EU GM Crop Regulation: A Road to Resolution or a Regulatory Roundabout?*

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I. Introduction

Since first embarking on the road of risk management options for the regulation of recombinant DNA (rDNA) activities and use in 1978, the European Union (EU) has largely failed to create a regulatory and policy environment regarding genetically modified (GM) crops and their cultivation that is (a) efficient, (b) predicable, (c) accountable, (d) durable or (e) inter-jurisdictionally aligned. Recent proposed regulatory changes announced by the European Union Commission (July 13, 2010) aim to allow member states to enact restrictive measures on cultivation of GM crops based on broadly scoped non-scientific criteria[1]. In light of the European Union Commission's proposal, this paper reviews the EU's past efforts to effectively regulate GM crops, critically assesses the impacts of the new regulatory proposals, and examines some of the key outstanding issues with the current EU regulatory framework that will need to be considered as the EU moves forward into its next phase of GM crop governance.

II. Historic review of the EU GM Crop regulatory framework

The EU has a long history in its regulatory approach to the technology of rDNA and its applications. Building on Galloux *et al.*'s analysis[2] of the EU's public policies in the area of biotechnology five regulatory policy phases can be identified along the EU GM crop regulatory policy pathway, namely:

1. Non-legislation period (1973–1983)
2. Reorganisation period (1983–1986)
3. First legislation period (1986–1991)
4. Second legislation period (1992–2001)
5. Third legislation period (2001–to date)

1. Non-legislation period (1973–83)

Regulation in the European Union pertaining to the use of rDNA stems from the early 1970s. In July 1974, resulting from the "Berg letter" published in Science[3], the United Kingdom established a Committee (the Ashby Working Party) to advise on whether rDNA research should proceed within the UK. In December 1974, the Ashby Working party recommended that such research should continue, provided adequate safeguards were put in place (HMSO, 1974). By reporting so promptly, the concepts developed by the Ashby Working Party were used by UK scientists and other European scientists during the February 1975 Asilomar conference in the USA. In 1978, the European Commission proposed a regulatory approach to research on rDNA that would have required statutory notification and authorisation by national authorities

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1 Commission Proposal for a Regulation of the European Parliament and the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory COM (2010) 375.

2 Jean-Christophe Galloux, Helene Gaumont Prat and Ester Stevers, "Europe", in John Durant, Martin W. Bauer and George Gaskell (eds), *Biotechnology in the Public Sphere: A European Sourcebook* (London: Science Museum 1998), pp. 177 *et sqq.*, at p. 180.

3 Paul Berg, David Baltimore, Herbert W. Boyer *et al.*, "Potential Biohazards of recombinant DNA Molecules", 185(4148) *Science* (1974), p. 303.

for all activities involving recombinant DNA[4,5,6]. In this document the definition of rDNA work was identical to that of "genetic manipulation" in the UK regulations that came into force in August, 1978[7]. The proposed approach was later replaced by a non-binding Council Recommendation[8]. This recommendation, which was based on the US and UK's experiences regarding rDNA and the desire of the Commission to avoid fixed statutory controls, simply asked EU member states to adopt laws, regulations and administrative provisions requiring "notifications" as opposed to "authorizations" to carry out rDNA work[9].

2. Reorganisation period (1983–1986)

In October 1983, a European Commission communication[10] addressed the concept of regulating biotechnology under the following three headings:

- biological safety,
- the consumer and the bio-industry,
- the regulation of products and their free circulation.

At that time there was a clear intention by the European Commission to attempt to "*ensure regulatory provision to maintain rational standards*".

In 1986, the OECD published its *Recombinant DNA Safety Considerations* booklet that is now known as the "The Blue Book"[11]. This OECD document was one of the first attempts to harmonize biosafety principles. It contained guidelines for assessing the safety of large scale use of rDNA organisms. By the mid-1980s several European member states introduced national biotechnology regulatory frameworks (e.g. Denmark was the first European country to adopt legislation specifically on rDNA, with its June 1986 *Gene Technology Act)*.

At the end of 1983, Étienne Davingnon, then EU Commission Vice-President and the EU Commissioners for agriculture and internal markets, proposed the formation of a Biotechnology Steering Committee (BSC) to be chaired by the Director-General of DG XII (Science, Research and Development). This BSC was formally established in early 1984. In 1985, another new body, the Biotechnology Regulation Inter-service Committee (BRIC), was also formed. BRIC was chaired jointly by DG III (Internal Market) and DG XI (Environment). Key aims of BRIC were to ensure the coherence of scientific data which would form the basis of risk assessment, and moreover to avoid unnecessary duplication of testing between various sectors[12]. One of the tasks completed by the BRIC was an inventory report of Member States' biotechnology regulations. While the report drawn up by BRIC highlighted the desire for a pan EU regulatory framework, it indicated that some states, particularly the U.K., France and the Netherlands, seemed inclined to view existing legislation as a basic requirement to which countries might add further requirements relevant to their particular situation – geographical, climatic or regional[13].

3. First legislation period (1986–1991)

In November 1986, the EU Commission's communication to the European Council (COM (86) 573) entitled *A Community Framework for the Regulation of Biotechnology*[14] (drawn up by the BRIC) put forward a more restrictive approach than had been advocated by industry or by Member States with the greatest experience of biotechnology. In May 1988, the EU Commission published proposals for two Council Directives: one on the contained use of genetically modified microorganisms and the other "on the deliberate release to the environment of genetically

4 European Commission Proposal for a Council Directive establishing Safety Measures against the Conjectural Risks associated with recombinant DNA Work – C301/5-7 (1978).

5 Mark Cantley, "The Regulation of Modern Biotechnology: A Historical and European Perspective. A Case Study in How Societies Cope with New Knowledge in the Last Quarter of the Twentieth Century", in Dieter Brauer (ed.), 12 *Biotechnology: Legal Economic and Ethical Dimensions* (Weinheim: Wiley-VCH Verlag 1995), pp. 501 *et sqq.*, at p. 513.

