the three supply chains but also to provide each one with the economic viability to survive. Isolation is guaranteed by three tools: a threshold, a label and a traceability system. At EU level, Regulation 1829/2003 establishes a 0.9 % tolerance labelling threshold[13] and Regulation 1830/2003 governs traceability for GMO-labelled products. However, it is up to the Member States to decide which measures are necessary to achieve the 0.9 rule. This decision is quite important because it determines the feasibility of each chain. Moreover, the discretionary power afforded by Article 26a of Directive 2001/18/EC allows the Member States to add elements to the concept of coexistence. For example, the Walloon decree of 2008 has introduced the goal of "*préserver la liberté de choix des consommateurs pour les produits qu'ils consomment*"[14], putting it at the same level as freedom of choice for farmers[15]. German[16], Portuguese[17] and French[18] laws have similar interpretations. Consequently, the subsistence of the three chains is acknowledged as an economic value not only on the supply side (freedom of enterprises) but also on the demand side (consumers' rights regarding food diversity).

To sum up, "coexistence" could be understood as a general project of "*pluralisme technologique*"[19] that aims to guarantee the right to produce and consume with or without GMO through the isolation of GM, conventional and organic supply chains. For this purpose, coexistence takes advantage of three EU tools (a threshold, a label, and a traceability system). The 0.9 labelling threshold[20] is the border between the GM and non-GM chains, and the traceability system[21] guarantees their inviolability. However, the choice of what measures would achieve the 0.9 threshold lies in the hands of the Member States.

Coexistence is a new version of the old principle of freedom of trade and industry. The more that technological pluralism is preserved, the more will freedom of choice be assured to producers and consumers. Coexistence of GM, non-GM and biological crops means that, for the first time in history, a new

11 In 2003 the United States, Canada, and Argentina requested the establishment of a WTO panel concerning certain measures taken by the EC and its Member States affecting imports of GM products. The controversy was two-sided: on one hand, the so called *de facto* moratorium on the approval of GM products; on the other hand, the Member State-level measures – safeguards measures – affecting the circulation of authorised GMO. On 29 September 2006 the Panel found in both that the EC and its Member States acted inconsistently with their obligations under WTO law, but, taking into account that the moratorium had ended in August 2003, it did not include recommendations on that aspect. WTO Panel Report "European Communities – Measures Affecting the Approval and Marketing of Biotech Products" (WT/DS291, 292, and 293), circulated on 29 September 2006.

12 European 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 farming, OJ 2003 L 189/36, p. 40.

13 Applicable also to organic products according to Council Regulation (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, OJ L 189, pp. 1–23.

14 Article 1 of Wallon *Décret relatif à la coexistence des cultures génétiquement modifiées avec les cultures conventionnelles et les cultures biologiques du 19 juin 2008,* published in the *Moniteur Belge* on 8 August 2008.

15 In the 2003 recommendation the European Commission said that coexistence was linked to consumer choice, but this right of choice was not included in the concept of coexistence

16 Explanatory Statements of the German Act reorganising legislation concerning genetic engineering (*Gesetz zur Neuordnung des Gentechnikrechts – GenTG*), published in the *Bundesgesetzblatt* on 3 February 2005. See the English version of the TRIS (Technical Regulations Information System; Ref. 2004-133-D): "It [coexistence] maintains the freedom of choice for consumers as well as agricultural and food producers as to whether or not they wish to buy, use or produce genetically modified products and contributes to pacification".

17 Explanatory Statements of the Portuguese *Decreto Lei No 160/2005* of 21 September 2005, published in *Diário da República* on 21 September 2005. See the English version of the TRIS (Ref. 2005-271-P): "It must be guaranteed that no agricultural system will be excluded in the European Union as the existence of different agricultural production systems is a prerequisite for ensuring a high degree of consumer choice in terms of agricultural products and for allowing farmers to freely choose the type of agricultural production to be used".

18 Article L. 531-1 of the French *Code de l'Environnement*: "*La liberté de consommer et de produire avec ou sans organismes génétiquement modifiés, sans que cela nuise à l'intégrité de l'environnement et à la spécificité des cultures traditionnelles et de qualité, est garantie* ..." (in accordance with the version established by the French *Loi no 2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés*, published in the *Journal Officiel de la République Française* on 26 June 2008).

