On the relationship between EC and national regulations concerning the GMOs: the Greek case

Giorgos Balias*

INTRODUCTORY REMARKS

According to the decision No. 243267/3-3-2005 of the Greek Deputy Minister of Agricultural Development and Food of Greece (Gov. Gazette B' 320/11-3-2005), as of the publication of the decision and for a two year period it is forbidden to trade in Greece seeds for the cultivation of 17 genetically modified MON 810 corn hybrids, which are included in the 13th Addendum (EC C230A/17.9.2004) of the 22nd Full Issue of the Common List of plant species varieties. On 7 April 2005 the Greek authorities notified the Commission of the above decision and requested that the said national measure be approved according to Article 8 of Directive 2002/53/EC.

The Commission issued on 10 January 2006 the decision 2006/10/EC (OJ 2006 L 7/27), according to which Greece is not allowed to ban the trade of corn hybrid seeds containing the genetic modification MON 810, registered in the common varieties list (article 1); the decision calls upon Greece to abide by the above decision twenty days after notification at the latest (article 2).

Following the above, the question is asked: What are the possibilities for Greece to react to the above decision and what can the legal basis and foundation of the above possibilities be.

EC legislation on Genetically Modified Organisms (GMOs) is complex and vague, thus allowing for a wide margin for interpretation of rules. Specifically, the complexity and vagueness stem from the fact that, in this specific issue, three legal orders are involved: national, EC and international (through the Cartagena Protocol, which the Community signed and which was concluded in the name of the Community by the decision 2002/628/EC of the Council[1]). Each of these three legal orders is empowered to intervene and contributes to the determination of the legality of the acts of the Community or national bodies. This arises both from the Community legislative texts themselves (e.g. Directive 2001/18/EC, Directive 2002/53/EC, Regulations 1829/2003/EC and 1830/2003/EC, etc) and from the Cartagena Protocol[2].

At the same time, Community case law, although quite instructive, has not as yet solved but a few issues, since the cases raised in EC courts have not been sufficient in order to lead us to the conclusion that it [EC case law] constitutes a standard for dealing with the problems related to the regulations on GMOs[3].

With that said, we can reasonably assess that there are serious possibilities that the reaction on the part of Greece against the above decision of the Commission will

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* Lawyer, Athens, Greece. The author is expressing his personal views, and by no means his clients' ones.

[1] OJ 2002 L 201/48.

[2] See article 14 (1) of the Protocol in conjunction with article 300 (7) of the Treaty of the European Communities.

[3] See mainly, ECJ, Judgment in Case C-514/99, *France v. Commission*, [2000], ECJ, Judgment in Case C-6/99 , *Greenpeace France v. ministère de l'agriculture et de la pêche*, [2000], ECJ, Judgment in Case C-1/00, *Commission v. France*, [2001], ECJ, Judgment in Case C-236/01 , *Monsanto Agricoltura Italia*, [2003], Court of First Instance, Judgment in Cases T-366/03 and T-235/04, *Austria v. Commission*, [2005]. Available at: http://curia.eu.int/jurisp

bear favourable results, provided however that: a) the appropriate procedure and line of argument will be followed, and b) it [the reaction] will rest on appropriate legal basis.

POSSIBLE REACTIONS ON THE PART OF GREECE

In this chapter we will discuss whether there are different possibilities for Greece's reaction, which of those can have the greatest chances of success and with what legal argumentation.

I. First: Greece maintains its prohibition and appeals to the Court of First Instance requesting: a) that Decision 2006/10/EC of the Commission of 10 January 2006 be annulled, and b) that the enforcement of the decision be suspended pending the court's judgement.