6 Donald Fredrickson, *The recombinant DNA Controversy: A Memoir: Science, Politics, and the Public Interest 1974–1981* (Washington: ASM Press American Society for Microbiology 2001), at p. 246.

7 Health and Safety (Genetic Manipulation) Regulations (1978). SI 1978, No. 752.

8 Council Recommendation Concerning the Registration of Work involving recombinant Deoxyribonucleic Acid (DNA), COM 82/472/EEC of 30 June 1982 Official Journal, L 213, p. 15.

9 Cantley, "The Regulation of Modern Biotechnology", *supra* note 5, at p. 2.

10 EU Commission Communication to the Council entitled Biotechnology in the Community, COM (83) 672 – 3 October 1983.

11 OECD, Recombinant DNA Safety Considerations (Paris 1986).

12 František Sehnal and Jaroslav Drobník, "White Book genetically modified Crops – EU Regulations and Research Experience from the Czech Republic (Prague: Academy of Sciences of the Czech Republic 2009), at p. 12.

13 The European Community and the Regulation of Biotechnology: An Inventory. European Commission 1986, BRIC/1/86.

14 EU Commission Communication to the Council entitled *A Community Framework for the Regulation of Biotechnology*, COM (86) 573.

modified organisms"[15]. These proposals contained some concessions to scientific considerations in the preamble and the explanatory sections. However, the scope and content of the directives proposed departed from the scientific advice of the time. For example, the European Molecular Biology Organisation (EMBO) formally considered the proposed Directives and came to a unanimous opinion that any EU legislation should not focus on the biotechnological technique used but on the safety or otherwise the products generated with it[16].

On May 18, 1989 sixteen European Nobel Laureates in Medicine and Chemistry wrote an open letter to the President of the European Parliament, the EC Council and the European Commission in support of EMBO's "product" not "process" regulatory approach[17]. The European Council adopted a common position in November 1989 and the proposed Directives returned to Parliament for second reading. When the directives were discussed at committee level in the European Parliament there was a noticeable increase in restrictive amendments. Some commentators felt that the rise of the "Green" party in the mid-1980s in the European parliament and throughout continental Europe focused many Members of the European Parliament (MEPs) on the "*acute sensitivities of public opinion to gene technology*"[18]. It is likely that within this political climate, support for restrictive amendments to the proposed directives was exceptionally forthcoming. Nevertheless, the 16 European Nobel Laureates wrote yet another letter before the second reading in Parliament on February 8, 1990 again highlighting their concerns with the proposed legislation.

During the European Parliament's plenary session in 1990, where the directives were voted upon, there was also a narrow defeat of an amendment proposing a five-year moratorium on GMO field releases[19]. The two directives 90/219/EEC and 90/220/EEC were finally adopted on April 23, 1990[20]. Directive 90/219/EEC dealt with the contained use of GM microorganisms, while Directive 90/220/EEC regulated the deliberate release of GMOs into the environment within the EU. Despite scientific advice to the contrary, both used the process of "genetic modification" as their regulatory trigger.

4. Second legislation period (1992–2001)

Directive 90/220/EEC never fully achieved its primary goal of regulatory harmonization across the EU. If compliance with rules is a key indicator of legitimacy, by the mid 1990's the EU's GMO regulatory framework was beginning to lose its legitimacy[21]. Several member states had begun using the "safeguard" clauses in Directive 90/220/EEC to prevent the commercial release of certain GM products within their jurisdiction. Directive 90/220/EEC began to be seen as deeply inadequate, and eventually disintegrated during the infamous so called *de facto* moratorium on new authorizations of GM crops. Following declarations from twelve (of then fifteen) Member States that they were opposed to further authorisations of GMOs, the Commission halted the submission of GMOs through the authorisation process; hence a *de facto* moratorium was established[22]. During this legislation period no new GMO approvals were granted from April 1998 onwards. Clearly, failures within the regulatory policy system forced the EU into this *de facto* moratorium situation which stalled approvals of GM products (predominantly GM crops). This stalemate situation occurred due to differing ideas of risk, some clear cultural and historical differences between Member States, and also the continued rise of "biopolitics" as a key arbiter of science policy develop-

15 EU Commission Proposal for a Council Directive on the contained Use of genetically modified Microorganisms and Proposal for a Council Directive on the deliberate Release to the Environment of genetically modified Organisms, COM (88)160.

16 Minutes from the 40th meeting of the Council of the EMBO, 1st October 1988: "… any legislation should focus not on the technique but on the safety or otherwise of the products generated with it. ... Over the last 15 years, experience has shown that recombinant DNA methods, far from being inherently dangerous, are an important tool both for understanding properties of life and for developing applications valuable to humankind and the environment. EMBO strongly believes that there is no scientific justification for additional specific legislation regulating recombinant research per se. Any rules or legislation should only apply to the safety of products according to their properties, rather than according to the methods used to generate them".

17 Sehnal and Drobník, "White Book genetically modified Crops" *supra* note 12, at p. 4.

18 Cantley, "The Regulation of modern Biotechnology", *supra* note 5, at p. 2.

19 *Ibid*.

20 Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms OJ 1990 L 117/15 and Council Directive 90/219/EEC on the contained use of genetically modified organisms.

21 Grace Skogstad, "Supranational Regulation and Contested Accountability: The Case of GMO Risk Regulation in the European Union", *EUI Working Paper SPS No. 2008/07*(2008).

22 Maria Lee, "Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy", in Luc Bodiguel and Michael Cardwell (eds), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford: Oxford University Press 2010), pp. 101 *et sqq.*, at p. 104.

ment within the EU[23]. Thus under renewed political pressure and with a *de facto* moratorium in place, the EU once again returned to the legislative process to put in place a new Directive relating to GMOs.

