

## GM Foods, Risk, Precaution and the Internal Market: Did Both Sides Win the Day in the recent Judgment of the European Court of Justice?

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Almost exactly one year after the famous judgments of the Court of First Instance on the precautionary principle,<sup>1</sup> the European Court of Justice (hereinafter “the Court”) has issued a preliminary ruling further exploring this concept. The ruling arose from a national dispute concerning a temporary ban on novel foods produced from genetically modified organisms (hereinafter “GMOs”).<sup>2</sup> This recent *Monsanto* judgment is the first case in which the Court has directly invoked the precautionary principle regarding Member States’ power to adopt a provisional prohibition on the marketing of GMO-derived novel foods.<sup>3</sup> Simultaneously, the Court lent an ear to the arguments of Monsanto by declaring the validity of the simplified procedure laid down in the novel foods Regulation 258/97 and based on the contentious concept of substantial equivalence. Thus, it seems to have favoured the free circulation in the Community market of novel foodstuffs notwithstanding the presence of residues of genetically modified (hereinafter “GM”) protein, on the condition that there is no risk to human health.<sup>4</sup>

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<sup>1</sup> Case T-13/99 *Pfizer Animal Health S.A. v. Council* 2002 ECR II-3305 (hereinafter *Pfizer*); case T-70/99 *Alpharma Inc. v. Council* 2002 ECR. Cf. also Olivier Segnana, *The Precautionary Principle: New Developments in the Case Law of the Court of First Instance*, Vol. 3 German Law Journal (GLJ) No. 10 (1 October 2002); Caoimhín MacMaoláin, *Using the precautionary principle to protect human health: Pfizer v Council*, 28 European Law Review (ELRev.) 723 (2003).

<sup>2</sup> Judgment of the Court of 9 September 2003 case C-236/01 *Monsanto Agricoltura Italiana SpA and Others v. Presidenza del Consiglio dei Ministri and Others*, nyr in the ECR, available at <http://curia.eu.int> (hereinafter *Monsanto* case).

<sup>3</sup> Cf. however a similar case concerning GM maize and the Directive 90/220 on GMO Deliberate Releases C-6/99 *Association Greenpeace France and Others v. Ministère d’Agriculture et de la Pêche and Others*, 2000 ECR I-1651 (hereinafter *Greenpeace* case).

<sup>4</sup> *Monsanto*, para. 84, 110 and 133.

## A. Background

### I. Facts of the case

According to Community law, all novel foods, including GM foods or foods derived from GMOs, must undergo authorization before they can lawfully enter the European Union market.<sup>5</sup> Community harmonization also provides that foodstuffs which are produced from GMOs, but no longer contain them, may be placed on the market under the so-called “simplified procedure” which merely requires that the Commission is notified of them. The use of this procedure is allowed when products in question are “substantially equivalent” to comparable conventional foods: evidence of which can be given by a national food assessment body or based on available and generally recognized scientific evidence.<sup>6</sup> Between December 1997 and October 1998, three notifications, which concerned the placing of foods produced from various GM maize lines on the market,<sup>7</sup> such as corn flour or corn oil, were made to the Commission under the simplified procedure. These notifications were submitted by Monsanto Europe SA and other companies active in the field of production of GM plants. In addition to those notifications, the producers provided the opinion of the United Kingdom scientific assessment body (the Advisory Committee on Novel Foods and Processes) which had concluded that the notified products were substantially equivalent to traditional maize and “safe for use in food”.<sup>8</sup>

Meanwhile, taking account of the controversies which surrounded both the use of the simplified procedure (which does not require a full risk assessment) and the concept of substantial equivalence,<sup>9</sup> the Commission and the Member States agreed within the framework of the *Standing Committee on Foodstuffs* that they would cease to apply this procedure to GM novel foods containing transgenic proteins as of

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<sup>5</sup> Art. 1-3 EC Regulation 258/97 (hereinafter “Regulation 258/97”) on novel foods and novel food ingredients O.J. 1997 L 43/1 as amended by EC Regulation 1829/2003 on genetically modified food and feed O.J. 2003 L 268/1. The latter act replaces Regulation 258/97 with respect to GM food (their authorizations and labelling).

<sup>6</sup> Art 5, Regulation 258/97.

<sup>7</sup> Bt-11, MON 9 and MON 10 GM maize lines with the increased resistance to pests and tolerance to herbicides.

<sup>8</sup> *Monsanto* (note 2), para. 18.

