The division of powers between the EU and the Member States with regard to deliberate release of GMOs (the new Directive 2001/18)

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I. Introduction

[1] The first directives regulating the use and trade of genetically modified organisms (GMOs) were adopted at the Community level in 1990.(1) These acts formed a core of the Community gene technology legal regime and harmonised the authorisation procedures prior to both contained use and deliberate release of genetically modified organisms. Accordingly, no GMO may be placed on the European Union market without obtaining a written consent for it and only after an appropriate environmental risk assessment has been carried out. Under the old Deliberate Release Directive 90/220, 18 GM products were allowed to be placed on the Community market following either the Commission decisions or Member States consent (2) and over 1000 were notified to the Member States authorities for experimental purposes. (3)

[2] The genetically modified organism (GMO) means "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination". (4) GMOs, received through genetic engineering, may be used as food (e.g. GM soybean, maize, or tomatoes), feeds, seeds, forestry materials or pharmaceuticals. (5)

[3] The progress and development of modern biotechnology sector, including genetic engineering, has been accelerating over the last years. (6) It offers a lot of novel opportunities for health care, agriculture or food production. (7) On the other hand, however, the potential implications of genetically modified products for society at large and the environment cause fears among consumers and impose new challenges and responsibilities on the regulators. (8) This is mainly linked to unknown risks for the environment and the humans which might spring from new technologies. Hence, the argument goes, the trade of GM products needs to be strictly controlled, in accordance with a precautionary principle claiming that when scientific evidence is inconclusive, preventive action should be taken before the dangerous and irreversible consequences occur, *i.e.* without waiting for - more - certainty. (9)

[4] In response to the growing safety concerns (10) and the need of adjusting the authorisation procedures (including the risk assessment and risk management) to rapidly changing environmental and market conditions the new Directive 2001/18 was adopted and it will enter into force on the 17th October 2002. (11) The revised rules on the deliberate release of GMOs intend to set up a more effective and transparent system of authorisations and ensure a better level of protection for human health and the environment. (12) Actually, no new GMO has been approved on the EU market since 1998 due to the opposition and political declaration of five Member States which called for suspension of authorisations until the revised legislation is passed. (13) However, after the adoption of the new Directive 2001/18 there is still *de facto* moratorium on the approval of new GM products on the EU market. (14) In 2001, these Member States confirmed the reluctance towards further GMO authorizations until the complete labelling and traceability Community provisions are also in force. (15)

[5] Facing the controversies over GMOs, that is the problem of *de facto* moratorium on the one hand and the impasse in the European regulatory process on the other, it is important to analyse the division of powers between the EU and the Member States with regard to deliberate release of GMOs. This paper examines the division and exercise of these powers under the new regime introduced by the Directive 2001/18. The matter is of great concern as the Member States still use political means in trying to evade the legal consequences under the new EU regime despite the harmonisation of the authorisation procedures for GMOs. One of the questions then arising is whether or not more decisive power should be given to the Member States. Another asks whether they will have more powers within the legal framework under the new Deliberate Release Directive? What are the changes in comparison to the old Deliberate Release Directive? Who really decides on deliberate releases of GMOs into the environment?

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[6] Usually, the discussion on the division of powers between the EU and the Member States focuses on legislative powers. (16) However, a decision on deliberate release of GMOs to the environment is administrative in nature and that is why the division of executive powers will also be dealt with here. Both the competent national authorities and the EU institutions take part in the process. The first part of the paper concentrates on the power to create law and the extent of the Community legislative competence. The second one analyses how is this law applied, namely, who has the power to allow the placing of a GMO on the market. The next explores the possibility for Member States to differentiate from the Community provisions and shows how they can legally restrict the deliberate release of GMOs. The last one makes an attempt to draw the conclusions.

II. The Community's Legislative Power Revisited

[7] An exploration of the problem of the division of powers between the EU and the Member States will have to start with an analysis of the legislative competence to create relevant legal provisions concerning deliberate release of GMOs to the environment. According to the principle of attribution of powers (Art. 5 of the EC Treaty) the existence and scope of Community competence is limited to the powers conferred upon it. Where the Community possesses law-making power it is normally defined in a separate Article and it will constitute a legal basis for action in the area in question. (17) There is, however, no provision of the Treaty attributing the competence to the Community in the field of genetic engineering so the power to adopt measures like the directives on deliberate release must be assessed concerning the aim of these acts.