In June 1999, the Council of Ministers met for a twenty-hour session in Luxembourg to consider the issue of GMOs. Before the meeting, European politics had become intensified because of the EU parliamentary elections taking place that same year. In addition, GM crops had become a hot topic in the public sphere due to the extensive media reporting of the infamous Arpad Pusztai rat feeding experiments[24] and experiments reporting possible effects of *Bt* pollen on Monarch butterflies[25]. In fact, during the EU Parliament election of 1999, GM crops were a topic that many MEP candidates reported to have confronted on the campaign trail. At the Council meeting in June, there was a French-sponsored declaration calling for a moratorium on all GMO approvals. With an absence of any legal authority to declare such a formal moratorium it became clear the French position was largely "biopolitical" posturing[26].

During the Council of Ministers meeting, it quickly became apparent that there were two substantially different declarations that embodied very separate approaches to the regulation of GMOs. The first statement asked the Commission to *"... without delay draft rules ensuring labelling and traceability of GMOs and GMO derived products and state that, pending the adoption of such rules, in accordance with preventive and precautionary principles, they will take steps to have any new authorisations to allow for growing and placing on the market suspended".* The member state signatories to this declaration included France, Greece, Italy, Denmark and Luxembourg. The second declaration requested that it would *"... not authorise the placing on the market of any GMOs until it is demonstrated that there is no adverse effect on the environment and human health"*. This was signed by Austria, Belgium, Finland, Sweden, Germany, Spain and the Netherlands. A number of countries (Britain, Ireland, and Portugal) did not sign any of the above declarations. Eventually, the Environment Ministers agreed that there was no legal basis for a moratorium. They also agreed on proposals that included:

- Post-marketing monitoring of GM crops;
- New risk assessment rules;
- Phasing out antibiotic marker gene use;
- Formal bioethics studies;
- Examination of the liability clause; and
- Increased public input and information[27].

The Council of Ministers meeting highlighted the deep political divisions within the EU on the issue of GM crops. Not only were there divisions between Member States, but also there were considerable differences on the issue between the institutions of the EU, namely the Council, the European Parliament and the European Commission.

During this period the biopolitical issues faced by policy makers at the science/policy interface became very evident. One such example was a speech to the EU Parliament by Commissioner Margot Wallstrom during the consideration of the new Directive. In her address she stated, *"I am also fully aware of the political importance of certain other aspects raised by the proposed amendments. It is clear that antibiotic marker genes need to be phased out and be replaced with alternatives as soon as practically possible. A phase-out is already foreseen in the common position. The Commission agrees to strengthen this political message".* Yet she simultaneously flipped between the two sides of the science/policy interface when she added in the same speech that: *"At the moment there is no scientific evidence that all GMO's of this type (i.e. containing antibiotic resistance marker genes) present adverse effects to human health and the environment. Instead we should continue to carry out a comprehensive case by case risk analysis".* While the amendments that would have banned such GMOs immediately were rejected, it was decided that the year 2005 should be the definite date for the "phasing out" of GMOs that contain antibiotic resistance marker genes rather than phasing them out progressively[28]. It is noteworthy that an EU funded review study subsequently published in 2007 found no scientific basis to argue against the use and presence of antibiotic selectable marker genes as a class of transgenic plants.[29] The new legislation

23 Shane Morris and Catherine Adley, "Evolving European GM Regulation: An Example of Biopolitics at Work", 18(8) *Trends in Biotechnology* (2000), pp. 325 *et sqq.*, at p. 326.

24 Stanley Ewen and Arpad Pusztai, "Effect of Diets containing genetically modified Potatoes expressing Galanthus Nivalis Lectin on Rat small Intestine", 354(9187) *The Lancet* (1999), pp. 1353 *et sqq*.

25 John Losey, Linda Rayor, Maureen Carter, "Transgenic Pollen harms Monarch Larvae", 399 *Nature* (1999), 20 May, p. 214.

26 Morris and Adley, "Biopolitics", *supra* note 23.

27 *Ibid.*

28 Koreen Ramessar, Ariadna Peremarti, Sonia Gomez-Galera *et al.,* "Biosafety and risk assessment framework for selectable marker genes in transgenic crop plants: A case of the science not supporting the politics", 16 *Transgenic Research* (2007), pp. 261 *et sqq.,* at p. 261.

29 *Ibid.*

that resulted from this second legislative period (i.e., Directive 01/18/EEC[30]) was exceptionally difficult to pass due to the entrenched position of members of the EU Parliament. It was finally adopted in March, 2001 by co-decision (via a conciliation committee process) between the EU Council and Parliament[31].

5. Third legislation period (2001–today)

The so-called *de facto* moratorium on GM approvals did not lift until the final outcome of the political process that produced the new Directive 2001/18/EC (which took effect in 2001, along with the later entry into force of Regulations 1829/2003, 1830/2003 and 1946/2003). The European Commission then sent to ten Member States a letter of *"mise en demeure"* because it was considered they had not implemented Directive 2001/18/EC in time, and in some cases proceedings were brought by the EC pursuant to Article 228 EC to the European Court of Justice (ECJ).