<sup>9</sup> For the critique of this concept cf. *inter alia* Melanie Steiner, *Food Fight – the Changing landscape of Genetically Modified Foods and the Law*, 9 (2) *Review of European Community and International Environmental Law* (RECIEL) 152, 156 (2000).

January 1998.<sup>10</sup> Still, the Commission considered it appropriate to use the simplified procedure for the products concerned here even after that date, because foods produced from similar maize lines had already been placed on the Community market under this procedure.<sup>11</sup> In response, Italy began an exchange of letters with the Commission expressing concerns about the safety of the products in question. It claimed, above all, that the relevant products were not substantially equivalent to conventional counterparts, and more generally contested the appropriateness of the simplified procedure. In its letters Italy relied on the scientific opinions of various Italian scientific bodies. In particular, it referred to the opinion of *Istituto superiore di sanità* (dated 28 July 2000) which noted the presence of GM proteins in the foods concerned, but nonetheless concluded that the consumption of those foods “does not appear to present any danger to human and animal health”. Ultimately however, the Italian Government adopted a Decree temporarily suspending the free circulation of the GMO-derived foods in question on the national territory.<sup>12</sup> The Decree was based on the safeguard clause contained in Regulation 258/97, which allows the Member States to restrict or suspend the trade in, and use of, a novel food if it has detailed grounds for considering that the use of the food endangers human health on the basis of new information, or on a reassessment of existing information.<sup>13</sup>

In order to clarify the possible safety doubts, the Commission consulted the Scientific Committee on Food<sup>14</sup>, which arrived at the conclusion that “the information presented by the Italian authorities does not provide specific scientific grounds for

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<sup>10</sup> The Standing Committee on Foodstuffs, composed of representatives of the Member States, was set up under the Council Decision 69/414/EEC of 13 November 1969, O.J. 1969 (II) p. 500, cf. *infra* 14. On the Commission committees see generally Ellen Vos, *Institutional Frameworks of Community Health and Safety Regulation: Committees Agencies and Private Bodies* (1999).

<sup>11</sup> *Monsanto* (note 2) – Opinion of AG Alber – hereinafter “AG Opinion”, para. 24.

<sup>12</sup> Decree of the President of the Council of Ministers of 4 August 2000 on the precautionary suspension of the trade and use of certain transgenic products within national territory under Art 12 of Regulation 258/97 (GURI No. 184 of 8 August 2000, p. 9), see *Monsanto* (note 2), para. 16, 22-31.

<sup>13</sup> Art. 12, Regulation 258/97.

<sup>14</sup> The Scientific Committee on Food was set up under the Commission Decision 74/234/EEC of 16 April 1974, O.J. 1974 L 136/1. Under EC Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, O.J. 2002 L 31/1, both committees the Scientific Committee on Food and the Standing Committee on Foodstuffs were partly replaced or renamed.

considering that the use of novel foods at issue endangers human health".<sup>15</sup> In the light of that opinion, the Commission introduced before the Standing Committee on Foodstuffs a draft decision contesting the Italian Decree. However, in light of the general concerns of a number of Member States the simplified procedure, and regarding the application of the substantial equivalence concept to novel foods produced from GMOs, the Commission did not proceed to a formal vote on the Italian legislation.<sup>16</sup> This behaviour was directly linked to the *de facto moratorium* for any GMO authorizations which had been in place in the European Union since 1998.<sup>17</sup>

Nevertheless, the Italian Decree, which resulted in the temporary ban of GM maize-derived foods in Italy, was challenged before *Tribunale amministrativo regionale del Lazio* (hereinafter "TAR") by Monsanto and the other companies involved on the basis that it infringed Community law. The applicants maintained, *inter alia*, that the grounds for invoking the safeguard clause by the Italian authorities were not adequate and that the foods at issue, though containing some residues of transgenic protein, could not be classified as GMOs. Their opinion was that the Italian Decree should be annulled.<sup>18</sup>

## II. Referral to the European Court of Justice

Since the Italian TAR had concluded that the action brought by Monsanto concerned the interpretation and validity of Community law, it stayed national proceedings and referred the questions to the Court for a preliminary ruling. It asked whether the GMO-derived novel foods, like the ones at issue, which still contained residues of transgenic protein at certain levels could be considered as substantially equivalent to conventional foods and therefore marketed in the Community under the simplified procedure of Regulation 258/97. Furthermore, the TAR requested the Court to rule on the validity of the simplified procedure and to determine whether it complies with Community law principles such as the precautionary principle, proportionality and reasonableness. In view of the potential risks to human health

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<sup>15</sup> Opinion concerning a submission from the Italian authorities raising concerns for the safety of certain products approved under the notification procedure of Regulation (EC) 258/97, expressed on 7 September 2000, CS/NF/DOS/11 ADD 4 REV 2 Final, available at <http://europa.eu.int>.

