

The Right to Adopt Post-Market Restrictions of Genetically Modified Crops in the EU – A Shift from De-Centralised Multi-Level to Centralised Governance in the Case of GM Foods

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*Joined Cases C-58/10 to C-68/10 Monsanto SAS and Others*¹

I. Facts

The present preliminary ruling has been made in the context of several proceedings in France involving Monsanto SAS (Monsanto) and the French Minister of Agriculture as well as several individuals and private entities. The questions referred to the Court by the French Conseil d'État concerned the lawfulness of a temporary suspension of cultivation of Mon 810 – a genetically modified maize developed by Monsanto – that was issued by the French Minister of Agriculture.

MON 810 is being used as animal feed in the EU. It was authorised for the first time in 1998 under Directive 90/220 on the deliberate release into the environment of genetically modified organisms (GMOs).² In the period of 2001–2003 the EU legislative framework for GMOs was overhauled, and as a result more stringent regulations concerning the deliberate release and the placing on the market of

GMOs were adopted.³ Directive 90/220 was replaced by Directive 2001/18.⁴ The latter regulates two types of deliberate release of GMOs into the environment, namely pre-commercial field trials⁵ and the commercial cultivation of GM crops and plants.⁶ In addition, Regulation 1829/2003 on genetically modified food and feed was enacted. This act regulates the circulation on the internal market of genetically modified food and feed products.⁷

Genetically modified agricultural plants, which are cultivated for the purpose of being placed on the market as food or feed, such as MON 810, fall under the scope of application of both Directive 2001/18 and Regulation 1829/2003. Due to this overlap the applicant has the choice of either applying for two separate authorisations (ie under the Directive for cultivation and under the Regulation for marketing as food or feed) or for a single authorisation under the Regulation, which covers both purposes of use.⁸ In case of a single application under Regulation 1829/2003 the latter becomes *lex specialis* in relation to the Directive with the consequence that certain provisions of the Directive do no longer apply (by virtue of Article 12 of Directive 2001/18).

It should be noted that the procedures for both prior-authorisation of GMOs and the adoption of post-market restrictions differ depending on the choice of the respective legal regime (ie of the Directive or of the Regulation). The Directive follows a de-centralised approach to both the process of market authorisation for GMOs and the adoption of post-market safeguard measures. Article 23 of the Directive gives Member States the right to provisionally restrict the cultivation of a GMO in order to react to potential risks emerging after that product has been authorised. The condition for the adoption of a safeguard measure is that the Member State in question “has detailed grounds for considering that a GMO (...) constitutes a risk to human health or the environment” as a result of new or additional

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1 Judgment of the Court of 8 September 2011, OJ C 100, 17.4.2010, not yet published.

2 OJ 1990 L 117, p. 15.

3 See Maria Weimer, “Applying precaution in EU authorization of genetically modified products – challenges and suggestions for reform”, 16(5) *European Law Journal* (2010), pp. 624–657; Theofanis Christoforou, “The regulation of genetically modified organisms in the European Union: The Interplay of Science, Law and Politics”, 41(3) *Common Market Law Review* (2004), pp. 637–709.

4 OJ 2001 L 106, p. 1.

5 Part B of Directive 2001/18.

6 Part C of Directive 2001/18.

7 See Article 3 of Regulation 1829/2003: GMOs for food use, food containing or consisting of GMOs; and food produced from or containing ingredients produced from GMOs. For GM feed see Article 15.

8 See Article 17 (5) of Regulation 1829/2003, which requires the fulfillment of additional requirements of documentation in accordance with Directive 2001/18 for applications covering cultivation.

information made available after the original authorisation.