Throughout this legislative period the EU's regulatory framework regarding GM crop cultivation still did not function effectively. What appeared to be a unified European policy stance against GM crops was the result of a complicated balancing of different countries' changing views and interests through the European political institutions[32]. Certain EU Member States continued to invoke safeguard clauses and at the EU Council level divisions continued thus forcing the EU Commission itself to make decisions on GM approval dossiers. This situation revealed profound differences from country to country on the issue of GM which translated into a major source of tension at the science/policy interface. This is not surprising as Member States have faced continued internal political pressures regarding GM crops. For example, since 2000 there have been over 70 serious attacks of vandalism on GM experimental field trials across the EU[33] which has resulted in reports of experimental trials of GM plant technology being relocated outside the EU[34,35]. The political pressure experienced internally by Member States can be clearly observed in two particular cases where political distortion of the risk assessment process seems evident:

a. The German government in April 2009 formally suspended the commercial growing of the genetically modified maize varieties containing the Bt insect-resistance trait MON810 based on alleged fresh data concerning potential negative environmental impacts of these varieties. In contrast, the German Central Committee on Biological Safety (ZKBS) concluded on the 7 July 2009 that based on all available scientific information available the cultivation of MON810 poses no risk to the environment[36]. Subsequent analysis of the case has clearly shown the German government selected several individual studies to justify their political U-turn while ignoring the vast majority of research relating to Bt maize expressing Cry-1Ab protein[37];
b. On October 31, 2007, the French government temporarily suspended the cultivation of maize MON810. On 7 December 2007 the French Ministry of Ecology created a committee composed of 34 experts (including 15 scientists) entitled the Comité de Préfiguration pour une Haute Autorité sur les OGM (CPHA) to examine the impact of MON810 on the environment[38]. On January 8, 2008, French President Nicolas Sarkozy stated he was willing to invoke a safeguard measure prohibiting the cultivation of maize MON810 if the committee raised *"serious doubts"* concern-

30 Council Directive 01/18/EEC on the deliberate release into the environment of genetically modified organisms repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

31 Gregory Shaffer and Mark Pollack, "The EU regulatory System for GMOs", in Ellen Vos and Michelle Everson (eds), *"Uncertain Risks Regulated: Facing the Unknown in National, EU and International Law"* (New York: Routledge-Cavendish 2009), pp. 269 *et sqq.*, at p. 279.

32 Javier Carrau, "Lack of Sherpas for a GMO Escape Route in the EU", 10(8) *German Law Journal* (2009), pp. 1169 *et sqq.*, at p. 1180.

33 Marcel Kuntz, "Academic and governmental Research on GMOs has been the Target of numerous Acts of Vandalism in Europe", 1 July 2010, available on the Internet at <http://ddata.over-blog.com/xxxyyy/1/39/38/37/public-research-vandalized.pdf> (last accessed on 2 October 2010).

34 Sybille de La Hamaide, "Limagrain Moves GM Tests To The US Due French Ban", Reuters, Feburary 29, 2008, available on the Internet at <http://www.planetark.org/dailynewsstory.cfm?newsid=47254> (last accessed on 2 October 2010).

35 Anna Meldolesi, "Pea Trials flee to US", 28 *Nature Biotechnology* (2010), p. 8.

36 German Federal Office of Consumer Protection and Food Safety, "Stellungnahme der ZKBS zur Risikobewertung von MON810" (2009), Az. 6788-02-13, 7 July, available on the Internet at <http://tinyurl.com/23e5377> (last accessed on 2 October 2010).

37 Agnès Ricroch, Jean Bergé and Marcel Kuntz, "Is the German Suspension of MON810 Maize Cultivation Scientifically Justified?", 19(1) *Transgenic Research* (2010), pp. 1 *et sqq.*, at p. 11.

38 Agnès Ricroch, Jean Bergé and Marcel Kuntz, "Is the Suspension of MON810 Maize Cultivation by Some European Countries Scientifically Justified?", *Information Systems in Biotechnology* (2010), pp. 8 *et sqq.*, at p. 9.

ing the safety of MON810[39]. The next day, the CPHA's report was submitted to the French government. Within twenty-four hours the French government quickly announced to the press that the CPHA had found that *"new scientific studies ... establish serious doubts about the effects of MON 810 maize"*[40]. The following day (January 11, 2008) twelve of the 15 CPHA scientific experts protested publicly as the report was supposed to be only a draft and did *"not contain the words 'serious doubts', nor does it qualify the new scientific evidences as 'negative'"*[41]. On February 7, 2008, the French government formally suspended the authorization of MON810 cultivation. Subsequently, the French Food Safety Agency (AFSSA) and the European Food Safety Authority (EFSA) both found the claims used by French political leaders to justify the safeguard clause had no scientific basis. Both organisations confirmed their earlier findings that MON810 was safe for human consumption. The French Ministry of Ecology then justified keeping the safeguard clause, not based on health concerns but on environmental grounds[42]. However, this environmental basis was again rejected by EFSA when it renewed approval for MON810 to be used as seed for cultivation on June 15, 2009[43]. Several journalists have suggested that the French Government's U-turn on MON810, the only GM crop in commercial use in France, was as a result of a 2007 political agreement with environmentalists that ensured the French nuclear industry was not targeted in France's national environment debate (the "Grenelle de l'environment") in return for action against GM crops[44,45]. Indeed, French Prime Minister François Fillon has admitted that the decision to start the procedure for the approval suspension of GM maize MON810 was based on a *"compromise sealed in the 'Grenelle de l'environment'"*[46].

More recently, political moves at high levels within the EU have indicated that the EU will once again revisit the legislative process concerning GM products. In mid 2008, during the French Presidency of the EU, the French Government launched a pan-Europe GM working group to draw up proposals for changes to the current authorisation process for GMOs. At the same time, EU Commission President José Manuel Barroso launched his own high-level "Sherpa" working group to examine the GM issue in Europe. The Prime Ministers of each of the EU's 27 member states were asked to nominate a special representative to take part in this high-level initiative. On December 4, 2008 European Environment Ministers at the 2912th Environment Council meeting unanimously issued a declaration on GM that included a range of conclusions, including that environmental long-term effects of GM crops and the effects of GM plants on the different ecosystems in the EU needed to be assessed[47]. On March 2, 2009 a Dutch proposal to the Environment Council was made that the choice of whether or not to cultivate GM-crops should be left to individual member-states. In June 2009, the EU Commission launched an evaluation by an external contractor of the legislative framework on GM food and feed. While not yet completed, this exercise intends to cover the two major aspects of the current legislation: the risk assessment and regulatory approval process, and also the associated

39 Nicolas Sarkozy, "Press Conference Statement by the President of the Republic Nicolas Sarkozy", 8 January 2008, available on the Internet at <http://www.sarkozynicolas.com/nicolas-sarkozy-conference-de-presse-8-janvier-2008-texte-integral/> (last accessed on 2 October 2010).

