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viewpoint

GM directive deficiencies in the European Union

The current framework for regulating GM crops in the EU weakens the precautionary principle as a policy tool

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The European Union (EU) is currently not the most welcoming place for genetically modified (GM) crops. In 2001, the EU agreed on a directive to regulate the approval process for the cultivation and use of GM crops in the member states—but seven years later, no crop has been approved under the agreed legislation. In fact, the only commercial GM crop that has been approved for environmental release in the EU is an insect-resistant maize variety developed by Monsanto (St Louis, MO, USA). Although it was approved before the EU's 2001 directive came into effect, various member states are still refusing to allow it to be grown. The regulatory reluctance of the EU to approve GM crops has brought it into conflict with the USA and others through a World Trade Organization (WTO; Geneva, Switzerland) trade dispute case in which the EU is accused of trade protectionism.

The disagreement took another turn in November 2007 when Stavros Dimas, the European Commissioner for the Environment, announced that applications by Syngenta (Basel, Switzerland) and Pioneer Hi-Bred International (Johnston, IA, USA), to grow two insect- and herbicide-resistant transgenic strains of maize, should be rejected on the basis of environmental concerns. Yet, Dimas's decision disregarded earlier science-based evaluations by the European Food Safety Agency (EFSA; Parma, Italy), which found that both varieties would not have "an adverse effect on human and animal health or the environment". The EFSA's report was delivered to the European Commission in April 2005, and updated in November 2006. Although the Commission was required to make a decision within three months of receiving the EFSA's report, it took nearly a year until it finally issued a draft decision stating that neither crop should be approved for cultivation. The decision referred to 11 papers that cast doubt on the crops' environmental safety and, although these studies were published after the EFSA's update in 2006, the Commissioner did not ask the EFSA or its scientific panel to comment further on these.

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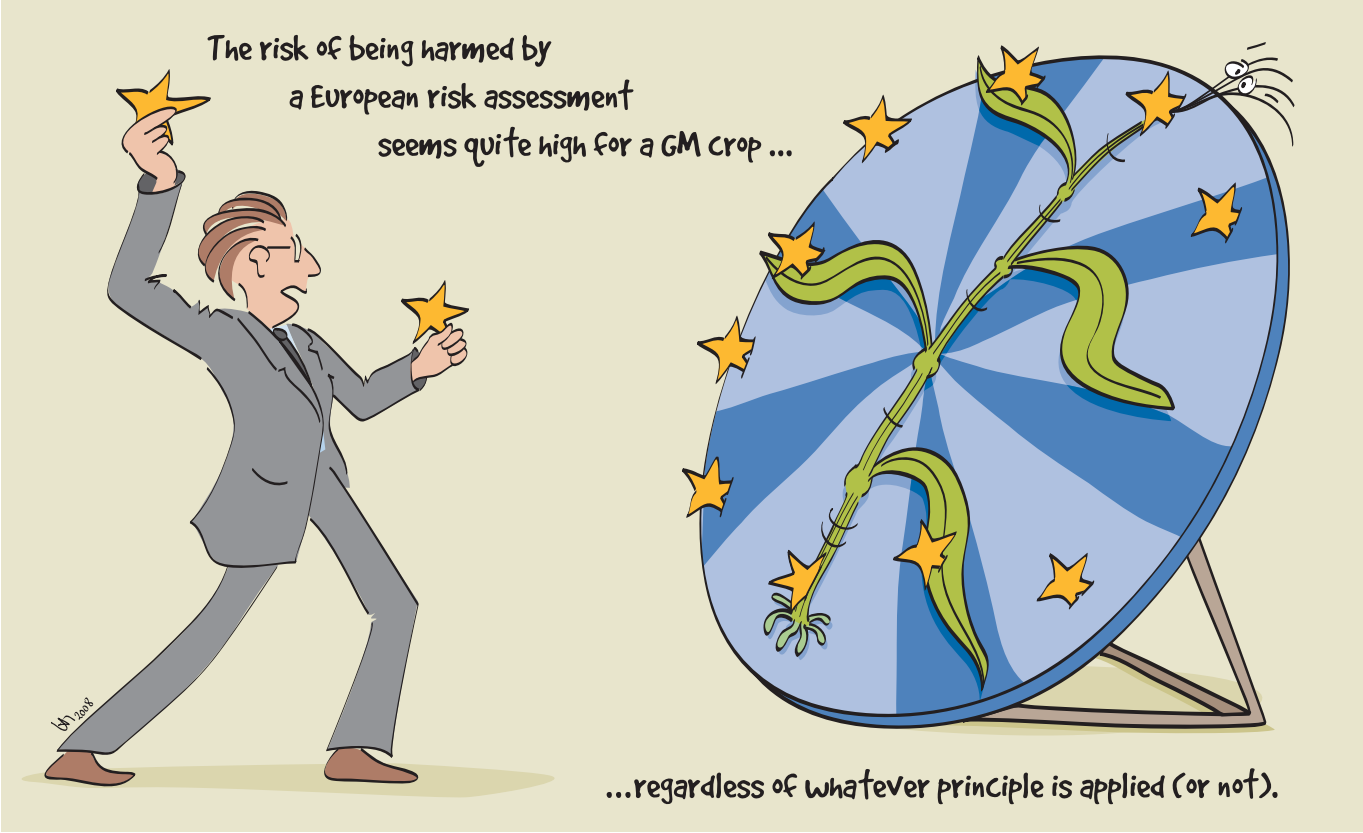
Not surprisingly, Dimas enraged many scientists who felt that the Environment Commissioner was showing disdain for both the EFSA itself and its scientific advisory system (Abbott & Schiermeier, 2007). Moreover, Dimas's decision not to approve two varieties of GM maize in the EU, against the EU's officially sanctioned scientific advice, has recently been criticized as 'bad governance' and an example of how the EU's regulatory framework for GM plants remains subject to biopolitics (Anon, 2007).

