Introduction

The European Union's system for the authorisation of GM agri-food products for import and cultivation is still not being applied correctly. In theory, the underlying legislative framework is workable. In practice, GM policy and regulation has become a political football and is dysfunctional. Several Member States and the European Commission have been condemned by the Court of Justice of the European Union ('CJEU') for failure to implement and/or comply with key aspects of the legislative framework. Yet many of the most strident departures from the legal framework have passed unchallenged. Some states regularly act against the best available scientific advice, often referring to questionable ‘new’ scientific evidence which is consistently rejected when assessed by the independent European Food Safety Authority (EFSA). This broken system has prevented almost all cultivation of GM crops in the EU, increased dependency on imports of GM commodities and threatens import trade flows in agricultural products generally because of asynchronous approvals.

Far beyond the biotechnology sphere, this approach to the rule of law sets negative precedents which threaten good administration more generally and the legal certainty necessary for operators to invest in and commercialise new technologies. Recent developments suggest that companies may be willing to use legal action to counter politicisation of the product authorisation process. Litigation appears to be considered a legitimate means to address longstanding concerns. This is only likely to be strengthened by the recent judgment of the General Court in Case T164/10, Pioneer Hi-Bred International, Inc v Commission, concerning the failure to expedite the approval procedure for the cultivation dossier on insect-resistant GM maize 1507. In a clear and unequivocal ruling, the court signalled that it will not tolerate reliance on political considerations over binding legal procedures and independent science. This is a fillip to other industry sectors suffering from political deadlock.

Legislative Failure

The system’s failure can be measured in two ways. First, the authorisation procedure for cultivation was designed to regulate the placing on the market of GMOs, but the outcome is that, since the entry into force of Directive 2001/18 in October 2002, just one event has been actively authorised for cultivation,3 with two others remaining on the market as notified ‘existing’ products awaiting authorisation renewal.4 Second, the overwhelming majority of the 65 or so GM product applications which have received EFSA opinions, were not processed by the European Commission within the timelines foreseen in the legislation.5

Various stakeholders have analysed the application and effectiveness of the system. Two European Commission funded studies wrote respectively: ‘The risk management phase is not fully operational mainly because of the time taken to reach decisions’6 and ‘... the process has been able to stall without any legal implications ... where timelines

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1) In 2006, the WTO Dispute Panel concluded that there has been ‘... a general moratorium on final approvals’ in the EU and ‘an effective decision not to make full use of the relevant procedures to complete the approval process’: European Communities – Measures Affecting The Approval And Marketing Of Biotech Products, 29 September 2006, paragraphs 7.704 and 7.1274.

2) For example, see the decision by ‘Food and Chemical Toxicology’ to retract Professor G. E. Séralini’s 2012 long-term rat-feeding study, which alleged that biotech corn and herbicides caused tumours and multiple organ damage, and led to premature death in laboratory rats. In retracting the paper, the editors stated that ‘the results presented are inconclusive’ and ‘do not meet the threshold of publication’ (retraction letter dated 19 November, 2013).


5) ‘On average, over 11 months pass between a receipt of an opinion from EFSA and the first Member states Vote’ (source: http://www.europabio.org/approvals-gmos-european-union). (See Note 10 below).

have been specified, these have not necessarily been complied with.\textsuperscript{7} A 2013 report produced by 25 European science academies wrote of the ‘Time-consuming and expensive regulatory framework in the EU, compounded by politicization of decision-making by Member States and other policy inconsistencies’.\textsuperscript{8} A British Government advisory body wrote in 2013 that ‘... the framework for controlling GMOs in the EU is out-dated and not fit for purpose.’\textsuperscript{9} Even the European Commission has formally acknowledged to the European Parliament that it regularly fails to comply with legal timelines when it comes to GM authorisations: ‘Most applications with an EFSA opinion were presented to the SCFCAH after the three-month deadline.’\textsuperscript{10}

The Court’s Admonishments

The main explanation brought forward for the collapse of the system is that Member States are fundamentally divided: some want to promote GMOs to boost national productivity and support food security and/or to ensure livestock farmers’ access to feed. Others want to ban GMOs, disregarding the best available scientific evidence and the applicable law.