Under Regulation 1829/2003 the procedures for both the authorisation of genetically modified food and feed and post-market restrictions are carried out at EU level. Article 34 of the Regulation provides for the possibility of adopting so-called emergency measures “where it is evident that products authorised by (...) this Regulation are likely to constitute a serious risk to human health, animal health or the environment.” As regards the procedures for the adoption of emergency measures Article 34 refers to provisions concerning food and feed safety emergencies laid down in Regulation 178/2001 on the general principles and requirements of food law.⁹ Under these emergency procedures of Regulation 178/2001 the Commission, in principle, has the prerogative of enacting post-market restrictive measures aiming at managing occurring food crises.

In 2008 the original authorization for MON 810 held by Monsanto was due to expire. Monsanto did not apply for a renewal of authorisation under Directive 2001/18, the legal successor of Directive 90/220. Instead the company notified MON 810 as a so-called “existing product” in accordance with Article 20(1) of Regulation No 1829/2003. The latter provision allows GMOs (with a food or feed purpose) that have been lawfully placed on the market before the entry into force of the Regulation to be transferred to the legal regime of the latter. Thus, GMOs that have been previously authorised under Directive 90/220 may continue to be marketed in the EU provided that the authorisation holder notifies the product under Regulation 1829/2003 within a certain period of time. Following the notification of MON 810 under the Regulation, Monsanto applied for a renewal of its market authorisation under the same Regulation.

While this application was pending at EU level, the French Minister of Agriculture issued a temporary suspension of cultivation of Mon 810¹⁰ until a decision on the renewal of authorisation had been taken. Subsequently, Monsanto and various other applicants brought actions for annulment of the ban before the Conseil d’État. The Conseil d’État decided to stay the proceedings, and to refer three questions to the Court of Justice for a preliminary ruling. The essential legal question in that case concerned the correct legal basis for the national suspension of MON 810, namely either Article 23 of Directive 2001/18 or Article 34 of Regulation 1829/2003, or possibly both of these provisions.

II. Judgment

1. The first question

The first question referred to the Court by the French Conseil d’État concerned the choice of the applicable legal basis. In essence, the Conseil d’État asked whether an existing product such as MON 810, which has been authorized under the Directive 90/220, later notified under the Regulation 1829/2003, and is now pending authorization under the latter, falls under the scope of Article 12 of Directive 2001/18. The latter exempts GMOs authorised under EU sectoral legislation, such as Regulation 1829/2003, from the scope of application of Articles 13 to 24 of the Directive under certain conditions. As a consequence Article 23 of Directive 2001/18 would become inapplicable to post-authorisation restrictive measures regarding MON 810; while Article 34 of Regulation 1829/2003 would be the applicable legal basis on which post-authorisation emergency measures would have to be based.

The Court’s response to this question was concise. It did not consider necessary to interpret Article 12 of Directive 2001/18, as suggested by the Conseil d’État, but found that Regulation 1829/2003 provides sufficient interpretative information to determine the applicable legal basis in this case – which ultimately was the main rationale behind the first question.¹¹ Without much ado, the Court based its reasoning on the combined textual reading of the provisions of Articles 20 (5) and 17 (5) of Regulation 1829/2003 to conclude that national provisional measures suspending or prohibiting the use of GMOs may be adopted pursuant to Article 34 of Regulation 1829/2003; and that Article 23 of Directive 2001/18 does not apply. The essence of this textual argument was that, firstly, according to Article 20 (5) of Regulation 1829/2003 all existing products in the sense of Article 20 (1) are subject to the provisions of that Regulation (among them Article 34). And secondly, this also makes Article 17 (5) applicable to existing products with the consequence that certain information concerning the environmental aspects of the risk assessment and monitoring as provided for by Directive 2001/18

9 Namely to Articles 53 – 54 of Regulation 178/2002.

10 In fact, the French authorities have issued a series of consecutive orders within the period of three months, all of which aimed at restricting the cultivation of MON 810. For the sake of simplification this report summarizes them as one temporary suspension.