Based on current reality, this possibility has not chances of success, because it is highly probable that the appeal will be rejected on formal grounds (omission of essential form) as follows.

a) According to articles 16 and 18 of the Directive 2002/53/EC[4], a member state may submit a request to the Commission, requesting that it be recognized the right to prohibit the use of a genetically modified variety, in the whole or part of its territory, for reasons concerning the possible existence of risks for human health or the environment. If, moreover, there is imminent risk for human health or the environment, the state concerned may accompany the submission of the above request with the national measure prohibiting the variety or varieties under discussion. In our case, Greece did not submit such a request, but only proceeded to the prohibition. There is, therefore, the risk of rejection because the procedure provided for was not followed[5].

b) According to articles 16 and 18 of the Directive 2002/53/EC, as follows from the above (paragraph a), the only reason provided for imposing a prohibition of cultivation of one or more varieties, is the possibility that it or they harm, from a plant health perspective, the cultivation of other varieties or species, or that it or they bear risks for human health or the environment. In the ministerial decision No. 243267/3-3-2005 no such reason is mentioned and accordingly it is very probable that it [the appeal] will be rejected because of a complete lack of reasoning[6].

c) Matters are complicated even further by the fact that Greece, in the document accompanying the notification to the Commission (7 April 2005) of the measure of prohibition, states that the prohibition was imposed because of the possible negative effects, which the cultivation of the 17 genetically modified corn hybrids would cause to the environment, without presenting even minimum scientific evidence or information thereon. Later, on the 4 May 2005 Commission request that Greece provides clarifications regarding risks of harm to human health or the environment. Greece clarified (with the 12 May 2005 answering document) that the negative effects, caused on agricultural environment by the cultivation of the 17 genetically modified varieties, are of an economic nature and do not concern the environment in

[4] Council Directive 2002/53/EC of 13 June 2002, OJ 2002 L 193/1.
[5] For the requirements concerning the validity of acts of the European Community, as well as of the national authorities, see, Isaac, Droit Communautaire general, 8th ed., (Paris, 2001).
[6] Ibid.

general or human health. Because there arises a contradiction regarding Greece's line of argument concerning the need for prohibition, it is very probable that the appeal will be rejected on grounds of contradictory reasoning[7]. It should be noted that the clarification provided on the negative effects of an economic nature is not per se mistaken, as we will show later.

II. Second: Greece maintains its prohibition and awaits the Commission's initiation of the procedures for referring to the Court of First Instance. At the same time Greece must necessarily prepare a new dossier, containing both the scientific arguments and the legal foundation, and submit it to the Commission according to articles 16 and 18 of Directive 2002/53/EC.

In this case Greece has to proceed to the following steps: A) compile new scientific data, which will form the scientific documentation of the request's submission, and B) organize the legal of its request. Both steps should aim at a) supporting the request for the provision of consent by the Commission to the prohibition of the cultivation of the 17 genetically modified MON 810 corn varieties as per article 16 (2) of Directive 2002/53/EC and b) founding the notified national measure of prohibition as per article 18 of Directive 2002/53/EC. The latter will be a new Ministerial decision which, without bearing the mistakes and omissions of the previous one (as determined above), will be fully reasoned and with a clear and enhanced legal basis. Specifically:

A. Scientific documentation

The scientific documentation is of decisive importance because, in E.U. legislation and case law, the evaluation of risks to human health or the environment constitutes a necessary requirement for its management by E.U. bodies or national states[8]. We must, however, make clear that in the matter of GMOs (as well as in other relevant matters) the above evaluation cannot be full and conclusive, because of the scientific uncertainty resident and, consequently, the documentation is not primarily based on full scientific knowledge but also on scientific indications and information on possible risks of harm to human health or the environment[9]. Therefore, the scientific documentation we speak of consists of either proof or indications and information concerning dangerousness. [10]

The point of departure for the above scientific documentation is that the consent for marketing the genetically modified corn (Zea mays L. Series MON 810) was given with the decision 98/294/EC of the Commission, of 22 April 1998 (OJ 1998 L 131/32), according to the provisions of Directive 90/220/EEC of the Council. Apart from the legal issues (which we will mention in section B) arising from the implementation of Directive 90/220/EEC in relation to the latter legal regime that is in force, issues are also raised regarding the scientific evaluation undertaken in the past

[7] Ibid.
[8] See Communication from the Commission on the precautionary principle, COM (2000) 1, final, 2-2-2000.
[9] O. Todt, <<Regulating agricultural biotechnology under uncertainty>>, Safety Science, 2004, pp. 143-158.
[10] On this point, E.U. case law is clear. See indicatively, ECJ, Judgment in Case C-180/96, *U.K. v. Commission*, [1998], Court of First Instance, Judgment in Case T-13/99, *Pfizer v. Council*, [2002], Court of First Instance, Judgment in Case T-74/00 and others, *Artegodan v. Commission*, [2002]. Available at : http://curia.eu.int/jurisp