The manifest dysfunction has already been the subject of a 2006 WTO Dispute Panel Report, which found that with respect to Directive 90/220 and successor Directive 2001/18, ‘... the general de facto moratorium resulted in a failure to complete individual approval procedures without undue delay, and hence gave rise to an inconsistency with Article 8 and Annex C of the SPS Agreement’.\textsuperscript{11} This is widely credited with having restarted the EU GM authorisation system. At the EU level, several judgments from the CJEU since the 2006 WTO Dispute Panel Report, confirm an ongoing failure to apply the agreed legal framework. The following is a non-exhaustive list\textsuperscript{12} of cases indicating the disregard for the rule of law.

France

In Case C-121/07 (December 2008),\textsuperscript{13} France was fined a lump sum of €10 million for its failure to comply with the 2004 Court of Justice ruling on its failure to transpose Directive 2001/18/EC into national law. Having transposed the law, it then failed to apply it. In Joined Cases C-58/10\textsuperscript{14} and C-68/10\textsuperscript{15} (8 September 2011) (referred for a preliminary ruling from the French Conseil d’Etat) the Court of Justice confirmed that GMOs authorised as seeds for the purpose of planting and lawfully on the market pending an application for renewal may not have their use or sale provisionally suspended or prohibited by a Member State pending the renewal decision. France’s purported reliance on the ‘safeguard clause’\textsuperscript{16} in Directive 2001/18/EC was unlawful. Equally, it could not invoke the ‘emergency measures’ clause in Regulation (EC) 1829/2003 unless it followed the applicable procedures for so doing and could establish, in addition to urgency, the existence of a situation which is ‘likely to constitute a clear and serious risk to human health, animal health or the environment’.\textsuperscript{17} This was not the case.
Italy

In Case C-36/11 (September 2012) (referred for a preliminary ruling from the Italian Consiglio di Stato), the Court of Justice confirmed that the cultivation of a GMO cannot be made subject to a national authorisation procedure when the use and marketing of those varieties are already authorised pursuant to Regulation (EC) No. 1829/2003 and those varieties have been accepted for inclusion in the common catalogue provided for in Council Directive 2002/53/EC. The fact that Directive 2001/18/EC permits the adoption of co-existence measures in Member States under certain conditions did not entitle it to prohibit in a general manner the cultivation of such GMOs pending their adoption.

European Commission

In addition to the application of unlawful national procedures designed to delay and block marketing and use of approved GMOs (noted above), the Commission has employed more subtle but no less flagrant delaying tactics. Its omissions – failures to act – have unduly delayed the approval of GM products. There are two notable examples which have been the subject of litigation, but many more undue delays have been documented by concerned parties.

In Case T-293/08 (June 2010), BASF Plant Science formally requested the Commission to adopt a decision approving the Amflora potato (genetically modified for enhanced content of the amyllopectin component of starch). The Commission stated that it would only be able to proceed on receipt of a fresh scientific opinion from EFSA to which the Commission had sent a fresh mandate (immediately following BASF's request to proceed with the approval procedure). Some two years after the initial request, the Commission adopted the required decision, thereby bringing to an end its failure to act. Accordingly, there was no need for the General Court to adjudicate, avoiding potential public condemnation. This illustrates that the proverbial ‘day in court’ is not always necessary to encourage EU institutions to fulfill their obligations but it may nonetheless be necessary to initiate proceedings.

In Case T-164/10 (September 2013), the General Court condemned the Commission for its failure to advance a Pioneer Hi-Bred International dossier through the final stage of the applicable comitology procedure for a decision on the approval of insect-resistant genetically modified maize 1507 for cultivation. The General Court ruled ‘... that the European Commission has failed to fulfil its obligations ... by failing to submit to the Council the application for the final vote on authorisation. It confirmed that ‘... the Commission cannot, in a dilatory manner, repeatedly request opinions from EFSA’. In areas of scientific complexity there is always likely to be new scientific information available in the future but this is not a legitimate basis for delaying approval decisions. Accordingly, the Commission cannot repeatedly seek scientific opinions from EFSA, or other independent advisory bodies, in order to delay action. This is all the more so where EU regulatory regimes provide that new material information which becomes