11 Para 57–58.

needs to be provided also when notifying an existing product. This being the case, Article 17 (5) of the Regulation declares Article 23 of Directive 2001/18 to be inapplicable.¹²

2. The second question

In essence the second question was whether the Member States may adopt emergency measures under Article 34 of Regulation 1829/2003, and under what conditions. The Court was thus asked to interpret the provisions of Article 34 of Regulation 1829/2003 and of Articles 53–54 of Regulation 178/2002, to which the latter Article refers.

The Court began by observing that according to the wording of Article 34 of Regulation No 1829/2003, that provision, first, lays down the substantive conditions under which a GM product may be the subject of emergency measures and, second, refers to Articles 53 and 54 of Regulation 178/2002 as regards the procedures which are to be followed in such cases.¹³ From that it follows that the substantive conditions of Articles 53 and 54 of Regulation 178/2002 do not apply to emergency measures adopted under Article 34 of Regulation 1829/2003.¹⁴

With regard to the procedural conditions of both articles, Article 53 concerns emergency measures that maybe adopted by the Commission whereas Article 54 concerns measures adopted by the Member States. Consequently, if a Member State wishes to adopt measures under Article 34 it needs to fulfil both the substantive provisions of Article 34 of the GMFR and the procedural provisions of Article 54 GFL.¹⁵ These procedural conditions require Member

States first to inform the Commission officially of the need to take emergency measures, and second, where the Commission has not acted in accordance with Article 53, to inform immediately the other Member States and the Commission of the interim protective measures adopted.¹⁶ In other words, the right of the Member States to adopt emergency measures on the basis of Article 34 of Regulation 1829/2003 was found to be merely subsidiary or exceptional as opposed to the principal power of the Commission in this regard.¹⁷

3. The third question

Finally, the third question referred to the Court concerned the issue of the risk threshold to trigger post-authorisation restrictions by the Member States as laid down in both Article 23 of Directive 2001/18 and Article 34 of Regulation 1829/2003. In essence, the Conseil d'État asked how the conditions for the adoption of safeguard or emergency measures by the Member States as laid down in both these provisions should be interpreted in the light of the precautionary principle.

Since the Court in its reply to the first question already ascertained that Article 34 of Regulation 1829/2003 was the applicable legal basis in this case, it now narrowed down its answer to the third question to what degree of requirement Article 34 of the Regulation imposes on the Member States in respect of the adoption of emergency measures.¹⁸

In responding to this question the Court first interpreted the wording of Article 34 of the Regulation. In a concise manner and without much explanation it stated that “the expressions ‘likely’ and ‘serious risk’ must be understood as referring to a significant risk which clearly jeopardises human health, animal health or the environment. That risk must be established on the basis of new evidence based on reliable scientific data.”¹⁹ This textual reading was then backed up by a reference to the traditional formula developed in previous case law that protective measures (under Article 34 in that case) cannot validly be based on a purely hypothetical approach to the risk, founded on mere assumptions which have not yet been scientifically verified; and that such measures may be adopted only if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case, which indicate the necessity of the measure.²⁰

¹² Para 58–63.

¹³ Para. 66.

¹⁴ This would have been important for the right of Member States to adopt emergency measures insofar as Article 53 of Regulation 178/2002 provides as a condition for the Commission to act that the risk cannot be contained satisfactorily by means of measures taken by the Member States. It thus makes the action of the Commission subsidiary to the action of the Member States under Regulation 178/2002. See on that Opinion of AG Mengozzi, para. 49.

¹⁵ Para. 69.

¹⁶ Para. 70.

¹⁷ See Opinion of AG Mengozzi, para. 53.

¹⁸ Para. 75.

¹⁹ Para. 76.

²⁰ Para. 77.