(in 1998) in comparison to the current situation, i.e. after about 8 years have passed. In particular, there are two new components, which must form the pillars of scientific documentation: i) the monitoring plan, and ii) new scientific data indicating risks to human health or the environment. Specifically:

i) The monitoring plan:

The monitoring plan, as accepted in 1998 under Directive 90/220/EEC, differs differs from that provided for in Directive 2001/18/EC[11]. In particular, for the approval of MON 810 (decision 98/294.EC of the Commission, of 22 April 1998) a monitoring plan was submitted that fulfils nearly none of the requirements as provided for by the current regulative framework. Consequently, the approved monitoring plan does not correspond to the protection level under the regime in force. Therefore, based on the above, it is necessary that the scientific documentation focuses on this particular fact and highlights the reasons that require the elaboration of a new monitoring plan, able to fulfil the requirements of current legislation.

ii) New scientific data

Since 1998 there have been many scientific studies indicating that there exist risks of harm to human health or the environment from the release of GMOs[12]. However, there are also studies showing that no such risk exists. What is important is that as many as possible and, if possible, peer reviewed studies of the first category must be presented, so that scientific uncertainty is shown, which is a necessary requirement for the application of the precautionary principle. The presentation of these views must support the basic position on possible risk in a way that shows logical coherence and reasoning. We should stress at this point that the scientific views of the first category must not be simply mentioned, but must be included in their published form in the dossier to be submitted.

As is obvious, this part of the dossier, because of its special characteristics, must be organised by experts (from within and without the administration) according to the rules of science, taking account of the relevant multidimensional features of GMOs.

B. Legal basis of the request and of the new national measure of prohibition

The legal basis of the request must be expanded and include all appropriate EC regulations. In other words, it should not only be limited to Directive 2002/53/EC. Before discussing these regulations it is necessary to note that these should be

[11] See articles 13 para. 2, 19 para. 3, 20 and Appendix VII of Directive 2001/18/EC, as well as Decision 2002/811/EC of the Council of 3 October 2002 on the designation of guidelines to complement Appendix VII of Directive 2001/18/EC, OJ 2002 L 280/27.

[12] See, indicatively, Contamination by genetically modified maize in Mexico much worse than feared, available in: www.etcgroup.org/documents/NR_Maize_10_03ENG3.pdf, *UK GM Science Review Panel*, An Open Review of the Science Relevant to GM Crops and Food Based on the Interests and Concerns of the Public (2003), First Report, available at www.gmsciencedebate.org.uk/report/pdf/gmsci-report1-pt1.pdf Among the more recent publications are: V. Prescott et al. (Journal of Agriculture and Food Chemistry, 2005, p. 9023), M. Malatesta, (European Journal of Histochemistry, 2005, p. 237) and T. Traavik, (European Food Research and Technology, 2006, p. 185.)

interpreted in the light of the precautionary principle, which is both explicitly mentioned in E.U. legislation on GMOs and, according to EC case law, it constitutes a general principle of EC law, i.e. a binding legal rule[13].

1. Directive 2002/53/EC

a) As we presented above (section Ia), according to articles 16 and 18 of the Directive 2002/53/EC, a member state may submit a request to the Commission, requesting that it be recognized the right to prohibit the use of a genetically modified variety, in the whole or part of its territory, for reasons concerning the possible existence of risks for human health or the environment. If, moreover, there is imminent risk for human health or the environment, the state concerned may accompany the submission of the above request with the national measure prohibiting the variety or varieties under discussion. From the text itself it arises that risks are mentioned, which do not require proof but "reasonable grounds of concern" or "if it is determined … that it is possible to harm …" (articles 16 para. 2c and 18). In view of the facts that i) the approved monitoring plan fulfils nearly none of the requirement as provided for under the current regulative framework[14], and ii) data are presented showing the existence of a risk to health or the environment, the precautionary principle should be applied and, accordingly, both the request and the national measure of prohibition have to be accepted[15].