40 Cyrille Souche, "Maïs OGM 'MON 810': Le sérieux doute des experts", 10 January 2008, available on the Internet at <http://www.cdurable.info/Mais-OGM-MON-810-vers-l-interdiction,758.html> (last accessed on 2 October 2010).

41 TF1 News, "OGM : 12 scientifiques de la Haute autorité se sentent trahis", 11 January 2008, available on the Internet at <http://lci.tf1.fr/science/environnement/2008-01/ogm-scientifiques-haute-autorite-sentent-trahis-4896599.html> (last accessed on 2 October 2010).

42 Ricroch, Bergé and Kuntz, "Suspension of MON810", *supra* note 37.

43 European Food Safety Authority, "Scientific Opinion on Applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto", *EFSA Journal* (2009) 1149, pp. 1–85.

44 Yves Thréard, "Les OGM, une affaire très politique", Le Figaro, 12 February 2009, at p. 14, also available on the Internet at <http://www.lefigaro.fr/debats/2009/02/12/01005-20090212ARTFIG00001-les-ogm-une-affaire-tres-politique-.php> (last accessed on 2 October 2010).

45 Gil Riviere-Wekstein, "La Communauté scientifique mise hors jeu", Revue Agriculture et Environnement, 11 January 2008, available on the Internet at <http://www.agriculture-environnement.fr/spip.php?article283&decoupe_recherche=doutes%2520s%25E9rieux> (last accessed on 2 October 2010).

46 Charles Jaigu, "Fillon: la majorité sera jugée «au bout de cinq ans»", Le Figaro, 14 January 2008: *"Concernant les OGM, Fillon a défendu sa décision de déclencher la procédure de suspension du maïs génétiquement modifié MON810 en estimant qu'il s'agissait d'un «compromis scellé dans le 'Grenelle de l'environnement'»"*.

47 Council of the European Union, "*Council Conclusions on Genetically Modified Organisms (GMOs)*", 2912th Environment Council meeting, Brussels, 4 December 2008.

labelling requirements. On June 24, 2009 a number of Member States (namely Austria, Bulgaria, Ireland, Greece, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Poland and Slovenia) requested that the Commission give Member States the freedom to cultivate GM plants based on *"relevant socio-economic aspects"*. On July 13, 2010 the EU Commission announced a proposal for the addition of one article to Directive 2001/18/EC, which would explicitly allow Member States to restrict or prohibit cultivation of GMOs on their territories. Member States could use any grounds to do so, other than those covered by the health and environmental risk assessment of the EU authorization process.

III. Preliminary regulatory impact assessment

While the EU Commission has not yet officially consulted stakeholders (e.g., scientists, industry, consumers, farmers groups etc) nor carried out a formal regulatory impact assessment on the proposed changes to the GM regulatory framework, a number of potential qualitative risks and benefits can be identified even at this early stage. Any assessment is currently only cursory in nature due to the limited information provided by the EU Commission in their proposal. Based on such scant information the proposed amendments may carry the following qualitative risks:

1. Market/economy risks

The market/economy risk relates to the generation of uncertainty and lack of policy coherence across the EU single market. The current proposals will likely result in an inefficient, unstable and fractured market for GM seeds in the EU based on a myriad of inter-jurisdictionally unaligned GM cultivation opt out criteria amongst different Member States. This can occur if Member States exercise their rights to apply different socio-economic aspects to their respective cultivation regulations that could shift and change over time.

2. Political risks

Those wanting to establish GM free Regions envisage such regions as free from both GM commercial cultivation and GM research field trials. However, the Commission's new proposals currently only cite/apply to commercial cultivation thus socio-economic reasons cannot be applied to field trials which are based on a Member State's competent authority's scientific risk assessment pertaining to environmental/biosafety risks.

3. Legal risks

a. There is a risk that the European Court of Justice (ECJ) might be requested to determine the proportionality of the adopted regulation and it seems unlikely that absolute measures such as total bans on cultivation based on socio-economic grounds would pass the test of EU law conformity (see M. Weimer in this issue).
b. Member States may encounter conflicts between their obligations stemming from WTO law and the Cartagena Protocol depending on the criteria they apply in restricting GM crop cultivation (see S. Poli and M. Weimer in this issue). In addition, individual EU member states with their own *sui generis* approach to banning of cultivation on socio-economic grounds are quite likely to face bilateral legal challenges from other countries within the framework of the WTO that will be difficult to deflect due to the absence of common EU legislation on the specific issue of socio-economic grounds for banning GM crop cultivation.

4. Innovation/competiveness risks

a. A stable regulatory and policy environment is required for innovation to flourish. Considering the high turnover rate of Member States governments coupled with a current standard of considering socio-economic risks, national GM cultivation policies banning cultivation on socio-economic grounds will be highly susceptible to national political fluctuations thus impeding and preventing long term innovation strategies. This is likely to negatively impact on Lisbon Agenda goals of promotion of innovation and investment in EU member states. Such lack of stability could lead to incomplete research programs, cancelled EU funded projects, flight of capital and scientific knowledge from the EU, and employment uncertainty within the plant science research commu-

nity making the EU a unattractive research and development location for the agri-food sector[48].

b. The precedent of establishing a non-harmonized socio-economic regulatory framework could form the basis for future regulatory policy in other emerging technology areas leading to ever increasing diversification across EU Member States in their regulatory responses to products of innovation. In effect, an *a la carte* approach to GM crop regulation across EU member states could precipitate *a la carte* approaches to many other areas and issues (e.g., nanotechnology, etc.) across the EU (on the basis for precedent having now been established).

On the other hand, the proposed amendments may carry the following qualitative benefits:

5. Market/economy benefits

A socio-economic rationale for banning GM cultivation could offer slight savings in identity preservation costs to a small subsection of the market.