In addition, the Court also took the opportunity to elucidate the institutional aspects related to the regulatory scheme established by Regulation 1829/2003. Referring to its objective of avoiding artificial disparities in the treatment of a serious risk, the Court maintained the role of the Commission as the main risk manager in the post-authorisation phase. The Court did that by stating that “the assessment and management of a serious and evident risk ultimately come under the sole responsibility of the Commission and the Council, subject to review by the European Union Courts.”²¹ As long as no decisions regarding an authorised product have been adopted at EU level, the Member States retain the competence to adopt protective measures under the combined provisions of Articles 34 Regulation 1829/2003 and Article 54 Regulation 178/2002, which then are subject to judicial control by the national courts whilst the uniformity of EU law may be ensured by the Court under the preliminary ruling procedure.²² However, as soon as the Commission adopts a decision at EU level following comitology, the factual and legal assessments relating to that case and contained in such a decision are binding on all Member States.²³ After that clarification of the institutional aspects, the Court returned to its answer to the third question, which was that “with a view to the adoption of emergency measures, Article 34 of Regulation No 1829/2003 requires the Member States to 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.”²⁴

III. Comment

Monsanto and others is the last in a series of judgments by the European Courts, in which the legality of national derogations from the EU legal framework on genetically modified organisms (GMOs) was in question.²⁵ Most of these cases concerned the legal interpretation of derogation-clauses laid down in both EU primary and secondary law²⁶, and thus the question under which substantive conditions Member States may legitimately restrict GMOs already authorised by the EU on their territory. What is interesting about the present case, however, is that for the first time the question of the applicable legal basis for a national ban of GMO seeds was raised. The main legal problem addressed by the European Court, therefore, was to ascertain which legal re-

gime (that of Directive 2001/18 or that of Regulation 1829/2003) should govern the adoption of national post-authorisation restrictions of “existing products”. Although this case seems to concern a merely transitional problem, ie that of GM products authorised under the framework of the Directive while notified and pending authorisation under the Regulation, it is also significant with regard to more general issues of precautionary multi-level governance of GMOs in the EU, as will be shown below.

1. The choice of the applicable legal regime for “existing products”

According to the Advocate General (AG) Mengozzi the main legal question raised in this case pertaining to the correct legal basis for provisional national restrictions of the cultivation of “existing” GM products presented the Court with a “relatively limited” legal problem.²⁷ The Court seems to share this view, which is reflected in the little effort that it conducted in making the legal argument sustaining Article 34 and thereby also the legal regime of Regulation 1829/2003 as the applicable legal framework. The first question, which concerned this issue, was dealt with within four short paragraphs mainly restating the wording of the relevant provisions of Regulation 1829/2003 (ie Articles 20 (5) and 17 (5)). Beyond this textual interpretation, the Court did not find it necessary to engage with any further methods of legal interpretation pertaining to legislative purpose of the legal instruments in question, the relationship between both legal regimes (ie Directive 2001/18 and Regulation 1829/2003), or any other systematic arguments.

21 Para. 78.

22 Para. 79.

23 Para. 80.

24 Para. 81.

25 See Case C-6/99 *Greenpeace France and Others* [2000] ECR I-1651; Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105; Joined Cases T-366/03 and T-235/04 *Land Oberösterreich and Republic of Austria v Commission* [2005] ECR II-04005 and Joined Cases C-439/05 P and C-454/05 P *Land Oberösterreich and Republic of Austria v Commission* [2007] ECR I-07141; Case C-165/08 *Commission v Republic of Poland* [2009] ECR I-06843.

26 For primary law Article 114 (5) of the TFEU; for secondary law: legal clauses contained in EU legislation on GMOs, see below in this case-note.