b) According to article 16 para. 2b of the above Directive, a member state may proceed to prohibit the use of a variety in its territory if it establishes that "the variety does not produce, in any part of its territory, results that correspond to those achieved with another, comparable variety, accepted in the territory of said member state, or if it is known that the variety is not appropriate for cultivation in any part of its territory, due to its [the variety's] nature or to the ripening category which it belongs to." The above provision entails that the term "results" has an expanded content, which includes social and economic impacts from GMOs cultivation. This becomes more clear by the contradistinction in the text of the provision ("or the variety is not appropriate for cultivation in any part of its territory, due to its nature or to the ripening category which it belongs to.") Hence it arises that, because impact on health or the environment is at least uncertain as regards, mainly, the extent and type of harm, it is impossible to determine with accuracy the social and/or economic impact[16]. What could be accurately determined, however, is that, because Greece bears certain particular characteristics, namely that 16% of economically active population is employed in agriculture and that plots are small in area and, consequently, of high density, the social and/or economic impacts of any possible harm will be great and

[13] The most important decisions recognising the precautionary principle as a general principle of EC law are: Court of First Instance, Judgment in Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00 and T-141/00, *Artegodan GmbH et al. v. Commission*, [2002] ECR II-4945, para. 184, ECJ, Judgment in Case C-192/01, *Commission v. Denmark* [2003], paras. 49-52), ECJ, Judgment in Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del consiglio dei ministri* [2003], paras. 110-113 and 133. Available at : http://curia.eu.int/jurisp

[14] Cited above, note 11.

[15] "Well founded reasons" and non-fully-proved risks of harm, as requirements for applying the precautionary principle, are mentioned both by the Commission (see Communication from the Commission (cited above, note 8), and the EC judge (see indicatively the decisions cited above, notes 10 and 13.)

[16] O. Todt, <<Regulating agricultural biotechnology under uncertainty>>, cited above, note 9.

irreversible. Moreover, social upheaval that may be caused by the possible cross-pollination of genetically modified varieties with conventional or organic crops may be very great, since the local social fabric will be torn apart due to the disputes or legal battles[17]. This phenomenon will be very intense in Greece because of the two reasons we mentioned, i.e. the percentage of population employed in agriculture and the density of plots (small holdings). Besides, under the Cartagena Protocol decision making on the use of GMOs must also take account of socio-economic impact[18], whereas such impact is not clearly provided for in EC law on GMOs. Therefore, because this differentiation brings about a lower level of protection under E.U. law compared to the protection level of the Protocol, then, according to article 14(3) of the Protocol, EC legislation is not applied and the solution may be sought in the Protocol, but via EC law, since the Community is party to the Protocol, which it concluded by Decision of the Commission[19]. According to article 300(7) of the Treaty of the European Communities, since the Protocol has been incorporated in the EC legal order, it has a superior position in comparison to derivative law. So, to the extent that said provisions of the Protocol are more concrete and aim at higher protection, they supersede the corresponding EC provisions. The Protocol's provisions on the socio-economic impact of GMOs undoubtedly aim at a higher level of protection than that of EC regulations and, consequently, it is they that should be applied.

Because, based on the findings mentioned, the results produced by the cultivation of the MON 810 varieties do not correspond to those of comparable conventional ones, all the more so because they [the results] are probably worse, it follows that the requirements set out by the above Directive, in conjunction with article 14(3) of the Protocol, are fulfilled, and consequently both the request and the national measure of prohibition of the MON 810 varieties are lawful and well-founded as per articles 16 para. 2 and 18 of Directive 2002/53/EC.