18) C-36/11, Pioneer Hi Bred Italia.
19) Article 26a.
22) Decision 2010/135/EU.
23) Beyond GMOs, Case T-301/12, Laboratoires CTRS v Commission (July 2013) provides a further recent example of the Commission’s reluctance to follow independent scientific assessments from the Committee for Medicinal Products for Human Use, recommending that a marketing authorisation be granted for the medicinal product Orphacol, used to treat two rare but very serious liver disorders.
available must be notified to the authorities by the applicant or approval holder.\(^{24}\) The court held that the Commission must stick to the legally prescribed processes and timelines and act ‘swiftly’ and without delay, as required.\(^{25}\) It may not rely upon general political considerations\(^{26}\) to illegally delay the authorisation procedure for GMOs. The fact that the Commission was unlikely to gain Member State support if it put a proposal to a vote was entirely immaterial.\(^{27}\)

Whilst there is no doctrine of binding precedent (stare decisis) before the CJEU,\(^{28}\) the common practice is to refer to and apply past judgments. The judgment in the Pioneer case is a very strong indication that in other cases where there is excessive delay (which breaches the legislative timelines for the approval of GM products) the Commission is likely to face defeat before the General Court unless it promptly remedies the situation. Moreover, multiple damages actions for tortious liability would be likely to follow, pursuant to Article 340(2)\(^{29}\) of the Treaty on the Functioning of the European Union (‘TFEU’). These actions need not be limited necessarily to companies who submitted dossiers but may also be anticipated from a wider range of interests who suffer from such delays (such as grain traders, and feed and food companies). The scale of the issue is striking. The Commission will have to act promptly if it is to maintain its credibility as guardian of the Treaties and avoid the possibility of a stampede to the courts.\(^{30}\) It should be recalled that whatever the political pressure (from Member States or other stakeholders), the Commission is under an obligation to act in a manner which is ‘completely independent’ and that independence must be ‘beyond doubt’ at all times.\(^{31}\) To this end, it is striking that, at the College of Commissioners’ meeting on 6 November 2013,\(^{32}\) the Director General of the Commission’s legal service felt it necessary to remind Commissioners that according to the principle underlying Directive 2001/18, ‘... the Commission must propose to authorise the marketing of GMOs for cultivation unless a scientific assessment proved that there was a risk for the environment or health’. On the same occasion, he underlined ‘Article 41 of the Charter of Fundamental Rights of the European Union, which provides that every person had the right to have his or her affairs handled within a reasonable timeframe.’ Certain Commissioners appear to have suggested moving away from a politically uncomfortable science-based system: ‘... for some, the need for the Commission to have political leeway to decide on the request for authorisation; likewise, the importance for the Commission to act as a political body, without taking cover behind a “technocratic” argument’. In the same vein, some Commissioners expressed concern that ‘... action in this field would be exploited by populist Eurosceptic movements’. In other words, for some, political decisions should not be restricted by existing democratically adopted binding law.

**Beyond GMOs: More Litigation Around the Corner?**

It is hard to demonstrate conclusively that the level of misapplication and failure to apply EU law is greater today than in the past. What is clear is that the more open conditions of standing (locus standi) before the CJEU as a result of the Lisbon Treaty is gradually rendering more action (and failures to act)\(^{33}\) subject to judicial scrutiny. Annulment actions may now be brought against a ‘regulatory act ... which does not entail...
implementing measures’ which is of direct concern to the claimant but who does not need to be individually concerned. The term ‘regulatory act’ ‘... must be understood as covering all acts of general application apart from legislative acts held’.34 Legislative acts are only regulations, directives and decisions ‘adopted by legislative procedure’,35 namely the ordinary legislative procedure or the special legislative procedure. Therefore regulatory acts are those which (i) are not legislative acts and (ii) do not require further implementing measures. Examples of these might be Commission regulations adopted in ‘implementing acts’36 (through a committee procedure) or the regulatory procedure with scrutiny. The General Court confirmed the liberalisation of standing in the Microban case.37 This will only increase the use of litigation as a strategic option and in time should influence the way EU decision makers think about the importance of the legal framework which binds us all.