Here, we argue that the EU's regulatory framework for GM crops is not likely to be sustainable in its present form, particularly given the rapid pace of advances in plant biotechnology. Furthermore, because the framework is solely process-based—so as to regulate GM plants but not other varieties, the genetic constitution of which has been modified by using alternative or traditional methods—it is not in accordance with the precautionary principle, which is the EU's chosen basis for risk assessment and the regulation of new technologies. Instead, we argue a more appropriate regulatory framework, which would more logically reflect the idea of the precautionary principle, should focus on comparatively assessing the potential environmental and health risks versus benefits of a product, rather than overly focusing on the process through which the product—a new plant variety—was created. In essence, the GM regulatory fiasco has largely been a construct of past policy decisions to choose a process rather than a product-based approach to regulate new plants or foods, including GM crop varieties.

In the context of GM crops, biopolitics can be defined as the process of political risk management, whereby policy-makers base their decisions—for example, whether a given crop harbours potential risks for human health or the environment—on more than just the scientific evidence. Such biopolitical impacts on EU policy and its regulatory instruments are not new. Indeed, it can be argued that the elaboration of GM crop policy within the EU has significantly relied on policy narratives driven by discourses and epistemic communities that deliberately disregard evidence generated by the scientific community. These narratives, which simplify complex situations, are often used by policy-makers to guide their decision-making (Roe, 1991). Biopolitical influences were already evident during



the formulation of EU Directive 2001/18 to regulate the deliberate release of genetically modified plants into the environment (Morris & Adley, 2000) and, as highlighted above, are still evident in contentious policy statements such as the one made by Commissioner Dimas (Morris, 2007a,b).

There are undeniable tensions in the relationship between scientific evidence, regulation and political decision-making (Taylor, 2006). Such tensions are commonplace—they are certainly not limited to the regulation of GM crops—and might not necessarily be inappropriate. Even if scientific research indicates that specific GM crop varieties pose no apparent risks to human health or the environment, politicians will remain sensitive to their own perceptions of what public opinion might be on these issues. In the public sphere regarding GM crops in the EU, it would seem that the manufacturing of dissent has been more successful than the manufacturing of consent, particularly regarding the propagation and amplification of messages about the potential risks of GM crops. In such a milieu, policy-makers face a barrage of what would seem to be important regulatory challenges raised by new biotechnologies, including GM crops. However, when public perceptions, rather than scientific evidence, become the main drivers for regulatory policy, it is logical—and quite effective—for interest groups to focus their efforts on promoting and amplifying regulatory challenges for policy-makers in order to influence the formulation of appropriate policies and regulations (Meyer-Emerick, 2007).