2. Directive 2001/18/EC[20]

It is clear that, since Directive 2002/53/EC requires scientific data on the existence of a risk of harm to human health or the environment, in order to allow the prohibition requested, the consent granted (i.e. that of 1998) to marketing GMOs is automatically subject to re-evaluation. This means that, at the same time, the provisions of Directive 2001/18/EC are applied, which concern both the evaluation of new or additional information made available after the consent (article 23 of the Directive) and the monitoring plan (Appendix VII of the Directive)[21].

a) Article 23 of Directive 2001/18/EC

According to this provision, a member state may prohibit or temporarily restrict in its territory the use and/or sale of a certain GMO as or in products, if there is new

[17] For more details, see J. Matthews Glenn, "Footloose: Civil Liability for GMO Gene Wandering in Canada", Washburn Law Journal, 2004, p. 548. European Economic and Social Committee, Opinion on the Co-existence between genetically modified crops, and conventional and organic crops, NAT/244, Brussels, 24-11-2004.
[18] Article 26 of the Protocol.
[19] Cited above, note 1.
[20] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC-Commission Declaration, OJ 2001 L 106/1.
[21] The monitoring plan was discussed above (under 1 a).

or additional information after the date of consent, which indicate that this certain GMO poses a risk for human health or the environment[22]. In this case, from the scientific informations cited, new data arise regarding the dangerousness of the MON 810 varieties. It should be stressed that the scientific informations presented need not constitute scientific proof, since the provision does not mention "proof" but "new or additional information"; moreover, it is not required that the new scientific informations are in accordance with the prevalent scientific opinion on the issue. This approach is also followed by the European Court of Justice in its decision of 29-5-1997[23], according to which the concept of the state of scientific and technical knowledge includes *the most advanced level*. According to the interpretation given by the Advocate General G. Tesauro, this wording includes all views (including minority views) because, as he notes, "from the moment that there is in the scientific community even one solitary voice (which, as history of science teaches, can in time become the common view) arguing that there is a fault or risk from the use of a product, the producer cannot argue that the risk was unforeseeable…"[24].

It should be noted that, according to article 23 para. 1 of the Directive, it is not necessary to submit a request, but only a notification of the measure of prohibition to the Commission as well as the other member states. Moreover, according to article 23 para. 2, the Commission requests the opinion of one or more scientific committees. On this point we must underline that the Commission does not require identical views, neither does the opinion of EFSA supersede that of the corresponding national scientific committees.[25] In particular, when there is a divergence of views on an issue among the Community's scientific committees or among the scientific committees of a member state and those of the Community, *"they are obliged to cooperate in order to either resolve said divergence of views, or to submit a common document, where the disputed scientific issues are clarified and the relevant points of lack of clarity regarding data are identified"*[26].

Therefore, based on the findings already mentioned, the requirements are fulfilled for applying article 23 of the Directive. Besides, this is also supported by the European Court of Justice[27], stating that: *"Moreover, respect for the precautionary principle is expressed, on one hand, in the obligation of the notifier, provided for in article 11, paragraph 6, of directive 90/220, to promptly notify the competent authority as regards new data concerning the risks the product poses for human health or the environment, as well as in the obligation of the competent authority, provided for in article 12, paragraph 4, to immediately notify the Commission and the other member states thereupon, and, on the other hand, in the discretion each member state has, provided for in article 16 of this directive, to restrict or prohibit, temporarily, the use and/or sale in its territory of the product, for which assent has been granted and regarding which [the member state] has well-founded reasons to believe it poses a risk to human health or the environment"*.[28]

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[22] This provision is the same as article 95 (5) EC.

[23] ECJ, Judgment in Case C-300/95, Commission v. U.K., case C-300/95, [1997] ECR I-2670.

[24] Opinion of the Advocate General G. Tesauro of 23-1-1997, in Case C-300/95, Commission v. United Kingdom, [1997] ECR I-2659.

[25] Articles 28-30 of Regulation 178/02, which applies in this case.

[26] Article 30(4) of Regulation 178/02.

[27] ECJ, Judgment in Case C-6/99, *Association Greenpeace et al., v. Ministère de l'Agriculture et de la Pêche, et al.*), [2000] ECR I-1651.

[28] Ibid., Para. 44. We should note that article 16 of Directive 90/220/EEC mentioned in the judgment corresponds to article 23 of Directive 2001/18/EC.