19 Hermitte, Marie-Angèle, "*La nature juridique du projet de coexistence entre filières OGM et filières non-OGM: pluralisme technologique et liberté du commerce et de l'industrie*", 1 *Cahiers Droit, Sciences & Technologies* (2008), pp. 161 *et sqq*.

20 Regulation EC 1830/2003, at Article 4.7.

21 Regulation EC 1830/2003 and EC 65/2004.

technology will not rapidly replace the older one, but rather both of them will be preserved to guarantee production and consumer diversity and reversibility in case of failure.

The coexistence project was born as a social agreement between those in favour of GM and those who were against. Its core idea is the preservation of diversity in production methods so that operators may freely choose the most convenient method. Consequently, the system that best guarantees this conservation is the most suitable one. For guaranteeing individual freedom it is necessary that others tolerate some restrictions. Taking into account that good practices do not assure this tolerance, a compulsory coexistence rule framework is the only model which guarantees the greatest market freedom.

Coexistence rules, by their very nature, create restrictions for GM and non-GM farmers (including those ones who farm organically) and also for third parties (neighbours, seed suppliers, carriers, store companies, etc.). The problem is that if they are stricter with one chain than with the others, they could be favouring one kind of production over the others. Consequently, any unbalanced distribution of charges could generate disproportionate restrictions on one particular supply chain, thus affecting the free movement of goods or even the right of choice that, paradoxically, is what the coexistence project attempts to guarantee.

III. Economic risks arising from the coexistence policy

The existence of different markets for GM, conventional and organic products implies the risk of economic losses in case of unintentional ('*adventitious*') presence of GMOs in non-GM products. Non-GM products have to be labelled as GM whenever they contain "*adventitious or technically unavoidable presence*"[22] of GMO traces over 0.9 %. Consequently, one of the aims of co-existence is to avoid the adventitious mixture of GM and non-GM material and to compensate farmers for the potential damages arising from it. Taking into account that "polluted" products could be sold in the market as GM, economic damages are usually limited to a reduction in the price or the loss of ecological status[23]. However many Member States[24] defend a wider concept of economic damages, including in their coexistence legislation the protection of particularly fragile rural economies, normally rich in organic production, where the presence of GMOs could easily destroy a complex ecosystem involving agro-biodiversity, cultural know-how, and production quality.

In the next part we will analyse first the possible sources of GM mixtures, then look at some interesting liability rules specifically designed to compensate coexistence risks. Finally, we will explore the possibility of establishing GMO-free regions on the basis of coexistence rules.

22 Taking into account Article 12 of Regulation 1830/2003, the 0.9 threshold refers only to the unintentional and incidental commingling of trace amounts of GMOs.

23 Assemblea Pagesa – Plataforam Transgenics Fora – Greenpeace "*La imposible co-existencia. Siete años de transgénicos contaminan el maíz ecológico y el convencional: una aproximación a partir de los casos de Cataluña y Aragón*", 2006, at p. 63, available on the Internet at http://www.greenpeace.org/espana/reports/copy-of-la-imposible-coexisten (last accesed on 15 January 2010).

24 For example see Upper Austria Provincial Act regarding precautionary regulations and measures in the sphere of genetic engineering (*Landesgesetz über Regelungen und Maßnahmen zur Gentechnik-Vorsorge*), published in the *Landesgesetzblatt für Oberösterreich* on 6 July 2006, Article 4 (English version at TRIS, Ref. 2005-610-A).