27 See AG Mengozzi, para. 1.

The legal opinion of the AG was more elaborate in this regard. While also suggesting Article 34 of Regulation 1829/2003 as the applicable legal basis, the AG had chosen a different path of legal reasoning. Following the formulation of the first question by the Conseil d'État the AG examined, if existing products fall under the scope of application of Article 12 of Directive 2001/18.²⁸ The main purpose of this provision is to exempt GMOs authorised under EU sectoral legislation, such as Regulation 1829/2003, from the scope of application of Articles 13 to 24 of the Directive where sectoral legislation contains provisions at least equivalent to those provided in these Articles (eg regarding environmental risk assessment, risk management, safeguard clause etc). Therefore, for GMOs *authorised* under Regulation 1829/2003, the latter constitutes a *lex specialis* vis-à-vis Directive 2001/18. Existing products such as MON 810, however, are merely *notified* under the Regulation, while pending authorisation. The AG suggested that Article 34 of the Regulation is nonetheless applicable, because the term “authorised” in Article 12 of the Directive should be interpreted broadly. Because the notification as an existing product under Article 20 (1) of the Regulation was the actual condition allowing MON810 to legally be placed on the market (in the transitional period of the pending application for authorisation renewal), it had the *de-facto* effect of an authorisation. The designation of this act as authorisation or notification was considered to be a formality.²⁹

Article 12 of Directive 2001/18 could arguably be interpreted in stricter terms than those chosen by the AG. In the EU (and in other legal orders) the prior-authorisation and the notification schemes constitute two different regulatory approaches with considerable legal and practical differences for both the regulatory authorities and the regulatées.³⁰ One of the most important differences is that under

the prior-authorisation scheme a product may not be placed on the market before the process of risk evaluation has been completed by the authorities. It could therefore be argued that the *lex specialis* effect of Regulation 1829/2003 would unfold only once the process of authorisation including a complete risk evaluation under this Regulation has been completed. This shows that when focusing on Article 12 of the Directive as the relevant provision to be interpreted, this case could, in principle, be argued in favour of maintaining the applicability of Article 23 of the Directive until the renewal of authorisation under the Regulation.

The Court decided not to engage with these arguments, and instead chose a textual interpretation of Regulation 1829/2003 without however providing any kind of supporting arguments. Such arguments could have been, beyond the wording of Articles 20 (5) and 17 (5), the legislative purpose of Regulation 1829/2003, namely to replace the system provided by the Directive where the applicant so wishes.³¹ Another systematic argument could have been the combined reading of Articles 20 (5) and 17 (5) of the Regulation with Article 12 of the Directive, which would support the wide interpretation of the term “authorised” chosen by the AG. Overall, while a different interpretation of the legal provisions in question (especially Article 12 of the Directive) would have been possible in the present case, from the purely legal-technical point of view the Court’s conclusion regarding the legal basis was defensible.

2. Implications for EU multi-level governance of GMOs

Beyond legal technicalities this judgment could have significant legal-political and practical consequences³² for EU multi-level governance of GMOs. Behind the narrowly defined legal problem of the right legal basis lies the more general problem of the overlap and potential tension between the scope of application between the two legal regimes of Directive 2001/18 and Regulation 1829/2003. The AG’s view of the equivalence of both these regimes with regard to the level of requirement for the adoption of “emergency measures” does not convince.³³ It understates the differences in the way the Directive and the Regulation respectively constitute the distribution of regulatory authority between the EU and the national level.

28 See para. 30 where the AG states: “I note that, from a legal standpoint, the core issue in the main proceedings appears to consist in determining the scope of Article 12 of Directive 2001/18.”

29 Para. 36.

30 See for example the different procedures of notification and prior-authorisation for different substances under the REACH legal framework for the regulation of chemicals.

31 See in this sense also AG, para. 40.

32 There are currently six Member States who have suspended the use of MON 810 using the legal basis of Article 23 of Directive 2001/18.