<sup>16</sup> *Monsanto* (note 2), para. 35-37. It is worth noting that the simplified procedure was abandoned in relation to GM foodstuffs by the new EC Regulation 1829/2003 on genetically modified food and feed, *supra* note 5.

<sup>17</sup> Official Minutes of the Environmental Council of the EU, 24-25 July 1999, 9433/1/99 REV 1, annex II 14; see also Tamara Hervey, *Regulation of Genetically Modified Products in a Multi-Level System of Governance: Science or Citizens?*, 10 (3) RECIEL 321 (2001).

<sup>18</sup> Cf. *Monsanto* (note 2), para. 40, 50 and 86.

and the environment, the national court was essentially of the opinion that this procedure was invalid because it did not include a full risk assessment of the foods. Finally, the TAR asked as to what powers the Member States had to adopt protective measures, such as the Italian Decree, these being based on the precautionary principle.<sup>19</sup> In particular, the Italian tribunal sought to know whether a Member State was required to institute Community proceedings to challenge the lawfulness of the simplified procedure prior to the adoption of such measures.

## B. Findings of the Court

### *I. Objectives of Regulation 258/97*

In the first place it is worth noting that, when delivering its responses to the questions of the Italian TAR, the Court emphasized in particular the **two-fold objective** of Community harmonization in the field of novel foods. On one hand Regulation 258/97 sought to ensure the functioning of the internal market in new foodstuffs and, on the other, to protect public health against the risks to which they may give rise. The Court referred to this two-fold objective three times throughout the judgment in the course of interpreting the issues at stake: the concept of substantial equivalence, the legality and appropriateness of the simplified procedure and the lawfulness of the national protective measures.<sup>20</sup>

### *II. The concept of substantial equivalence and the application of the simplified procedure*

Both the national court and the Italian Government argued in the case that the premise underlying the concept of substantial equivalence was based on the assumption that GMO-derived foods no longer contain GMO material, and therefore that the simplified procedure had been wrongly applied to the foods at issue.<sup>21</sup> In response, the Court initiated analysis of the problem of substantial equivalence by noting that this notion constitutes a concept of Community law and therefore should be subject to an t autonomous and uniform Community interpretation, separate from those of the Member States. This interpretation ought to be arrived at in a three-dimensional context: having regard to the objectives of the Community novel foods Regulation 258/97, to the work undertaken by international scientific

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<sup>19</sup> *Monsanto* (note 2), para. 41-48.

<sup>20</sup> *Id.*, para. 74, 106 and 136.

<sup>21</sup> Cf. Art. 1.2 (b) and 3.4, Regulation 258/97.

institutions, and within the framework of risk analysis as commonly defined at international and Community level.<sup>22</sup>

Next, the Court defined the concept of substantial equivalence. In the Court's opinion, this does not in itself entail a safety assessment, but rather it "constitutes an approach for comparing the novel food with its conventional counterpart in order to determine whether it should be subject to a risk assessment as regards, in particular, its unique composition and properties". Secondly, the Court observed that this "concept must, more precisely, be understood as a specific method concerning novel foods, relating to the identification of hazards which comprises the first stage in scientific risk assessment ...[ and ]...which the differences observed between those foods and existing foods may involve".<sup>23</sup> The discovery of those hazards means simply the identification of biological, chemical and physical factors which can cause dangers to human health and the environment because of their presence within certain types of foods and which, therefore, require a scientific risk assessment to understand them better.<sup>24</sup> In other words, if an analysis of substantial equivalence identifies any hazards, the food must then be the subject of a full scientific risk assessment. The identification of those hazards is a matter for a national scientific body when it carries out an initial assessment of risks of novel foods before they are placed on the market (in order to potentially establish their substantial equivalence with the conventional counterparts). This potential establishment of substantial equivalence is a very pre-condition for the application of the simplified procedure.<sup>25</sup> The Court noted that an initial assessment of that kind took place in the present case.<sup>26</sup>

Then, the Court proceeded to state that substantial equivalence would be excluded if initial assessment by the competent body led to the discovery of any danger to human health. In consequence, novel foods produced from GMOs, such as the corn flour produced from GM maize at issue, **cannot be considered as substantially**

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<sup>22</sup> *Monsanto* (note 2), para. 72-74.

<sup>23</sup> *Id.*, para. 77, 79 and 129

<sup>24</sup> *Id.*, para. 79.