Because all requirements provided for in the provisions of article 23 of Directive 2001/18/EC, otherwise article 16 of Directive 90/220/EEC, are fulfilled, Greece's decision to prohibit the cultivation of the MON 810 varieties concerned is lawful and well-founded.

b) Article 31 paras. 6 & 7 of Directive 2001/18/EC in conjunction with Recommendation 2003/556/EC

According to article 31 para. 6 of the Directive, in 2003 and thereafter every three years, the Commission submits a report to the European Parliament and the Council concerning the experience of member states regarding the marketing of GMOs. Furthermore, according to para. 7 of the same article, the Commission concurrently, in 2003, also submits a special report concerning the implementation of the Directive (parts B and C) and evaluates, *inter alia*, the consequences of its implementation, taking into account the variety of European ecosystems and the socio-economic consequences from the deliberate release and marketing of GMOs. However, the Commission violated its obligations, since it did not take the steps provided for in the above provisions. This means that the Directive is inadequately implemented by the Commission, and, accordingly, the required level of protection and security for human health or the environment is not provided. Regarding this issue, the European Court of Justice in one of its judgments (of 13 December 2001)[29] stresses that, in the extent that EC regulations do not provide full protection or cannot be implemented[30], member states may proceed to enshrine national measures. Consequently, in this case, the national measure of prohibition is lawful because the as per above inadequate implementation of the Directive on the part of the Commission does not provide the protection required.

Furthermore, although there was no evaluation of socio-economic impact, according to the above, the Commission did issue Recommendation 2003/556/EC[31], that sets out the guidelines for co-existence of genetically modified, conventional and organic crops. In this Recommendation, the Commission notes that the commingling of crops with GMOs and crops without GMOs may have economic impact on producers[32]. These impacts include the reduction of selling price, the additional expenses for establishing monitoring systems and the cost of the measures for limiting mingling[33]. Member states are called upon to take measures for preventing mingling, such as designating isolation distances and interposition zones, creating oversight systems and records as well as designing training programmes and measures for resolving disputes[34]. They are also called upon to introduce civil liability rules covering damages from the mingling of crops, if existing rules are not sufficient[35]. Moreover, it is stipulated that the management measures will be applied on the level of a certain agricultural plot[36]. Based on the above, it follows that the

[29] ECJ, Judgment in Case C-1/00, *Commission v. France*, [2001] ECR I-9989.
[30] Ibid., paras. 115 and 124 respectively.
[31] Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, OJ 2003 L 081/32.
[32] Ibid., Preamble, point 5.
[33] Ibid., Para. 1.1.
[34] Ibid., Paras. 3.2-3.9.
[35] Ibid., Para. 2.1.9.
[36] Ibid., Para. 2.1.5.

Recommendation assigns member states discretion to regulate all issues concerning the co-existence of crops, only setting general specifications[37].

Due to the lack of evaluation reports on the part of the Commission regarding comprehensive socio-economic impacts from the marketing of GMOs it is not sufficient to apply management measures only to the level of a certain agricultural plot. Therefore, the infringement of article 31 paras. 6 & 7 of Directive 2001/18/EC, in conjunction with article 14(3) of the Cartagena Protocol (as presented above under 1.a) by the Commission, make the national measure of prohibition lawful and well-founded.

3. Regulation 1829/2003/EC[38]

In a first approach, it seems that the above Regulation does not apply, since the Commission's consent (1998) was granted before the provisions of said Regulation came into force. However, this conclusion is hasty, because it must be taken into account that many regulations have since been introduced in EC law, regarding GMOs, in order to ensure a high level of protection according to article 174 of the Treaty of the European Communities. It is therefore imperative, in view of the aim of protecting the environment or human health, that the Commission should re-evaluate risks emanating from this specific product (MON 810) in the context of EC provisions, i.e. that it also takes into account newer legislation, at least as a guide.