33 See AG opinion para. 42.

While Article 23 of the Directive allows the Member States to take “safeguard measures” under certain circumstances directly and at their own discretion, Article 34 of the Regulation speaks of “emergency measures,” and grants the right of adopting such measures solely and primarily to the Commission. The Member States only retain a residual right in case of Commission’s inaction. Therefore, Article 34 of the Regulation arguably constitutes a change of paradigms from a de-centralised approach to national derogations,³⁴ where decisional discretion to act is granted to national authorities, to a centralised approach where the Commission acts as a kind of “super” risk manager for the entire Union. This may be seen as problematic, if one considers that GMO cultivation raises issues of environmental impact, agricultural land use, and co-existence between GM and other agricultural products. These aspects of GMO cultivation originally motivated the adoption of the de-centralised approach to post-approval risk management by the Member States. The latter are arguably better equipped to monitor, assess, and to react to risks potentially occurring on location in their territories, which is why the principle of subsidiarity supports the de-centralised approach to safeguard measures under Directive 2001/18.

It is worth noting that de-centralisation and flexibility within the EU legal regime for GMOs were among the reasons why some scholars have described this regime as exemplifying features of new, experimentalist or multi-level governance.³⁵ Further features of the de-centralised approach under the Directive can be seen in Article 26a, which leaves the management of co-existence in the hands of the Member States thus taking it out of the scope of EU harmonisation. Moreover, a recent legislative proposal by the Commission aims at granting the Member States the right to restrict the cultivation of GMOs on national territory on so-called socio-economic grounds.³⁶ This shows that there are significant differences in the governance approaches to post-market management of GMOs between the legal regime of Directive 2001/18 and that of Regulation 1829/2003.

It could be argued that the de-centralised approach to GMO cultivation for now remains valid for GMOs authorised under the Directive. However, it is likely that the relevance of the Directive in future regulation of GM seeds will decrease beyond the case of “existing products.” The Court’s ruling can be seen as strengthening the right of GMO producers to choose

the applicable legal regime thus replacing the Directive’s framework with that of Regulation 1829/2003. The latter also covers cultivation of GM seed while offering applicants the advantage of filing only one application for authorisation that would cover both the cultivation and the subsequent marketing of a GMO as food or feed. Article 34 of the Regulation offers the applicant an additional advantage, because it restricts the right of the Member States, many of which are opposed to GMO cultivation, to adopt restrictive measures in the first place, as has now been confirmed by the Court. It seems likely that companies will use the possibility of opting out, so-to-speak, from the legal regime of the Directive as far as GMOs with food and feed purposes are concerned. The present case illustrates that this is already happening. It seems, therefore, that the legal situation at present as confirmed by the Court effectively empowers the applicants by giving them the choice of avoiding the applicability of Directive 2001/18.

The present judgment does not consider these issues, nor does it engage with arguments speaking against the application of Regulation 1829/2003 to the cultivation of GMOs.³⁷ It confirms the trend towards a wider scope of application of the Regulation, and thus the trend towards more centralised governance of GMO releases in the EU. At the same time, the remaining scope of application for the Directive is arguably small (namely for GMO field trials and GMOs cultivated for other purposes than food and feed). This creates a legal situation where GMOs cultivated for food and feed purposes and those cultivated for other purposes are treated differently without apparent substantive justification.

34 This approach is still being maintained in several legal acts of Union law, such as for example the Novel Foods Regulation and the REACH Regulation. However, seeing the problems for the internal market experienced with the use of safeguard-clauses by the Member States legal changes can be expected in the future.

35 See Patrycja Dabrowska, “EU Governance of GMOs: Political Struggles and Experimentalist Solutions?”, in Charles F. Sabel and Jonathan Zeitlin (eds), *Experimentalist Governance in the European Union* (Oxford; New York: Oxford University Press, 2010); Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a new Technology* (Cheltenham, UK; Northampton, MA: Edward Elgar, 2008).

36 See on this Maria Weimer, “What Price Flexibility? The recent Commission Proposal to allow for national ‘opt-outs’ on GMO cultivation under the Deliberate Release Directive and the Comitology reform post-Lisbon”, 1(4) *European Journal of Risk Regulation* (2010), pp. 345–352; Karolina Zurek, “Indicating Reasons for National GM ‘Opt-outs’”, 2(2) *European Journal of Risk Regulation* (2011), pp. 241–244.