<sup>25</sup> *Id.*, para. 70-71 and 130.

<sup>26</sup> Unfortunately, the Court did not conduct an analysis of the second method for establishing the substantial equivalence of foods, which is provided by Regulation 258/97, namely when it is based upon available and generally recognized scientific evidence. The use of this method could, in theory, enable by-passing of the involvement of any scientific body before novel foods are marketed. This issue was raised by Advocate General in his opinion, cf., AG Opinion, para. 86-87.

**equivalent** to traditional foodstuffs when each of the **two** following **conditions** is satisfied:

1. the competent body has identified the existence of a risk of potentially dangerous effects to human health; and
2. this risk has been identified on the basis of scientific knowledge or evidence available at the time of the initial assessment of foods.<sup>27</sup>

Yet, the Court further held that a mere finding, based on the above criteria, that certain foodstuffs are not substantially equivalent is not in itself such to imply that the foodstuffs in question do in fact present a danger. That is to say, identification of risk does not directly imply danger. It solely means that the condition for the application of the simplified procedure was not met, and thus that the products in question must undergo a full scientific risk assessment under the normal procedure. On the other hand, the foods may still be considered substantially equivalent even if they present differences in composition but have no effect (no risk) on human health.<sup>28</sup> Whether the relevant conditions are fulfilled is, however, a matter to be determined *in casu* by a national court in the light of the above interpretation of the Court.<sup>29</sup> Accordingly, while rendering a final judgment in the national proceedings, the Italian TAR will have to decide if the GMO-derived novel foods concerned are in fact substantially equivalent. It is worth noting, that it will be very difficult to conclude that *they are not* because, as the Advocate General rightly observed, none of the parties in the present case, including the Italian Government, had stated that the contested foods presented a risk to human health.<sup>30</sup>

Moreover, the Court stated that the application of the simplified procedure to such novel foods justifiably considered to be substantially equivalent, should not be considered as the “relaxation of the safety requirements” required in respect of novel foods.<sup>31</sup> This observation related to the scruples of the Italian court that use of the simplified procedure was not sufficient to ensure a high level of protection of human health and environment, and was not such to guarantee compliance with the precautionary principle and the principle of proportionality. Furthermore, the

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<sup>27</sup> *Monsanto* (note 2), para. 81, 84 and 137.

<sup>28</sup> *Id.*, para. 77 and 82.

<sup>29</sup> *Id.*, para. 84, 99 and 126.

<sup>30</sup> *Monsanto* (note 2) AG Opinion, para. 51.

<sup>31</sup> *Monsanto* (note 2), para. 80.

Court refuted the TAR's argument by stating that the simplified procedure could not be considered inappropriate because Community law established a series of other procedures for re-examining the outcome of the procedure for establishing substantial equivalence. These involve re-assessment of the status of a GMO-derived product at Community level, the possible adoption of protective measures by Member States in the form of a safeguard clause, and verification of those measures, again, at the Community level. In the Court's view, these various procedures are sufficient guarantees of the safety of novel foods and have been especially established to provide for the close cooperation between the Commission and the Member States and their scientific bodies.<sup>32</sup> In addition, the specific procedure for the adoption of national bans safeguards the observation of the precautionary principle.<sup>33</sup> Finally, the Court pronounced that since the simplified procedure did serve to fulfil both dimensions of the two-fold objective which underlies Community Regulation 258/97 on novel foods, it could not be perceived to be a non-proportionate measure as the Italian TAR had alleged.<sup>34</sup> In conclusion, the Court did not find any legal factor which would indicate the invalidity of the simplified procedure.

### *III. Member States' powers to adopt temporary bans*

The second significant matter which formed the core of the questions referred to the Court by the Italian TAR was that of the power of the Member States to adopt temporary protective measures to prohibit GMO-derived novel foods on the national market, thereby restricting their free circulation (the use of the safeguard clause).<sup>35</sup>

In the first place, the Court explained that recourse by a Member State to the safeguard clause was formally justified when the material conditions for its application formulated in Art. 12 of the Regulation 258/97 were met, for example, because there had been a breach of one or more of the rules of the regulation resulting in a possible risk to human health or environment.<sup>36</sup> This might arise, for instance, fol-

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<sup>32</sup> *Id.*, para. 130-132.

<sup>33</sup> *Id.*, para. 133, see also section III below.

<sup>34</sup> *Id.*, para. 47, 136-138 .