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Indeed, within the social science literature, various authors have proposed that risk assessments should not depend solely on scientific evidence, but should also take into account political, social and regulatory factors (Winickoff *et al*, 2005). Sheila Jasanoff at the John F. Kennedy School of Government (Cambridge, MA, USA) has argued that the political culture itself is intimately linked to the way in which governments manage the uncertainties that accompany technological innovations and progress (Jasanoff, 2005b). However, the concept of political culture should not simply be reduced to assessments of public opinion by surveys or polls, but should also extend into governmental mores in which different governance approaches can have a role—for example, a culture of managerial rationality or of integration (Montpetit & Rouillard, 2008)—and where scientific evidence is considered to be just one form of input into the policy-making process. Furthermore, Jasanoff argues that scientific cultures are, at one and the same time, political cultures (Jasanoff, 2005a). Such arguments are reinforced by proposals that "biopolitics is largely articulated around the politics of knowledge; the politics of the definition and legitimation of risk" (Delanty, 1999).

Whether biopolitics in the context of EU GM crop policy is 'bad governance', as the recent editorial in *Nature* suggested (Anon, 2007), or just a result of the way in which regulatory frameworks are developed, is open to debate. Nevertheless, the EU's narrow political focus on GM is ensuring that its process-based regulatory framework—which considers that only GM crops should require thorough risk assessment—is becoming an insufficient tool to support the precautionary principle on which EU regulations are based. As both fundamental and biotechnological research with plants advances, it is clear that the EU's process-based regulatory framework for GM crops will find it increasingly difficult to consider the possibility of similar or equivalent risks posed by other, *sensu stricto*, non-GM-based approaches that can elicit similar effects, varieties and products. Such approaches include: *inter alia*, the selection of spontaneous mutants (known as sports); classical chemical- and radiation-induced mutagenesis; selection of somaclonal variants (Arun *et al*, 2007); interspecific hybridization, somatic hybridization and cybridization (Guo *et al*, 2004); mutagenesis owing to naturally occurring mobile DNA elements (known as transposons; Lai *et al*, 2005; Morgante *et al*, 2005); new targeted mutagenesis approaches, including TILLING (McCallum *et al*, 2000), zinc-finger nuclease (ZFN) strategies (Lloyd *et al*, 2005) and allele replacement through homologous recombination (Tzfira & White, 2005); heritable epigenetic modifications such as gene silencing (Cubas *et al*, 1999); grafting of non-GM components onto genetically modified rootstock (Gal-On *et al*, 2005; Kelley *et al*, 2005); and *cis*-genesis (Schouten *et al*, 2006). The limitations of a process-based approach to assess and regulate the risks from such a wide array of crop improvement technologies have been highlighted as a form of prejudice against new technologies such as GM (Spillane & Pinto, 2002). The opposition to intragenics, as opposed to transgenics, in which genetic modifications are not based on genes from other species, provides a clear example of a risk-assessment focus on the process of genetic modification (Russell & Sparrow, 2008). Yet, there is scant evidence that the current EU regulatory framework effectively mitigates essentially equivalent risks or benefits associated with non-GM crops—for example, herbicide-resistant crops produced by non-GM approaches. An alternative approach, which would be neutral with respect to technology prejudice, could consider comparatively assessing the risks and benefits of all plant varieties—whether produced by GM on non-GM technologies—on a product-by-product basis.

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The 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 about potential risks of genetic modification to human health and the environment. The COGEM report stated that: "With 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" (COGEM, 2006).

The reason why the EU focuses its GM policy so narrowly on the process, rather than the product, seems to be driven predominantly by trying to manage political risks relating to the 'GM stigma'. In doing so, it is to the detriment of a balanced precautionary approach relating to other types of risk, including risks to the environment, public health, the economy, energy security, other plant technologies, and various plant and food production systems. The UK's regulatory body, the Advisory Committee on Releases to the Environment (ACRE), addressed this resulting incongruity in its final report in 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" (ACRE, 2007). In addition, the report criticized the current EU regulations by emphasizing that: "this inconsistency is further illustrated by GM herbicide-tolerant crops that require an extensive environmental 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 showed that the impact of GM crops on the environment is comparable with that of non-GM crops expressing the same herbicide-resistance trait if the crop management regime is the same (Firbank *et al*, 2005).