25 Data Sources: Bock, Anne-Katrin/Lheureux, Karine/Libeau-Dulos, Monique et al., "Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture", Joint Research Centre – Institute for Prospective Technological Studies and European Science and Technology Observatory, 2002, available on the Internet at ftp://ftp.jrc.es/pub/EURdoc/eur20394en.pdf (last accessed on 15 January 2010). Messean, Antoine/Angevin, Frédérique/Gómez-Barbero, Manual et al. "New case studies on the coexistence of GM and non-GM crops in European agriculture", Joint Research Centre – Institute for Prospective Technological Studies and European Science and Technology Observatory, 2006, available on the Internet at http://ftp.jrc.es/EURdoc/eur22102en.pdf (last accessed on 15 January 2010); Dunwell, J.M. and Ford, C.S. "Desk study on technologies for biological containment of GM and non-GM crops", University of Reading (DEFRA Contract CPEC 47), available on the Internet at http://randd.defra.gov.uk/Document.aspx?Document=CB02036_3629_FRP.doc (last accessed on 15 January 2010).

26 European law recognises for certain crops the right of farmers to use part of the harvest as seeds in future campaigns. Even though maize is not among these crops, this right could be affected if GM varieties of potatoes or wheat are introduced in variety catalogues. See Article 14 of Council Regulation (EC) No 2100/94 on Community plant variety rights, OJ L 227, pp. 1–30.

27 At EU level, European Parliament and of the Council Directive 98/44/EC on the legal protection of biotechnological inventions, OJ L 213, pp. 13–21.

28 European Commission Draft Decision establishing, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, "thresholds for adventitious or technically unavoidable traces of genetically modified seeds in other products", 19 October 2004, unpublished in the OJ. This proposal was based on the Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds, (Opinion adopted by the Committee on 7 March 2001), SCP/GMO-SEED-CONT/002-FINAL.

Table 1: Quantification of mixture risks taking into account sources and co-existence measures

Source	Rate of mixture without co-existence	Co-existence measure		Rate of mixture expected	
				By measure	By source
Seed impurities	0.70%	Certified Seeds		0.50–0.30%	
Cross-pollination	1.50%	Isolation distances	20m	0.90%	0.20%
			50m	0.30%	
			100m	0.01%	
			200m	0,01%	
		Border rows		0.90%	
		Change flowering times or use hybrid seeds		0.60%	
Pre-sowing, sowing, harvest and post-harvest activities	0.50%	Training in good agricultural practices		0.10%	
TOTAL	2.70–1.50%			0.60%	

Note: Table 1[25] *is a simplified scheme. Mixture rates and the effectiveness of measures depend on several factors like field sizes, prevailing winds, and climatic and geographical conditions.*

1. Sources of mixtures and coexistence measures for controlling them

As far as maize is concerned, there are three main sources for mixtures: a) seed impurities, b) cross-pollination, and c) pre-sowing, sowing, harvest and post-harvest mixtures.

a. Seed impurities

From the farmer's point of view, seed impurities may easily be prevented by buying certified seeds which guarantee reduced levels of impurities. However, this measure has important socio-economic consequences: it fortifies the position of seed companies, which will have a captive market for both GMO and non-GMO production[26]. The monopoly on the GMO seeds market is already assured by intellectual property legislation[27], but the monopoly on non-GM seeds will be by coexistence one This particularly affects organic farmers who are used to sowing their own seeds, since they will be obliged to buy certified seeds every year to avoid the accumulative effects of crosspollination mixtures.

On the other hand, up to the present time there has not been any compulsory threshold for non-GMO certified seeds. This means that they are subject to the general 0.9 rule. However, it is clear that with this threshold at sowing, it would be very difficult to achieve that level at the end of the chain because of the accumulative effects of mixtures. For that reason, in 2003 the European Commission proposed a 0.3 threshold for maize and canola seeds[28]. This proposal was severely criticised, on one hand by environmental organisations wanting a zero risk limit[29] and on the other hand by associations of seed companies claiming that it would be too expensive to achieve, and instead suggesting a 0.7% threshold[30]. In the end, the initiative was not passed.

Nevertheless, samples of seeds taken in France (where 50% of European seeds are being multiplied) show that GMO traces in non-GMO seeds are very rare and in all cases fall below 0.9%[31]. Despite that fact, some Member States have developed "purity

29 Arguments against the project are well explained in Haerlin, Benedikt, "The European Union's planned Directive regarding the adventitious presence of genetically modified organisms in Seeds", available on the Internet at http://www.saveourseeds.org/fileadmin/files/SOS/memorandum_sos_eng.pdf (last accessed on 15 January 2010).