<sup>35</sup> Cf. Ellen Vos, *Differentiation, Harmonization and Governance in The many faces of differentiation in EU law*, 162, 167 (Bruno de Witte, Dominik Hanf, Ellen Vos eds., 2001); and in the similar context Patrycja Dąbrowska, *The division of powers between the EU and the Member States with regard to deliberate release of GMOs (the new Directive 2001/18)*, 3 GLJ No. 5 (1 May 2002).

<sup>36</sup> Article 12.1, Regulation 258/97 is worded as follows: „Where a Member State, as a result of new information or reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this regulation endangers human health or the environment,

lowing a supposed misuse of the simplified procedure.<sup>37</sup> In addition, the Court observed that recourse to the safeguard clause in an individual case was not affected by the “type” of procedure followed prior to the placing of the product on the market – simplified or normal – or by the criterion of the validity of that procedure.<sup>38</sup> In the light of the Court’s ruling, the very aim of any safeguard clause is to permit the introduction of protective measures, specifically, in order to remedy an emergency situation. Hence, the safeguard clause allows for an immediate Member States’ action without a former commencement of any legal steps (for example, challenging the lawfulness of the procedure used) or an obligation to employ a specific Community procedure for re-examination of the status of a novel food in question.<sup>39</sup> Consequently, the doubts of the Italian TAR were clarified – the lack of the activity of the Italian Government at the Community level preceding the adoption of a national protective measure, does not as such affect the validity of the latter.

Secondly, the Court went some way towards stipulating the substantive conditions which legalize the temporal restriction or suspension of the marketing of novel foods in the national territory with the aim of protecting human health. These can be enumerated as follows:

1. the demonstration of the **existence of a risk** to public health (or environment);
2. the measure “**may not properly be based on a purely hypothetical approach to risk**” or “**founded on mere suppositions, which are not yet scientifically verified**”;<sup>40</sup>
3. the measure must be “based on a **risk assessment** which is **as complete as possible** in the particular circumstances of an individual case.”<sup>41</sup>

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that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.”

Even though the text of the Regulation mentions the dangers, both, to human health and the environment, the Court in its analysis concentrated mainly on the first one “risk to public health”.

<sup>37</sup> *Monsanto* (note 2), para. 100.

<sup>38</sup> *Id.*, para. 104.

<sup>39</sup> *Id.*, para. 102-103.

<sup>40</sup> *Id.*, para. 105-106. Already confirmed in case C-192/01, *Commission v. Denmark*, judgment of 23 September 2003, nyr, para. 49-51 (hereinafter *Danish nutrients* case).

<sup>41</sup> *Id.*, para. 107.

Moreover, the outcome of the risk assessment must indicate that those protective measures are **necessary** in order to ensure that novel foods do not present a danger for consumers (or environment). In the Court's opinion, if the national protective measures adopted under the safeguard clause do not meet these conditions, they will adversely affect the twofold objective of the 1997 novel foods regulation, that is "the functioning of the internal market in novel foods and protecting public health against the risks to which those foods may give rise".<sup>42</sup>

Regarding the burden of proof, the Court turned to the literal wording of the Article 12 safeguard clause which requires that the Member States have "detailed grounds" for considering that the use of novel foods endangers human health or the environment. It means that the reasons that the Member States present after they have carried out a risk assessment "cannot be of a general nature". For example, the burden of proof requirement is satisfied when the Member States rely on "evidence which indicates the existence of a **specific risk**" which the novel foods concerned could involve.<sup>43</sup>

Nevertheless, these **conditions must be interpreted with due regard to the precautionary principle**, because the safeguard clause gives specific expression to this principle.<sup>44</sup> Moreover, this principle must, where relevant, constitute an "integral part of the decision-making processes leading to the adoption of any measure for the protection of human health" when based on a safeguard clause.<sup>45</sup> With respect to the understanding of the precautionary principle, the Court recalled the explanation already well-settled in the case law of both European Courts: "where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent".<sup>46</sup> Therefore, the Court concluded that the interpretation of the safeguard clause in light of the precautionary principle permitted for a certain relaxation of the above enumerated conditions. It may happen, according to the Court, that in the particular circumstances it is impossible to carry out "as full a risk assessment as possible" because of "the inadequate nature of available scien-

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<sup>42</sup> *Id.*, para. 106

<sup>43</sup> *Id.*, para. 108-109, Art. 12, Regulation 258/97.

<sup>44</sup> *Id.*, para. 110.

<sup>45</sup> *Id.*, para. 133.