6. Political benefits

a. National and local political benefits could be realised by certain political groups that have had political goals to introduce GM cultivation bans.
b. Political benefits could be accrued by the EU Commission in conceding on the issue of GM cultivation in return for more flexibility by Member States towards issues pertaining to GM food (increased tolerance thresholds for the presence of GM material) and GM feed (a non-zero threshold for the adventious low level presence of unapproved events).
c. Potential reduction in the frequency of Member States implementing health and environmental safeguard clauses on approved GM crops.

IV. Key outstanding issues with the current EU regulatory framework

While the EU Commission's current proposal yet again attempts to modify the European regulatory framework for GM crop cultivation, it leaves a number of key issues unresolved. These issues arise from the fact that the current EU regulatory framework regulates on the basis of the "process" that is used to create the traits in a new plant variety (i.e., singling out genetic modification from a whole host of modern plant biotechnology applications) rather than regulating the impacts of the new traits themselves.

Firstly, as Directive 01/18 is based on the precautionary principle (PP), it is expected that the directive would follow the EU's own official guidance on the PP[49]. These guidelines state that the PP should be employed in a proportional, non-discriminatory and consistent manner to examine the benefits and costs of an action or lack thereof and the scientific developments pertaining to the risk in question. In particular, the principle of non-discrimination decrees that similar risks should not be treated differently[50]. The reference to "*the nature of the production process*" is notable because it contradicts the EU's current GM policies and regulatory frameworks that focus exclusively on "genetic modification" and ignores other non-GM plant biotechnology applications which have been shown to be possibly as risky an environmental and health risk perspective[51]. For example, the UK's regulatory body, the Advisory Committee on Releases to the Environment (ACRE), highlight this risk contradiction in its final report of May, 2007. The report stated that: *"in recent years, it has become apparent that there are inconsistencies in the [EU] regulatory assessment of the environmental impact of GM crops in comparison with other agricultural crops and practices"*[52]. In addition, the report criticized the current EU regulations by stressing that: *"this inconsistency is further illustrated by GM herbicide-tolerant crops that require an extensive environmental*

48 As exemplified by Marion Guillou, President of France's National Institute for Agronomical Research (INRA) who stated INRA's work on new varieties now involves only conventional crops, for which research is less efficient, longer and more expensive. Sybille de La Hamaide, "French Researcher halts Development of GMO Crops", *Reuters,* October 31, 2010, available on the Internet at <http://www.forexyard.com/en/news/French-researcher-halts-development-of-GMO-crops-2010-10-29T080856Z-INTERVIEW>.

49 EU Commission Communication on the Precautionary Principle. COM (2000) 1, at p. 5

50 "[M]easures taken under the precautionary principle should be designed to achieve an equivalent level of protection without invoking the geographical origin or the nature of the production process to apply different treatments in an arbitrary manner", ibid

51 Shane Morris, "EU biotech crop regulations and environmental risk: a case of the emperor's new clothes?", 25(1) *Trends in Biotechnology* (2007), pp. 2 *et sqq.*, at p. 4.

52 ACRE, "Managing the Footprint of Agriculture:Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems", *Report of the ACRE Sub-group on Wider Issues Raised by the Farm-Scale Evaluations of Herbicide Tolerant GM Crops* (2007).

risk assessment before approval for cultivation and marketing whilst herbicide-tolerant crops produced by non-GM breeding methods can be grown without an equivalent assessment". The scientific support for this conclusion comes from farm-scale evaluations of GM and non-GM crops in the UK, which demonstrated that the impact of GM crops on the environment is comparable to that of non-GM crops expressing the same herbicide resistance trait if the crop management regime is the same[53]. Another example is the fact that the current process of the safety evaluation of GM versus conventionally bred plants is considered not well balanced and may not provide the best framework of adequate safety assessment[54]. These examples coupled with the evidence that the currently used "genetic modification" processes used to produce GM crops can have a lesser effect on the target genome or on gene expression than other breeding methods[55,56,57,58,59,60] or even different cultivation techniques[61] highlight systemic weaknesses in an EU regulatory framework that is intended to be based on the PP[62,63].

Moreover, the current EU regulatory framework rarely, if ever, applies the PP to assess the long-term social, environmental and economic costs of inaction – such as not deploying and supporting a new technology, including GM crops. This may reflect the current lack of an effective evidence-based system to balance both the risks and benefits of applying new biotechnologies. A more effective regulatory mechanism – for instance, a regulatory impact assessment framework by which bodies such as the EFSA could be mandated to also assess the benefits of GM crops relative to the perceived or potential risks – could create a more balanced and transparent risk/benefit assessment system. Currently, the EU lacks such a balanced framework to assess comparative risks and benefits from different crop improvement technologies – conventional breeding, induced-mutagenesis breeding, genetic modification, and others – and different production systems – conventional, organic, biodynamic, etc.

Secondly, the current EU regulatory framework for GM crops is not likely to be sustainable in its current form on a long term basis, particularly given the rapid pace of advances in plant biotechnology. Such shortcomings of the EU's current process-based GM policy were highlighted in a report by the Netherlands' Commission on Genetic Modification (COGEM), which advises the Dutch government regarding potential risks of genetic modification to human health and the environment. The COGEM report stated that advances in plant biotechnologies are blurring the definition of what is genetic modification and developments in this area are outgrowing the EU legislation[64]. Such new plant biotechnology techniques include: *inter alia*, the selection of spon-

53 Les Firbank, Mark Lonsdale and Guy Poppy, "Reassessing the environmental Risks of GM Crops", 23 *Nature Biotechnology* (2005), pp. 1475 *et sqq.*, at p. 1476.