Similarly, Kok *et al* (2007) have reiterated that the current process of the safety evaluation of GM compared with conventionally bred plants is not well balanced. The authors suggested that: "It 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" (Kok *et al*, 2007).

These issues, coupled with the fact that the transgenic processes now used to produce GM crops can have a lesser effect on the target genome or on gene expression than other breeding methods—which are classified as conventional simply owing to familiarity, rather than scientific understanding of the molecular changes associated with conventional plant breeding (Batista *et al*, 2008; Baudo *et al*, 2006; Lehesranta *et al*, 2005; Shewry *et al*, 2007)—illuminate weaknesses in an EU regulatory framework that is supposed to be based on the precautionary principle. Clearly, there are plenty of logical arguments for applying the precautionary principle to non-GM crops, especially if they express the same phenotypes as their GM counterparts (Morris, 2007a).

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Such arguments are strengthened further by a policy communiqué that the EU Commission published in 2000. It sets out "the Commission's approach to using the precautionary principle" and establishes guidelines for its application (EC, 2000). These guidelines state that the precautionary principle should be used in a proportional, non-discriminatory and consistent manner to examine the benefits and costs of an action, or lack thereof, and the scientific developments. In particular, the principle of non-discrimination decrees that similar risks should not be treated differently: "[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." The section of the quote that states "the nature of the production process" is notable because it contradicts the EU's own policies and regulatory framework for GM crops.

In addition to the lack of a comparative approach to risk assessment, which could include all crop varieties produced by GM or other approaches, the EU's regulatory framework might be overly focused on managing biopolitical risks in the face of public perceptions—perceptions that are manifest as public opinion. However, in terms of policy coherence, such regulatory policies are likely to be to the detriment of the EU's ambitious goal to create a knowledge-based economy by 2010, which the EU member states agreed to in the Lisbon Agenda (Rodrigues, 2003). It is certainly true that the strict regulatory requirements and the largely negative attitude engendered towards GM crops within the EU have affected applied plant research within the EU: many biotech companies and the agricultural industry have shifted their research enterprises outside the EU to North America, and favour foreign direct Research and Development investments in non-EU locations—a move that also has knock-on detrimental effects for fundamental research from which all applied research innovations are derived.

Furthermore, the current EU regulatory framework rarely, if ever, applies the precautionary principle 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 might 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 example, a regulatory impact assessment framework by which bodies such as the EFSA could be mandated to assess the benefits of GM crops relative to the perceived or potential risks—could create a more balanced risk–benefit assessment system. At present, the EU lacks such a balanced framework to assess comparative risks and benefits from both different crop improvement technologies—for example, conventional breeding and induced-mutagenesis breeding, genetic modification—and different production systems—for example, conventional, organic and biodynamic.

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The continued narrow framing and predominantly imbalanced application of the precautionary principle to advances in modern plant science impedes both the sustainability and the credibility of the precautionary principle as a policy tool. Clearly, science is only one variable in the risk assessment equation: "In practice, assumptions that have potential policy implications enter into risk assessment at virtually every stage of the process. The idea of a risk assessment that is free, or nearly free, of policy considerations is considered beyond the realm of possibility" (Covello & Merkhofer, 1993). The reality seems to be that such policy considerations are often biopolitical and easily based on a fear of negative political fallout or media coverage. With relative ease, such political hazards can be amplified by anti-technology pressure groups and business sectors who commercially benefit from marketing strategies that emphasize 'GM-free' products and practices, such as the organic farming industry and its associated investment community. However, as plant biotechnology research innovations advance, both technically and geographically, the EU's political leaders' biopolitical risk mitigation strategy—that is, solely regulating GM plants in isolation from non-GM plants—will most probably become unsustainable from the perspective of risk management.

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The opinions expressed herein are strictly those of the authors, who are citizens of the European Union. Shane Morris contributed to this article in his personal capacity. The views expressed are his own and do not represent those of the Government of Canada.


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