<sup>46</sup> *Id.*, para. 111-112; and *inter alia*, *Pfizer* para. 139; case C-157/96, *National Framers' Union and Others*, 1998 ECR I-2211, para. 63; C-180/96 *United Kingdom v. Commission* 1998 ECR I-2265, para. 99. Cf. also Joanne Scott, *Precautionary Principle before the European Courts*, (forthcoming).

tific data".<sup>47</sup> Still, the specific evidence resulting from the risk assessment which is accessible to national authorities should be based on "the most reliable scientific evidence available and the most recent results of international research". Such evidence, without precluding scientific uncertainty, must still allow national authorities to reach the reasonable conclusion that implementation of preventive measures is necessary to avoid the presence on the market of products which can be potentially risky to human health.<sup>48</sup> Thus, the Court generally reiterated the previous interpretations of the precautionary principle in the case-law.<sup>49</sup> That is to say, when the responsible institution – Community or Member State – needs to base its decision on the precautionary principle, a scientific risk assessment must first be carried out, and must be as complete as possible, account taken of the individual circumstances. Only then is the political risk management decision to follow.<sup>50</sup>

### C. Comment

Before advancing to a modest comment on the Court's findings, two key points should be summarized very briefly.

Firstly, with regard to novel foods produced from GMOs (for example, from the GM maize lines), the Court stated that the mere presence of residues of transgenic protein at certain levels did not exclude them from being considered substantially equivalent to traditional foods, on the condition that the existence of risk of potentially adverse effects to human health was not identified. In this sense, the Court accepted the broader interpretation of the concept of substantial equivalence, as suggested by the Advocate General in his opinion.<sup>51</sup> Consequently, such foods can be lawfully marketed in the Community under the simplified procedure laid down in the novel foods legislation.

Secondly, the Court acknowledged that the Member States do have powers to adopt measures derogating from Community harmonization in the field of novel foods by invoking the precautionary principle to protect public health. This principle has its specific expression in the form of the safeguard clause. However, Member States' protective measures are permitted only in so far as the outcome of the

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<sup>47</sup> *Id.*, para. 112; see also *Pfizer* para. 162.

<sup>48</sup> *Id.*, para. 113.

<sup>49</sup> See *supra*, note 45.

<sup>50</sup> Cf. also Segnana (note 1).

<sup>51</sup> *Monsanto* (note 2), AG Opinion, para. 56-57, 84-88.

risk assessment interpreted in the light of the precautionary principle evidently indicates that implementation of such measures is necessary to protect consumers from dangers of novel foods.<sup>52</sup>

To begin with, it is noticeably clear from the above depiction that in the present case – which is an exemplary illustration of an unavoidable dispute involving a collision between precaution and risk, on the one side, and the free movement of GM novel foods, on the other – that the Court recognized the significance of both aspects.

There are some strong arguments that show that the Court attaches much importance to the smooth functioning of the internal market for novel products, including those derived from modern biotechnology. Its manner of interpreting the concept of substantial equivalence, its willingness to countenance recourse to the simplified procedure, and then, the instruction that the mere identification of risk does not directly imply that foods are unsafe, demonstrate that the Court does not necessarily follow the restrictive opinion that the presence of GMO-derived products on the Community market is, as such, undesirable. The Court also did not find the concept of substantial equivalence to be invalid, which *nota bene* is in line with recent international developments.<sup>53</sup> The focal issue in the present case is therefore not whether novel foods produced from GMOs still contain transgenic residues, but whether they do or do not pose any risk. The Court's ruling appears to shift emphasis from the formal reading of the legalized scientific notions towards a more teleological interpretation, which accentuates the existence of real dangers for the population. The Court was probably aware of the fact that a very literal interpretation of the Regulation 258/97 could actually quite easily lead to the introduction and maintenance of unnecessary obstacles to the operation of the internal market. Perhaps such a literal interpretation was not the Court's intention. Otherwise, the Court might have rebutted the applicant's arguments by emphasizing that there were two possible methods for establishing substantial equivalence: according to the viewpoint of the national scientific body – as in the present case – or on the basis of available and generally recognized scientific evidence without the involvement of any scientific body prior to the entry of the novel foods in question onto the market. Since in this latter scenario only *post factum* control of safety is possible, the concentration of the analysis on this latter aspect could have led the Court to the

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<sup>52</sup> *Monsanto* (note 2), para. 114.

<sup>53</sup> *Id.*, para. 79; see also *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* adopted at the Twenty-Sixth Session of the Codex Alimentarius Commission, 30 June – 7 July 2003, available at <http://codexalimentarius.net>.

contention of the validity of the simplified procedure, in total or at least in part.<sup>54</sup> This would be the case if the Court had really been of the opinion that the second method was a substantial factor to be considered here. And if the Court had wanted to conclude that the GM-derived products at issue were not legally placed on the Community market.