30 ESA-EuropaBio "Adventitious Presence, Bringing Clarity to Confusion", European Seed Association and The European Association for Bioindustries, 2007, available on the Internet at http://www.europabio.org/positions/GBE/AP%20seed_260307.pdf (last accessed on 15 January 2010).

31 In France controls on local seeds are carried out by the *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes du Ministère de l'Économie, des Finances et de l'Emploi*, but imported seeds fall within the competence of the *Direction Générale de l'Alimentation du Ministère de l'Agriculture*. Samples taken in 2005 (last available information) did not reveal any GMO traces in France-multiplied seeds but in some imported ones. In all cases the presence was between 0.1 and 0.25%. See DGCCRF "*Enquête DGCCRF sur la présence d'OGM dans les semences conventionnelles*", 2006, available on the Internet at http://www.dgccrf.bercy.gouv.fr/fonds_documentaire/dgccrf/02_actualite/breves/brv1005b_bis.htm (last accessed on 15 January 2010); DGA "Bilan du plan de contrôle 2005 des semences importées de pays tiers", 2006, available on the Internet at http://agriculture.gouv.fr/IMG/pdf/bilan_controlev2_2005.pdf (last accessed on 15 January 2010).

requirements". As an example, after the Pioneer™ scandal in 2001[32] Austria introduced a controversial technical zero tolerance policy on seed purity standards[33].

b. 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% falls to the ground within a two-metre perimeter. To avoid cross-pollination, coexistence practices recommend isolation distances, border crop barriers, coordination in sowing to prevent simultaneous flowering dates, and the use of hybrid seeds which produce less pollen[34].

According to scientific reports of the Joint Research Centre, without anti-cross-pollination measures GM admixture could reach 1.5%[35]. Each anti-cross-pollination measure can be used alone or in conjunction with others. Although there are different approaches (from 0.1 demanded by organic organisations to 0.9 wanted by GMO seed companies), generally speaking coexistence regulations aim to keep cross-pollination below 0.20%. However, as described below, many disagreements have arisen over the most suitable anti-cross-pollination system.

For maize, recommended isolation distances range from 25 metres (Netherlands) to 600 metres (Luxembourg), while important differences exist between conventional and organic farmers[36]. The Spanish case is a good example of the disagreements over distances. Up to 2006, seed companies recommended 50 metres[37] while the 2005 Coexistence Bill[38] (never approved) proposed 220 metres.

Nevertheless, taking into account the data from the EU Joint Research Centre, with an isolation distance of 100 meters cross-pollination would be at just *0.01 per cent*, and it seems clear that an isolation distance of more than 50 meters could only be justified by precautionary principles.

Border rows and coordination among neighbours to avoid simultaneous flowering dates are not as effective as isolation distances, but they are very useful when used 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 metres of isolation plus 4 border rows plus a three-week gap in sowing dates, or by 16 metres of isolation distance plus a one week gap in sowing dates[39]. Other examples of combined

32 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, and the Austrian State paid €2.67 million in compensation."

33 In practice Austria has a 0.1 % threshold for seeds, which is the test detectable boundary. It only could be guaranteed by enclosed multiplication in huge greenhouses. See *Verordnung des Bundesministers für Land- und Forstwirtschaft über die Verunreinigung von Saatgut mit gentechnisch veränderten Organismen und die Kennzeichnung von GVO Sorten und Saatgut von GVO Sorten (Saatgut-Gentechnik-Verordnung)*, published in the *Bundesgesetzblatt für die Republik Österreich* on 21 December 2001. For a detailed comment in English, see Greenpeace "Austrian 'Purity Requirement' successful for past three years", available on the Internet at http://www.gmo-free-regions.org/Downloads/ WS_B5_ austrianseedpurity.pdf (last accessed on 15 January 2010).

34 A complete catalogue of anti crosspollination measures can be found in Commission Recommendation 2003/556/EC, p. 44.

35 Bock, Anne-Katrin/Lheureux, Karine/Libeau-Dulos, Monique *et al.*, "Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture", Joint Research Centre of the European Commission and Institute for Prospective Technological Studies, 2002, available on the Internet at ftp://ftp.jrc.es/pub/EURdoc/eur20394en.pdf (last accessed on 15 January 2010).