37 See critical voices among German scholars: Winter, *NVwZ* 2005, pp. 1133–1136; Roller, *Zeitschrift für Umweltrecht* 2005, pp. 113–117.

3. Substantive conditions for adoption of emergency measures – still an expression of the precautionary principle?

In its judgment in the case *Monsanto Agricoltura Italia* from 2003 the Court has provided the basis for an understanding of the safeguard-clauses laid down in EU legislation (such as Article 23 of Directive 2001/18),³⁸ and which allow for national derogation as a legislative expression of the precautionary principle. The latter principle is laid down in Article 191 (2) of the TFEU.

In the present judgment, however, the Court effectively departed from its previous case law.³⁹ It interpreted Article 34 of Regulation 1829/2003 as requiring for the adoption of emergency measures (at EU level, and in case of failure to act on the part

of the Commission, at national level) the likelihood of a significant risk to human health and the environment, which is evidenced by new scientific data, and establishes a situation of urgency. In fact, when interpreting the level of requirement under Article 34 under the third question the Court did not invoke the precautionary principle at all.⁴⁰

Thus, the Court did not take into account the findings of many years of research in the field of science and technology studies and risk governance, which indicate that modern technological risks defy traditional probability-based approaches to risk assessment.⁴¹ In the context of technological risks the main problem encountered in risk assessment is seen to be not just the calculation of probability of the occurrence of known negative outcomes, but the determination of the potential hazards as such. Moreover, the adequacy of choosing as narrow a condition as likelihood of a serious risk proven by new scientific evidence can be doubted. Such condition is likely to never be fulfilled in the case of agricultural biotechnology that interacts within a complex environmental system, the consequences on which could only appear in the medium and long term. The definition of risk chosen by the Court in the present judgment is closer to that of danger. In the latter, the expected hazard is known and likely to realise at some point requiring urgent preventive measures. The notion of risk, on the contrary, is more complex, and involves problems of scientific knowledge, uncertainty, indeterminacy, and ambiguity.⁴²

It should be noted that the narrow legislative wording of Article 34 has preconditioned to some extent the interpretation chosen by the Court. However, the AG's legal opinion shows that a less strict interpretation of Article 34 was possible.⁴³ The Court again chose to stick closely to the "black letter" of the legal text, and to interpret the conditions for the adoption of emergency measures in stricter terms than its AG.

38 But also in other pieces of EU legislation, such as the Novel Foods Regulation and the REACH Regulation.

39 In *Monsanto Italia Agricoltura* the Court when interpreting the safeguard clause of Regulation 257/97 (Novel Foods Regulation) stated that protective measures may be taken pursuant a safeguard clause interpreted in the light of the precautionary principle "even if it proves impossible to carry out as full a risk assessment as possible in the particular circumstances of a given case because of the inadequate nature of the available scientific data." See para 112 of the judgement.

40 Rather the principle was mentioned under the second question in order to argue the necessity of urgent action on the part of Member State in the sense of immediate communication of the adoption of emergency measures to the Commission, see para.71 of the judgment.

41 See for an overview Marjolein Van Asselt and Ortwin Renn, "Risk Governance", 4(4) *Journal of Risk Research*, pp.431–449 and Michelle Everson & Ellen Vos (eds), *Uncertain Risks Regulated*, (London: Routledge-Cavendish, 2009).

42 Van Asselt and Renn, "Risk Governance", *supra* note 41; Brian Wynne, "Uncertainty and Environmental Learning", 2 *Global Environmental Change* (1992), pp.111–127.

43 See AG's legal opinion, para.71: "in order to adopt emergency measures relating to genetically modified organisms pursuant to Article 34 of the regulation, it is necessary for the existence of a risk to human health, animal health, or the environment to be established, which is not merely hypothetical, and for the probability of such harm occurring to be significant, even though it has not necessarily been determined precisely."