Other Areas of Questionable Legality on GMOs

Nationalisation

In 2010, the European Commission proposed to amend EU legislation to include the possibility of allowing Member States to opt-out of allowing cultivation of a GM variety on its territory.38 An opt-out could be on any ground except health and environmental. An opinion from the European Council legal service identified ‘... strong doubts about the compatibility with the Treaties or with the GATT...’.39 The European Parliament legal service expressed similar serious doubts about the legality of the proposal. The legal services flagged concerns, inter alia, about compliance with Article III.4 of the GATT concerning the requirement of no less favourable treatment of like products.40 They also questioned compatibility with Article XXIII(b) of the GATT concerning nullification or impairment of benefit even in absence of another GATT violation (a far more exceptional route of challenge). Criticism on various aspects of the proposal, including its legal base and likely effects in law (if any) were also voiced by environmental NGOs and lawyers to industry and governments. This is an unusual and telling alignment of views. It remains to be seen whether the Commission will persist with the proposal given the issues raised.

Negative Effects for the EU

The example of the 1507 maize case illustrates the structural failure to properly implement the EU GMO approval system. This has not been without negative side-effects. The lack of cultivation of GM crops by European farmers costs them an estimated €400 to €900 million each year.41 In 2008, the impact on EU livestock farmers of not being able to import maize and maize products from the United States was estimated at an additional cost of €5 billion in total.42 Future trade disruption is increasingly likely because of the chronically slow authorisation system. The negative impact of private R&D investment leaving Europe should not be underestimated – R&D money is clearly moving elsewhere and leading researchers are following.

34) Case T-18/10, Inuit Tapiriit Kanatami and others v Parliament and Council, paragraph 56 (emphasis added).
35) Article 289(3) TFEU.
36) Pursuant to Article 291 TFEU and Regulation (EU) 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers.
37) Case T-262/10, Microban International and Microban (Europe) v Commission.
39) See Presidency Note to COREPER/Council (1744/10), 10 December 2010.
40) The analysis of justifications (under Article XX) concluded that these were unlikely to be successful.
Beyond GMOs there is a palpable sense among many regulated industries that political interference is ever more present in procedures which should deliver impartial, high quality, timely decision-making. Whilst playing to the crowd may serve short-term interests, policies and implementation driven by unsound reasoning risks ultimately reducing public confidence in the regulatory system and regulators. The inherent ‘anti-science’ tone of much of the public discourse on GMOs has a knock-on effect in other sectors such as food, medicines and nanomaterials. These trends deeply concern the private sector. For example, in October 2013, a group of global CEOs addressed an open letter to the Presidents of the European Commission, Council and Parliament deploring ‘... the negative impact of recent developments in risk management and regulatory policy on the innovation environment in Europe’. They expressed concern that the potential for technologies to advance welfare is being put at risk by ‘... an increasing preference for risk avoidance and the loss of scientific methodology from the regulatory process’.43

Lessons Learned

The GMO authorisation experience offers a number of lessons:

(1) The growing trend of politicisation of product authorisation processes has made it increasingly challenging to see the fair, workable and predictable process described in EU legislation. This is especially the case regarding so-called controversial products – GMOs, chemicals, plant protection products or pharmaceuticals.

(2) Companies are increasingly willing to use legal action to get their products treated according to the processes established in law. Action against the European Commission and Member States is considered a legitimate tool in an over-politicised regulatory environment.

(3) Legal action can work. The courts have ruled in a number of cases, that disregard of legislatively described authorisation procedures by regulators is not acceptable. The implications of the 1507 maize case go far beyond GM cultivation dossiers or even delayed dossiers for GM products for food, feed and import. The principles set out in the judgment would be equally applicable in any EU regulatory sphere where there is a procedural mechanism envisaged, with a role for the Commission to advance that procedure, where the Commission fails to exercise that function in a dilatory manner. Where the Commission fails to do so, it will be condemned by the CJEU and damages actions will be likely to follow.

(4) Disregard of legislative requirements harms the EU. The effect of unpredictable decision-making makes investment significantly less attractive. Current trends in the agri-food biotechnology sector already attest to this – investment is moving away from the EU rapidly – but biotech is by no means the only area.44 Environment, health and safety considerations can be integrated into robust regulatory regimes (and have been for GMOs) but these need not undermine legitimate commercial development through erratic and arbitrary implementation.


44) See, for example, ‘R&D trends for chemical crop protection products and the position of the European Market, A consultancy study undertaken for ECPA’, Phillips McDougall, September 2013, which concluded that ‘the share of global crop protection investment in R&D focussed on products for use in European markets has fallen from 33.3% in the 1980s to only 7.7% in the 2005 to 2014 period’: http://www.ecpa.eu/files/attachments/R_and_D_study_2013_v1.8_webVersion_Final.pdf.