36 For a detailed catalogue of isolation distances see European Commission Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming (Annex), COM(2006) 104, p. 15; and European Commission Report on the coexistence of genetically modified crops with conventional and organic farming (Annex), COM(2009) 153, p. 27.

37 APROSE "Guía 2006 de Buenas Prácticas para el Cultivo de maíz Bt", Asociación Profesional de Empresas Productoras de Semillas Selectas, available on the Internet at http://www.agrodigital.com/upload/maizBt.pdf (last accessed on 15 January 2010).

38 Spanish Bill of *Real Decreto por el que se aprueba el Reglamento sobre coexistencia de los cultivos modificados genéticamente con los convencionales y ecológicos*, available on the Internet at http://www.agrodigital.com/images/ogm.pdf (last accessed on 15 January 2010). The bill has never been approved, being the proposal for a standby situation.

39 Comisión Nacional de Biovigilancia "*Dictamen elaborado en respuesta a la pregunta realizada por La dirección general de agricultura al grupo de expertos de carácter científico de la Comisión Nacional de Biovigilancia sobre posibilidad de coexistencia entre variedades modificadas genéticamente y tradicionales*", 2006, available on the Internet at http://www.agrodigital.com/images/biovigilancia.pdf (last accessed on 15 January 2010).

measures are the Portuguese legislation, which allows GM farmers to choose between 200 metres of isolation or 25 border rows[40], and the current Spanish seed companies' good practice code, which recommends a combination of isolation distance (20 metres) plus 12 border rows[41].

Isolation distances and border rows presuppose a certain amount of coordination among neighbours. Coordination can be direct (through notification) or indirect (through a public register office which specifically identifies fields where GMOs are grown[42]). An important number of EU countries include one or both of these information obligations. For example, neighbours' notification obligations are imposed in Germany[43], Portugal[44], Denmark[45] and the Czech Republic[46]. Regarding "neighbours", they are not only farmers who sow in bordering fields, but also those who sow inside the isolation perimeter. That is the solution in Portugal[47], Czech Republic[48], Wallonia[49], and Spain[50]. Regarding Public Registries, an important issue concerns the openness and public access of the information disclosed. A non-restrictive diffusion of information, as appears to be supported by the French[51], Danish[52], and some Austrian regional[53] regulations, could facilitate sabotage actions and, consequently, discourage GM cultivation. By contrast, in Wallonia[54], Germany[55], Portugal[56], and Styria[57] information diffusion is restricted.

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

Training in good agricultural practices is the simplest way to guarantee segregation during pre-sowing, sowing, harvest and post-harvest activities. In some countries (Austria, Denmark, Germany and Portugal) training courses are compulsory, while in others (France, Spain, and United Kingdom) they are strongly recommended[58]. Consequently, the problem lies not in the training but in the high cost of segregation facilities. Segregation demands duplication of facilities, which can be very expensive. For example, cleaning the sowing and harvest machinery demands plenty of time and also money. Moreover, in regions with small-sized fields, such activities are not done by farmers but by third parties (professionals specialising in sowing or harvesting) who want to finish their work as soon as possible and who regard cleaning recommendations as "a waste of time". Messean[59] calculates 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 operation*. So, in regions where maize fields are smaller than one hectare, the cleaning costs would outweigh the economic advantages of GMO.

40 Portuguese *Decreto Lei No 160/2005* , at Annex I.

41 ANOVE "*Guía 2009 de Buenas Prácticas para el Cultivo de maíz Bt*", Asociación Nacional de Obtentores Vegetales, available on the Internet at http://www.anove.es/docs/maizbt_2009.pdf (last accessed on 15 January 2010).

42 In fact, Article 31 of Directive 2001/18/EC includes the obligation of creating such Registry Offices.

43 German Order on good farming practice in the cultivation of genetically modified plants (Order on the Cultivation of Genetically Engineered Plants) – *Verordnung über die gute fachliche Praxis bei der Erzeugung gentechnisch veränderter Pflanzen (Gentechnik-Pflanzenerzeugungsverordnung – GenTPflEV)*, published in the *Bundesgesetzblatt* on 7 April 2008, at § 3 (English version at TRIS, Ref. ?)