For instance, article 40 of Regulation 1829/2003/EC, amending Directive 2002/53/EC, provides that if the material derived from a genetically modified variety is intended for use in food or feed, the variety is only acceptable if it has been approved in accordance with the above Regulation. Because Regulation 1829/2003/EC sets out more strict requirements for granting approval and in view of the fact that it is imperative to ensure a high level of protection, during re-evaluation, the provisions of the above Regulation must be also taken into account. Specifically: a) According to articles 4 and 16 of the Regulation, the party requesting approval must prove that the GMOs to be approved do not have adverse impact, *inter alia*, on human health, animal health or the environment. As a matter of act, a reversal of the burden of proof is instituted, which was not provided for in Directive 90/220/EEC and Regulation 258/97/EC. The consent granted in 1998 does not take into account the high level of protection required by article 174 of the Treaty of the European Communities and implemented through the newer provisions of Regulation 1829/2003/EC. b) According to the Preamble of the above Regulation[39], scientific evaluation does not constitute a sufficient basis for managing the risk and "other legitimate factors must also be taken into account…" These factors are not mentioned but may be identified by reference to Regulation 178/2002/EC. In the Preamble of this Regulation[40], are indicatively mentioned the social, economic, traditional, ethical and environmental factors. However, the consent granted in 1998 does not take into account these factors.

[37] G. Balias, << Seeds of Distrust: The Coexistence of Genetically Modified and Conventional or Organic Crops in Greece>>, European Environmental Law Review, 2005, p. 318 et seq.
[38] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ 2003 L 268/1.
[39] Ibid., Point 32.
[40] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and the requirements of food law, establishing the European Safety Food Authority and laying down procedures in matters of food safety, OJ 2002 L 031/1 (point 19).

Whereas the consent granted does not take into account the above (under a and b) data, the request and notification of the national measure of prohibition are submitted legally.

4. The Precautionary Principle

As we already mentioned, the precautionary principle constitutes a general principle of EC law[41], while also being a fundamental principle permeating E.U. provisions on GMOs[42]. The issue raised is whether a member state, based on the precautionary principle, may make a decision relating both to risk assessment and risk management in a different way than that of the EC bodies. From theory and, mainly, from case law it follows that this is possible. Specifically, the European Court of Justice in its recent decision of 5 February 2004[43] stresses that *"it is clear that the evaluation of risk may show that there continues to exist scientific uncertainty concerning the existence or extent of real risks. In this case it must be accepted that a member state may, according to the precautionary principle, take protective measures without waiting for the existence and severity of the risks to be proved"*[44].
In another case[45] (in which there was a harmonization of member states legislations), the court noted that *"the applicant member state may, in order to justify maintaining such diverging national provisions, invoke the fact that it appraises risk for public health in a manner different than what the EC legislator did with the harmonization measure. In view of the inherent uncertainty as to the appraisal of the risks that, particularly the use of food additives, hold for public health, it is legitimate that diverging appraisals of said risks may exist, without necessarily being based on different or new scientific data"*.[46] The above note is doubly interesting: First, the possibility for different appraisal of the risk by member states and the Commission is explicitly recognized, which means that a member state may seek by national provisions to ensure a higher level of protection of public health than the EC harmonization measure.[47] Second, the diverging appraisals do not concern, necessarily, different or new scientific data, but may arise from a differing evalyation of the same data[48]. Even when competent scientists use identical data, they might reasonably and without mistake interpret the data somewhat differently. For this reason the judges need understand the origins of scientific disagreements so that they do not exclude the divergent opinions which are within the boundaries of reasonable scientific inferences[49]. It is therefore obvious that a member state may unilaterally

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[41] Cited above, note 13.
[42] See, e.g. article 1 and point 8 of the Preamble of Directive 2001/18/EC, points 20 and 21 of the Preamble of Regulation 178/2002/EC and article 1 of Regulation 1829/2003/EC (where general principles are referred to).
[43] ECJ, Judgment in Case C-24/00, *Commission v. France* [2004]. Available at http://curia.eu.int/jurisp
[44] Ibid., para. 56.
[45] ECJ, Judgment in Case C-3/00, *Denmark v. Commission*. [2003]. Available at http://curia.eu.int/jurisp
[46] Ibid., Para. 63.
[47] Ibid., Para. 64.
[48] For mor details, see Jasanoff, *Designs on Nature. Science and Democracy in Europe and the United Sates*, (Princeton-Oxford 2005).
[49] Cranor, <<Scientific Inferences in the Laboratory and the Law>>, American Journal of Public Health, 2005, pp. S121-S128 mainly, S124.

invoke the precautionary principle as a shield for the protection of the environment or human health without necessarily presenting new scientific data in relation to those current when the harmonization measure was instituted.[50]