54 Esther Kok, Jaap Keijer, Gijs Kleter, Harry Kuipera, "Comparative Safety Assessment of Plant-derived Foods", 50 *Regulatory Toxicology and Pharmacology* (2008), pp. 98 *et sqq.*, at p. 109:*"[i]t may be that the current distinction between GMO-derived and so-called conventionally bred new plant varieties does not in all cases provide the best framework for an adequate safety assessment of new plant varieties as the basis for a safe food supply also in the years to come. It seems advisable to screen all new plant varieties for their new characteristics by applying the comparative safety assessment, which may have different end-points"*.

55 Satu Lehesranta, Howard Davies, Louise Shepherd *et al.*, "Comparison of Tuber Proteomes of Potato Varieties, Landraces, and Genetically Modified Lines", 138(3) *Plant Physiology* (2005), pp. 1690 *et sqq*.

56 María Baudo, Rebecca Lyons, Stephen Powers *et al.*, "Transgenesis has less Impact on the Transcriptome of Wheat Grain than conventional Breeding", 4 *Plant Biotechnology Journal* (2006), pp. 369 *et sqq*.

57 Peter Shewry, Marcela Baudoa, Alison Lovegrove *et al.*, "Are GM and conventionally bred Cereals really different?", 18(4) *Trends in Food Science & Technology* (2007), pp. 201 *et sqq.*, at p. 207.

58 Rita Batista, Nelson Saibo, Tiago Lourenço, and Maria Oliveira, „Microarray Analyses reveal that Plant Mutagenesis may induce more transcriptomic Changes than transgene Insertion", 105(9) *Proceedings of the National Academy of Sciences* (2008), pp. 3640 *et sqq.*, at p. 3644.

59 Karl-Heinz Kogel, Lars M. Voll, Patrick Schäfer *et al.*, "Transcriptome and metabolome Profiling of Field-grown transgenic Barley lack induced Differences but show cultivar-specific Variances", 107(14) *Proceedings of the National Academy of Sciences* (2010), pp. 6198 *et sqq.*, at p. 6197.

60 Eugenia Barros, Sabine Lezar, Mikko Anttonen *et al.*, "Comparison of two GM Maize Varieties with a near isogenic non GM Variety using Transcriptomics, Proteomics and Metabolomics", 8(4) *Plant Biotechnology Journal* (2010), pp. 436 *et sqq.*, at p. 449.

61 Anna Coll, Anna Nadal, Rosa Collado, Gemma Capellades *et al.*, "Natural Variation explains most transcriptomic Changes among Maize Plants of MON810 and comparable non-GM Varieties subjected to two N-Fertilization farming Practices", 73(3) *Plant Molecular Biology* (2010), pp. 349 *et sqq.*, at p. 361.

62 Shane Morris and Charles Spillane, "GM Directive Deficiencies in the European Union", 9(6) *EMBO Reports* (2008), pp. 500 *et sqq.*, at p. 503.

63 Yann Devos, Karine Lheureux and Joachim Schiemann, "Regulatory Oversight and Safety Assessment of Plants with Novel Traits", in Frank Kempken and Christian Jung (eds), *Genetic Modification of Plants, Biotechnology in Agriculture and Forestry 64* (Berlin: Springer-Verlag 2010).

64 COGEM, "New Techniques in Plant Biotechnology", COGEM report CGM/061024-02 (2006), pp. 40 *et sqq.*, at p. 4: *"[w]ith the advance of technology, the distinction between genetic modification and other plant biotechnological techniques gradually blurs. In addition, such technological developments also outgrow the GMO legislation. At times it is not clear whether the products of some techniques are subject to the prevailing GMO legislation"*.

taneous mutants (sports); classical chemical and radiation-induced mutagenesis; selection of somaclonal variants[65]; inter-specific hybridisation, somatic hybridisation and cybridisation[66]; mutagenesis owing to naturally occurring mobile DNA elements (transposons)[67,68] novel targeted mutagenesis approaches, including TILLING[69], zinc-finger nuclease (ZFN) strategies[70], and allele replacement via homologous recombination[71]; heritable epigenetic modifications, such as gene silencing[72]; grafting of non-GM components on genetically modified rootstock[73,74,75] and cis-genesis[76,77]. In 2008 the EU Commission informed the EU Parliament (via a response to a parliamentary question) that a specific working group of external experts had been created to determine which of the newly developed plant breeding techniques would result in being captured by or excluded from EU regulations[78].

To effectively deal with above issues it is clear that the EU at some point will likely have to make the transition from a purely "process" based regulatory framework to a "product" based framework. This would allow a refocus of the risk assessment criteria to both better meet the current EU guidelines on the PP and to make the regulatory framework more sustainable in the face of ever advancing plant biotechnologies. Recent recommendations to the EFSA regarding the challenges and approaches for risk assessment regarding GM plants clearly highlight the fact that it defies scientific evidence to focus only on GM technology[79].

V. Conclusions

The history of the development of EU regulations pertaining to plant biotechnology and specifically genetic modification of plants, supports the observation that science and policy making are two arenas that are not cognitively and culturally distinct but rather engaged in processes of constant exchange and mutual stabilization[80]. Notwithstanding the complex relationship that exists at the science/policy interface, four key considerations are considered

65 Arun Balasubramaniam, Singh Brahmad, Sharma Shasi *et al.*, "Development of somaclonal Variants of Wheat (Triticum aestivum L.) for Yield Traits and Disease Resistance suitable for Heat stressed and zero-till Conditions", 103(1) *Field Crops Research* (2007), pp. 62 *et sqq.*, at p. 68.

66 Wen-Wu Guo, Devi Prasad, Yun-Jiang Cheng *et al.*, "Targeted Cybridization in Citrus: Transfer of Satsuma Cytoplasm to seedy Cultivars for potential Seedlessness", 22(10) *Plant Cell Reports* (2004), pp. 752 *et sqq.*, at p. 757.