44 Portuguese *Decreto Lei No 160/2005* , Article 4.1.e.

45 Danish Order on the cultivation of genetically modified crops (*Bekendtgørelse om dyrkning m.v. af genetisk modificerede afgrøder*), published in *BEK* on 28 February 2008, §18 (English version at TRIS, Ref. 2007-598-DK).

46 Czech Decree laying down details of the cultivation of genetically modified varieties (*Vyhláska o blizsích podmínkách pestování geneticky modifikavné odrudy*), published in the *Sbírka Zákonu Ceská Republika* on 20 March 2006, Article 2 and Annex I (English version at TRIS, Ref. 2005-687-CZ).

47 Portuguese *Decreto Lei No 160/2005* , at Article 4.1.e.

48 Czech Decree, Article 1.

49 Wallon *Décret,* Article 2.8.

50 Spanish Bill, Article 5.

51 French *Code de l'Environnement*, Article L. 663-1.

52 Danish Order at Article 11. Diffusion is not compulsory *per se* but this depends on the decision of the Ministry of Agriculture.

53 §5 and §8 Wiener Gt-VG, §5 and §9 Salzburg GtVG, §6 and §13 Bgld. GtVG, §6 and §13 Tiroler Gt-VG, §5 and §9 NÖ GVG, §5 and §10 Oö. Gt-VG 2006.

54 Wallon *Décret*, at Article 11.

55 German *GenTG*, at §16 a. In Germany it is not possible to publish the names of farmers but it is possible to find out the location of GM fields.

56 Portuguese *Decreto Lei No 160/2005*, Article 6.3. In Portugal the Public Registry publishes the name of the farming enterprise but not the specific location of the field.

57 Article §8 and §13 StGTVG 2006.

58 European Commission Reports COM(2006) 104, p. 11; and COM(2009) 153 (Annex), p. 20.

59 Messean, Antoine/Angevin, Frédérique/Gómez-Barbero, Manual *et al.* "New case studies on the coexistence of GM and non-GM crops in European agriculture", Joint Research Centre – Institute for Prospective Technological Studies and European Science and Technology Observatory, 2006, available on the Internet at http://ftp.jrc.es/EURdoc/eur22102en.pdf (last accessed on 15 January 2010).

2. Liability rules specifically designed to compensate coexistence risks

Apart from good practices in segregation, there are other important coexistence rules which could affect the development of GM crops. Specific liability regimes can determine the attitudes of farmers towards GM crops. Some countries have established specific rules for liability in relation to GMOs, but others regulate biotechnology damages through general tort laws. Germany and Austria have a specific strict liability regime. Denmark, Portugal and Belgian regions prefer a specific fault liability regime completed by a Public Compensation Fund. If farmers fulfil the co-existence recommendations but cross-pollination pollution still occurs, a Public Fund would compensate for the sale price reduction, costs of sampling and analysis, and any losses in organic areas caused by the presence of genetically modified material. Finally, in Spain and the Czech Republic there are no specific rules for compensating economic damages arising from GM crops[60].

The German liability regime for GMO is perhaps the strictest, since it does not allow any general exceptions like *force majeure* or acts of a third party. Transgenic flow is an Article 906 BGB "nuisance" that does not require evidence of fault[61]. If diffuse pollution occurs, all neighbours sowing GMOs would be held responsible, even if some of them had complied with good agricultural practices. That is why the largest German farmers' association (*Deutscher Bauernverband* – DBV) advises its members to be wary of planting GM crops because of their liability consequences[62]. The European Commission[63] and some scholars have qualified this regime as "disproportionate"[64].

Denmark is the first country to tackle the problem of no-fault mixture using a Public Compensation Fund[65], built up from levying 100DKK (€13) tax on each GM hectare planted. However, there were no GM crops in Denmark until 2008, and even now production is marginal[66], so it is difficult to analyse this measure's real effects.