Furthermore, the Court's ruling confirmed that the Member States are under a clear obligation to perform a scientific risk assessment prior to the introduction of any protective measures.<sup>55</sup> The Court laid emphasis on the approach to risk that the Member States should employ – it must not be purely hypothetical or based on suppositions which are not scientifically verified. The authority of this argument is enhanced by the fact that, shortly after the ruling in *Monsanto*, one of the Member States lost a case before the Court. Denmark's administrative practice prohibiting the free movement of certain foodstuffs was found to be unlawful because it was, *inter alia*, based on an inadequate approach to risk, that is to say, an approach which was too hypothetical.<sup>56</sup> The certain analogy of these two cases illustrates that in "risky products disputes" it is of no importance to the Court whether or not Community harmonisation is already in place. Protective measures, such as those in the Italian Decree, may be perceived to constitute a measure having equivalent effect to a quantitative restriction within the meaning of Art. 28 of the EC Treaty. The existence of Community harmonisation is relevant only in determining the legal base for the justification of such a measure; be it the relevant safeguard clause or Art. 30 of the EC Treaty. Still, it seems that both situations will be treated equally by the Court and that consideration of the arguments will take place within the framework of the internal market. Finally, the fact that the two-fold objective of the Regulation 258/97 was frequently highlighted also suggests a considerable degree of pro-market sentiment on the part of the Court.

On the other hand, however, the Court repeated the interpretation of the precautionary principle granting relatively broad discretion to governing institutions, which although settled in the case-law, has already been criticized for its vagueness and for the lack of legal certainty it provides for operators pursuing their commercial interest.<sup>57</sup> In the present case, the Court again gave a green light to the possibil-

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<sup>54</sup> Cf. Art. 3 (4), Regulation 258/97. This point was raised by Advocate General in his opinion, para. 86-87.

<sup>55</sup> Cf. the earlier findings of the Court of First Instance with regard to the Community institutions, *Pfizer*, para. 162. See also MacMaoláin (note 1), 726.

<sup>56</sup> *Danish nutrients* (note 39), where the *Monsanto* case is cited, para. 49, 56.

<sup>57</sup> Cf. MacMaoláin (note 1), 729.

ity of invoking the precautionary principle when the seriousness and reality of risk is not fully apparent. Albeit on certain conditions, the Court allowed those Member States imposing a temporary ban on novel food products with the aim of protecting human health to invoke this principle. In addition, the Court elaborated upon the application of the precautionary principle in the present context, instead of observing simply that this principle applies.<sup>58</sup> What is more, as Joanne Scott rightly observes, the Court stepped even further to declare, implicitly, that this principle could even impose on Member States positive obligations to act by observing that this principle must be an integral part of decision-making in the event that the safeguard clause is invoked. In addition, the same positive obligation seems to apply under the normal procedure, to the extent that the principle was declared to be relevant, even where not given specific embodiment.<sup>59</sup>

Having said that the precautionary principle continued to apply to protect human health, it should be mentioned that the Court seemed to be more conscious and more moderate about the extent of the discretion granted to the Member States institutions than the Court of First Instance was towards the Community institutions in its judgment.<sup>60</sup> The statement that public values, as human health should take precedence over economic considerations, included in many other judgments on the precautionary principle, does not appear in the present ruling.<sup>61</sup> In addition, the Court did not include in its findings any observation or explanation that the Member States while adopting preventing measures should analyse the level of risk which could or could not be acceptable for their consumers (as in those previous judgments).<sup>62</sup> Here, the Member States should only be able to conclude reasonably that such protective measures are necessary. The latter word, "necessary", may well suggest the application of the proportionality principle to such protective measures.<sup>63</sup> In the closely analogous situation, in the *Danish nutrients* case, the Court observed that "[s]uch measures must not be allowed unless they are non-discriminatory and objective".<sup>64</sup> Finally, according to the Court, the burden of proof

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<sup>58</sup> It did so in the *Greenpeace* ruling for what it was criticized as being too laconic, see Andrea Mastromatteo, *A lost opportunity for European Regulation of genetically modified organisms*, 25 *ELRev.* 2000, 425.

<sup>59</sup> Scott (note 45).

<sup>60</sup> Cf. MacMaoláin (note 1), 729.

<sup>61</sup> Cf. for example *Pfizer*, para. 456, 471.