Furthermore, as regards risk assessment, it would be advisable to proceed to some clarifications. The Commission, in its Communication on the precautionary principle in February 2000[51], stresses that, when instituting protection measures, the public's interest for maximum possible safety must be taken into account.[52] This means that the Commission accepts that the risk does not only have measurable scientific data, but also includes subjective data. The same view seems to be held by the EC judge, who notes that the risk is a function of the appraisal of adverse impact on health "and the more or less concrete perception of the risk in relation to the knowledge available".[53] Similarly, the U.S. National Research Council notes that, during characterization of the risk, both the impact on health and the environment, as well as social, economic, ecological and moral parameters must be taken in to account[54]. The same approach, in general terms, is followed by the Codex Alimentarius, where it is stressed that when appraising risks "the available quantitative information must be used in the largest possible extent {and similarly} the qualitative information must also be taken into account".[55] The same approach in a rather reasonable and illustrative manner is also adopted by the Appellate Body of the W.T.O.[56], which notes that: "It is important to take into account that the risk under evaluation in an appraisal of risk evaluation according to article 5.1 is not only the risk that may be ascertained in the scientist's laboratory under strictly controlled conditions, but also the risk as it really exists in human societies, in other words, the real possibility of adverse impact on human health in the real world, where people live, work and die."[57] Therefore, the co-existence of quantitative and qualitative data leads us to adopt the concept of acceptable risk, which may take the form of zero tolerance[58]. In EC law, acceptable risk is identified with the high level of protection of the environment, public health and consumers, the achievement of which constitutes a legal obligation for the EC (articles 2, 95(3), 152(1), 153 and 174(2) of the Treaty of

[50] In the above Judgment of the court (C-24/00, *Commission v. France*) it is stressed that a member state may prohibit in its territory products in lawful circulation in the Community, making use of article 30 EC (paras. 53-54 of the judgment) under the requirement that it has performed an evaluation of the risk, from which it has arisen that there is a risk from this specific product for public health (para. 55 of the judgment). It therefore follows that a member state may apply the precautionary principle and take measures as per article 30 EC and outside the framework of community harmonization (article 95 EC) as long as it proves scientific uncertainty.

[51] Cited above note 8.

[52] Ibid. para. 5.

[53] Court of First Instance in Case *Pfizer v. Council*, para 153, as cited above note 10.

[54] National Research Council, Understanding Risk. Informing Decisions in a Democratic Society, Washington D.C., National Academy Press, 1996, p. 3.

[55] Codex Alimentarius Commission, "Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius", par. 20, in: Report of the Eighteenth Session of the Codex Committee on General Principles, Paris, 7-11/4/2003, ALINORM 03/33A, APPENDIX IV.

[56] W.T.O., Report of the Appellate Body, Measures Concerning Meat and Meat Products (Hormones), 16-1-1998, WT/DS26/AB/R & WT/DS48/AB/R.

[57] Ibid., paras. 187 and 194.

[58] The zero risk does not exist. Nevertheless, the demand for zero risk might be interpreted as zero tolerance. See The Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, 2001, p. 210. Available at http://www.rsc.ca

the European Communities)[59] and ensuring which, in conditions of scientific uncertainty, is achieved by applying the precautionary principle[60].

CONCLUSIONS

Because, in this case, the requirements for applying the precautionary principle, as delineated by EC case law, are fulfilled, Greece may lawfully submit the request and notification and similarly proceed to institute the national measure of prohibition. Besides, since the Commission has "in the case of delicate and controversial cases, a sufficiently broad discretion and enough time…"[61], a member state may have the same, as long as the above requirements exist, as is true in this specific case according to what has been presented.

[59] The EC judge directly links acceptable risk to ensuring a high level of protection of health. See Court of First Instance (*Pfizer v. Council*) para. 152, as cited above note 10.

[60] For more details about the role of the precautionary principle in EC regulations concerning the GMOs, see T. Christophorou, <<The regulation of genetically modified organisms in the European Union: the interplay of science, law and politics>>, CML Review, 2004, p. 637-709.

[61] ECJ, Judgment in Case C-352/98, *Laboratoires pharmaceutiques Bergaderm SA*, [2000]. ECR, I-5291