67 Lai Jinsheng, Li Yubin, Joachim Messing and Hugo K. Dooner, "Gene Movement by Helitron Transposons contributes to the haplotype Variability of Maize", 102(25) *Proceedings of the National Academy of Sciences* (2005), pp. 9068 *et sqq.*, at p. 9072.

68 Michele Morgante, Stephan Brunner, Giorgio Pea *et al.*, "Gene Duplication and Exon Shuffling by helitron-like Transposons generate intraspecies Diversity in Maize", 37(9) *Nature Genetics* (2005), pp. 997 *et sqq.*, at p. 1002.

69 Claire McCallum, Luca Comai, Elizabeth Greene and Steven Henikoff, "Targeted Screening for induced Mutations", 18 *Nature Biotechnology* (2000), pp. 455 *et sqq.*, at p. 457.

70 Alan Lloyd, Christopher Plaisier, Dana Carroll and Gary Drews, "Targeted Mutagenesis using Zinc-finger Nucleases in *Arabidopsis*", 102 Proceedings *of the National Academy of Sciences* (2005), pp. 2232 *et sqq.*, at p. 2236.

71 Tzvi Tzfiraand, Charles White, "Towards targeted Utagenesis and Gene Replacement in Plants", 23(12) *Trends in Biotechnology* (2005), pp. 567 *et sqq.*, at p. 568.

72 Pilar Cubas, Coral Vincent and Enrico Coen, "An epigenetic Mutation responsible for natural Variation in floral Symmetry", 401(6749) *Nature* (1999), pp. 157 *et sqq.*, at p. 160.

73 Amit Gal-On, Dalia Wolf, Yehezkel Antignus *et al.*, "Transgenic Cucumbers harboring the 54-kDa putative Gene of Cucumber Fruit Mottle Mosaic Tobamovirus are highly resistant to viral Infection and protect non-transgenic Scions from Soil Infection", 14(1) *Transgenic Research* (2005), pp. 81 *et sqq.*, at p. 90.

74 Manjul Dutt, Li Jinyun, Karen Kelley *et al.*, "Transgenic Rootstock Protein Transmission in Grapevines", *International Symposium on Biotechnology of Temperate Fruit Crops and Tropical Species*, pp. 749 *et sqq.*, at p. 754.

75 Anders Smolka, Li Xue-Yuan, Catrin Heikelt *et al.*, "Effects of transgenic Rootstocks on Growth and Development of non-transgenic Scion Cultivars in Apple", *Transgenic Research* (2010), In Press DOI: 10.1007/s11248-010-9370-0.

76 Henk Schouten, Frans Krens and Evert Jacobsen, "Do cisgenic Plants warrant less stringent Oversight", 24 *Nature Biotechnology* (2006), at p. 753.

77 A. Wendy Russell and Robert Sparrow, "The Case for regulating intragenic GMOs", 21(2) *Journal of Agricultural and Environmental Ethics* (2008), pp. 153–181.

78 European Parliament: Parliamentary Question P-6606/07 2008. Jan Mulder (ALDE) to the Commission (9 January 2008) Subject: Cisgenesis. Answer from the Commission (3 March 2008).

79 EFSA, "Environmental Risk Assessment of genetically modified Plants – Challenges and Approaches", *EFSA scientific Colloquium Series – 8 June 2007* (2008), available on the Internet at <http://www.efsa.europa.eu/en/colloquiagmoera/publication/colloquiagmoera.pdf>: *"A paradigm shift would be required to change from risk assessment as it is currently practiced, to a more sophisticated assessment which balances risks and benefits: (i) The focus on only GM crops defies scientific evidence. In the longer term, risk assessors could develop an alternative approach on a scientific basis. 'Novelty' is one option. (ii) The status quo, in which risk assessment is interpreted very narrowly in terms of adverse impacts, is not sustainable, and perceptions of the quality of environmental risk assessments suffer as a result. A framework for the future is required. (iii) There is a need to build decision support tools for the risk assessors to better consider impacts of whole farming systems"* (last accessed on 2 October 2010).

80 Shelia Jasanoff, "States of Knowledge: The Co-Production of Science and social Order" (New York: Routledge 2004), pp. 320 *et sqq.*, at p. 157.

critical in regards to the development of good regulatory oversight models pertaining to emerging technologies: (1) public confidence and trust in the utility and relevance of a technology and its regulatory oversight; (2) regulations should avoid discriminating against particular technologies unless there is a scientifically-based rationale for such disparate treatment; (3) regulatory systems need to be more flexible and adaptive to rapidly-changing technologies; (4) ethical and social concerns of the public about emerging technologies that are based on evidence and not scientifically unfounded narratives need to be expressly acknowledged and addressed in regulatory oversight[81].

However, the current wording of the EU Commission's proposed new changes to Europe's GM crop regulatory framework do not satisfy any of Marchant *et al.*'s regulatory considerations outlined above. Thus, a more appropriate regulatory framework, better reflecting the ideals of the Precautionary Principle and regulatory sustainability, would focus on comparatively assessing the potential environmental, health and socio-economic risks versus the benefits of a product (e.g., a novel crop phenotype or characteristic), rather than simply overly focusing on (often hypothetical) risks of a very specific and narrow process (such as "genetic modification" as defined in EU legislation) through which a new plant variety was created.

Such an approach would also have "biopolitical" benefits of allowing decision makers greater scope and flexibility to frame and communicate risk mitigation options pertaining to products derived from an ever growing range of plant biotechnologies in terms of comparative risk and benefits of the plant trait in question rather than the process by which the trait was produced. This would provide the EU with the option to escape the regulatory roundabout it currently finds itself on regarding GM crops and successfully complete its journey on the road to resolution via the development of more rational risk mitigation measures that can effectively assess both risks and benefits.

81 Gary Marchant, Douglas Sylvester, Kenneth Abbott, "What Does the History of Technology Regulation Teach Us about Nano Oversight?", 37(4) *The Journal of Law, Medicine & Ethics* (2009), pp. 724 *et sqq.*, at p. 729.