<sup>62</sup> Cf. MacMaoláin (note 1), 727 and *Pfizer*, para. 150-153, 162.

<sup>63</sup> Cf. generally Grainne de Burca, *Proportionality and Subsidiarity as General Principles of Law*, in *The General principles of EC Law* (Ulf Bernitz, Joakim Nergelius eds. 2000).

<sup>64</sup> Cf. *Danish nutrients* (note 39), para. 53.

allowing for application of the safeguard clause requires that there is, at least, a specific risk to human health or environment. The Court also did not pay too much attention to the question of the novelty of the evidence demonstrating risk, concentrating rather upon the question of whether it serves to prove that risk. Again, it could have been a method for refuting the validity of the substantial equivalence concept for GM foods if the Court had so intended, because some new information relating to that concept had given rise to the adoption of a “new approach” in the EU policy on novel foods. That new approach finally resulted in the removal of this concept from the new Community legislation on GM food.<sup>65</sup>

To conclude, it can be said, that in this battle where considerations of risk and precaution rival those of the internal market, both sides may be thought to have won the day. In other words, the Court at least attempted to give a balanced ruling which weighs up the various competing interests. It did not exclude the possibility for Member States to invoke the precautionary principle. However, in view of its overall interpretation, neither did it leave much space for the adoption by Member States of arbitrary measures, such as those at issue in the current case. So the Court seems to have rendered a reasonable judgment in which both interests – the protection of human health and free movement – are given equal weight.

Perhaps the Court is seeking to exclude the possibility that those Member States supporting the *moratorium* on any GM products, will use the safeguard clause for purely political reasons.<sup>66</sup> If this is indeed the Court’s intention, this would send a clear message to politicians and to risk managers, emphasising that neither political reasons, nor arbitrary and capricious arguments are to be tolerated in the present context. In fact, it has already become a famous practice among Member States to utilize safeguard procedures for obtaining results which they could not achieve within the framework of the authorisation procedures established by Community legislation.<sup>67</sup> Interestingly as well, in the present preliminary ruling, the Court emphasized the role of national courts in deciding on the issue of whether a particular GMO-derived product is substantially equivalent to conventional food, but it did not pay much attention to the fact that a similar determination might be undertaken at the Community level via the comitology structure.<sup>68</sup> This even though the

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<sup>65</sup> See *supra* (note 5), *Monsanto* (note 2), para. 65–68.

<sup>66</sup> Cf. *EU split over controversial GMO authorisation*, EUobserver 8 December 2003, at: [www.euobserver.com](http://www.euobserver.com).

<sup>67</sup> Cf. *Vos* (note 35), 169.

<sup>68</sup> *Monsanto* (note 2), para. 71, 84, 99 and 126; Art.

importance of the latter possibility was stressed by the Advocate General.<sup>69</sup> Would this mean the will of increasing the significance of judicial review in case when political institutions are trapped in the impasse and stuck in the procedural blockage?<sup>70</sup> Perhaps the potential judicial vigour – implying a greater significance for a judicial review – might serve also to unlock the procedure impasse which has characterised comitology in respect of the GM debate.

Therefore, it is now the time for the Italian TAR to play its role and take a decision in this complicated case. The *de facto* outcome of the Court's ruling was that the action of the Italian government had not been justified. The TAR should not ignore this message from the Court.

One final comment should be made here. In the present case the Court followed a quite strict scientific discipline – even though it admitted that the current state of scientific knowledge might be inadequate – it still recalled science as a verification of risk, and scientific evidence as grounds for the management of risk.. However, what is vastly astonishing, is that the Court, whilst giving legal meaning to scientific notions did not specify what is meant by scientific experts or which the relevant scientific bodies might be. The Court's judgment is open to criticism in that it did not establish more clearly what is to be understood as the “most reliable scientific evidence available” or identify the relevant Community scientific institution(s), such as the European Food Safety Authority. Broader elaboration on the role of scientific expertise in the present context would be desirable. This is especially so in light of the fact that in the majority of disputes involving tension between human health and free movement, the main underlying problem seems to be a lack of trust in scientific expertise in general and as between various Member States in particular. Had the Court raised this issue, its ruling would be more complete and could have contributed more to the notion that consumers may be well protected even in an integrated, transnational, market.

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<sup>69</sup> *Monsanto* (note 2), AG Opinion, para. 135 and 150, cf. Art. 3 (4), Regulation 258/97.

<sup>70</sup> Cf. *EU postpones controversial GM decision*, EUobserver 10 November 2003, at: [www.euobserver.com](http://www.euobserver.com).