Portugal, by contrast, has a running Public Compensation Fund[67]. It is managed by an "Evaluation Group" (composed of authorities, farmers' associations, seed and feed companies) and is funded by a €4 tax on each bag of GM seeds, payable directly by the seed companies (Articles 5 and 6). In Belgium and the Netherlands, compensation funds are envisaged, but no further details have been disclosed[68].

3. GMO-free regions and GMO production zones

'Field by field' coexistence (i.e. when each plot can be devoted to a different supply chain) is very difficult to implement in small-field regions, where the enforcement of isolation distances without coordination among neighbours is almost impossible to achieve. Moreover, the costs of segregation in these regions can outweigh the economic advantages of GM crops, thereby reducing in practice the right of choice for GM farmers. Furthermore, in these regions the risks of crosspollination are much higher – constituting a restriction of the rights of non-GM farmers.

Consequently, zone-by-zone segregation could be a good solution for coordination problems. On one hand, GMO producers could reduce segregation and the costs of duplicate facilities. On the other hand, non-GMO farmers could find a legal basis to protect themselves against the pressures of technological change. This kind of coexistence would not necessarily have any important consequences for the internal market. If the distribution of GMO and non-

60 Economic damages arising from GM crops may be included in the general liability regime of the Civil Code or in the law of nuisance (under real estate law). For a detailed study concerning the different liability regimes, see Koch, Bernhard A. (ed.), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, 1st ed. (Vienna: Springer 2009).

61 German GenTG, §36a.

62 Coextra "German report: Public debate and stakeholder opinions", GM and non-GM supply chains: their Co-existence and Traceability, 2007, available on the Internet at http://www.coextra.eu/country_reports/public_debates_DE_EN.html (last accessed on 15 January 2010).

63 See the observations made by the European Commission on 26 July 2004 (Communication SG(2004) D/51510 – TRIS Ref. 2004/0133/D), in the Directive 98/34/CE framework: "In general, the proposed liability regime is likely to lead to a high and unpredictable economic risk for GMO farmers. The Commission would therefore only agree to the draft on the conditions that these provisions do not actually prevent the cultivation of GMOs in Germany."

64 Herdegen, Matthias, "The Coexistence of Genetically Modified Crops with Other Forms of Farming. The Regulation by EU Member States in the Light of EC Law", 2 *Journal of International Biotechnology Law* (2005), pp. 89 *et sqq*.

65 Danish Act 436/2004 on the Growing etc. of Genetically Modified Crops (*Lov om dyrkning m.v. af genetisk modificerede afgrøder*) published in *BEK* on 09 June 2004, (English version at TRIS, Ref. 2004-393-DK), § 9.

66 Danish Ministry of Food, Agriculture and Fisheries, "Danish Farmers trained to grow GMO crops", 10 September 2008, available on the Internet at http://www.fvm.dk/Default.aspx?ID=18488&PID=169747&NewsID=5238 (last accessed on 15 January 2010).

67 Portuguese *Decreto-Lei (Fundo de Compensação) No 387/2007*, published in *Diário da República* on 28 November 2007.

68 European Commission Report (Annex), COM(2009) 153, p. 40.

GMO zones were evenly balanced, there would be no quantitative restrictions on production. That is the case, for example, of seed multiplication zones[69]. However, because of European exigencies, zone-by-zone segregation can only be achieved "on the basis of voluntary [individual] agreements" among farmers[70]. Thus, general declarations like the "GMO-free regions"[71] would not accomplish what the EU understands by "coexistence" unless the explicit agreement of all farmers in the area was obtained. In this context, cooperatives and farmers' associations are very important for facilitating this concentration process. It would not be the first time that European farmers worked together to fix common production methods with the support of regional authorities[72].

Portugal, for example, has a clear zone-by-zone coexistence strategy. In this country coexistence legislation[73] encourages farmers' associations, seed companies and local authorities to organise GMO production zones[74] and non-GMO zones[75]. The Spanish Bill proposes similar solutions[76] which, however, have never been put into practice[77].

IV. Concluding remarks

Coexistence is a new version of the old principle of freedom of trade and industry. The more that technological pluralism is preserved, the greater the freedom of choice assured to producers and consumers. For the first time in history, a new technology is not likely to replace the previous one rapidly but, on the contrary, both of them will be preserved in order to guarantee production and consumer diversity and reversibility in case of failure.

Zone-by-zone segregation seems to be the most convenient way of organising coexistence. Agricultural traditions (intensive or extensive agriculture), the high cost of segregation facilities, and difficulties in the coordination of isolation distances in small- field regions – all these are factors which favour zone-by-zone segregation. Furthermore, this solution would not have an important impact on the internal market if the distribution of GM and non-GM zones were balanced, as the Portuguese example shows.

However, Member States should establish a legal framework. The introduction of GM crops without a coexistence strategy, as has happened in Spain, facilitates a rapid technological substitution which constitutes the antithesis of "co-existence"[78].

At all events, the golden rule for coexistence is to guarantee the viability of all supply chains. If a national regime were so protective or so permissive that it discouraged any one type of production, the coexistence policy would never achieve its aims. What would be even worse, the *social contract* that made possible the end of *de facto* moratorium would be broken.

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69 In these zones it is prohibited to cultivate the same kind of seed that is being multiplied to avoid crosspollination risks that could reduce the purity of seeds. Even though this is a restriction, it is not seen as an important influence on the free movement of goods in the internal market. See Anvar, Shabnam Laure, *Semences et Droit. L'emprise d'un modèle économique dominant sur une réglementation sectorielle,* PhD Dissertation, Université Paris I, 2009, p. 147.

70 European Commission Recommendation 2003/556/EC, p. 46.

71 This is a grouping of 260 regions, over 4500 municipalities and other local entities and tens of thousands of farmers and food producers in Europe that have declared themselves "GMO-free". Even though they partially recognise the coexistence policy, the inclusion of environmental arguments to justify the exclusion of GMO has reduced the possibility of this being declared compatible with EU law. See "Chapter of the regions and local authorities of Europe on the subject of coexistence of genetically modified crops with traditional and organic farming", Florence 4 February 2005, available on the Internet at http://www.gmofree-euregions.net:8080/docs/ajax/ogm/Charter_en.pdf (last accessed on 15 January 2010).

72 For example, Geographical Indication rules are normally determined by local production associations, or even seed multiplication regions where the cultivation of a particular seed is prohibited by law except for the purposes of multiplication.

73 *Decreto Lei No 160/2005*, Article 5 (*Zonas de produção de variedades geneticamente modificadas*) and *Portaria No 904/2006* (concerning proceedings for declaring a region GMO-free), Published on *Diário da República*, on 4 September 2006.

74 In 2008 these regions covered 2500 hectares, which is 51% of the total production of GMO. DGADR, "*Coexistencia entre culturas geneticamente modificadas e outros modos de produçao agricola*", *Direcçao-Geral de Agricultura e Desenvolvimiento Rural* (Portugal), available on the Internet at http://www.cibpt.org/docs/08042009relatorio2008coexistenciaportugal.pdf (last accessed on 15 January 2010).

75 The *Lagos* district was declared GMO free in 2007. *Despacho No 25306/2007* of the *Direcção Regional de Agricultura e Pescas do Algarbe*, published on *Diário da República,* on 5 November 2007.

76 Spanish Bill, at Article 8.

77 Taking into account that the bill has never been approved, "coexistence" in Spain today only concerns the EU binding framework (labelling and traceability) plus some non-binding agricultural practice proposed by seed companies. See footnote 41.

78 In Aragon, the most productive maize region, almost 60% maize is transgenic. Biological crops have being "expelled" and ecological maize production has dropped 70% in just four years. Moran, Carmen, "*El maíz transgénico está acabando con los cultivos del ecológico*", *El Pais*, 19 October 2006. The main reason for this reduction is the fact that the ecological certification authority has detected GM traces in 40% of tests. Assemblea Pagesa – Plataforam Transgenics Fora – Greenpeace, "*La imposible co-existencia. Siete años de transgénicos contaminan el maíz ecológico y el convencional: una aproximación a partir de los casos de Cataluña y Aragón*", available on the Internet at http://www.greenpeace.org/espana/reports/copy-of-la-imposible-coexisten (last accessed on 15 January 2010).