[8] The release of genetically modified products can affect the integrity and safety of the environment. Yet, the very protection and preservation of the environment is one of the fundamental objectives of Community policy and law. (18) It is questionable, whether harmonisation of provisions on GMOs which are to further this aim can be based on Article 175 (1) EC, because GM products are, at the same time, subject to trade and thereby closely linked to the functioning of the internal market. Therefore, the legal basis could also be Art. 95 EC. As a matter of fact, both Directives on deliberate release (90/220 and 2001/18) have been based on Article 95 EC. The Community exercised its legislative competence by issuing the harmonising directives on the environmental matters provided for within the framework of the internal market. This might be in some contrast to the Directive's own wording: Art. 1 of the ‘new' Directive (2001/18) sets as the objective the approximation of the laws, regulations and administrative provisions of the Member States and *the protection of human health and the environment while carrying both non-commercial and commercial deliberate release of GMOs*. Now, the old dispute sets off about whether or not Art. 95 was a proper legal basis in the case before us.(19)

[9] In the course of the following, some arguments will be presented whereafter the new Directive mainly aims at environmental protection and should therefore have been based on Art. 175. This choice is of significance because it determines whether the Member States' right to legislate despite the harmonisation attempts will be governed either by Art. 176 or Art. 95 paras. 4-5. (20) The question is, in other words, whether the opportunity for Member States to differentiate from the approximated Community provisions will be in the form of a minimum harmonisation technique (relating to environmental policy, Art. 176) or of a specific "opt-out" clause (with respect to internal market measures under Art. 95). (21) This difference excludes the possibility of a dual legal basis for the new Directive even if we were to claim that Community policies linked to environmental protection and the internal market were equally essential and when after the Treaty amendments the legislative procedure for both Articles is now the same, *i.e.* Art. 251 EC. (22)

[10] According to the European Court of Justice, the aim and content of a measure shall be the factors determining the legal basis of an act. (23) Furthermore, the decisive factor should be the main object of a measure. (24)

[11] Like the ‘old' Directive, the new one is process-oriented (25) and provides for a horizontal regulatory framework in the EU gene technology law. (26) It means, that the new Directive sets general safety rules and conditions to be followed while carrying deliberate release of any product being a GMO. Any further sectoral Community legislation must lay down all the safety and environmental risk assessment provisions at least equivalent to those of the new Directive. (27)

[12] As mentioned above, the objective of the new Directive is to harmonise laws of the Member States and to protect human health and the environment when carrying deliberate release of GMOs (Article 1) . (28) Thus, already first recitals of the Preamble declare the importance of the protection of the environment; and there are many others related to human health or environmental protection (risk and environmental assessment) or to the rights of the public concerning deliberate release and traceability of GMOs. (29) All this suggests that the aim and main object of the new Directive is to protect human health and the environment in the first place. Moreover, the economic optimism attached to the use of biotechnology is no longer included as it appears in the Preamble to the old Directive 90/220. (30) The explanatory memorandum for the new Directive also does not emphasise the necessity for further

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Community – wide regulation because of the internal market. (31) It is striking, how little the Preamble to the new Directive says about proper functioning of internal market while it is extensively describing goals of the environmental protection. The new Preamble also states that precautionary principle must be taken into account when implementing this Directive and this principle is primarily inherent exactly in the EC environmental policy (Art. 174 para. 2). (32)

[13] What is more, the content of the whole measure also aims primarily at the protection of human health and the environment. The new Directive develops the provisions on the national – Community authorisation procedures for GMOs to make them more reliable and extends the requirements for environmental risk assessment; imposes the obligation on the national competent authorities to monitor GMOs following their placing on the market; introduces the procedure in case of new risk of the GMOs and the scientific (obligatory) and ethical consultations within the procedures. (33) All these Articles serve the safety of the humans and the environment. Furthermore, only commercial releases of GMOs affect the operating of the internal market (they may be used and sold) when GMOs released for experimental purposes are not available to third parties. This makes part (B) of the new Directive exclusively environmental protection measure. (34)

[14] On the other hand, some arguments may be raised in favour of the opinion that the Directive harmonises rules to provide for the proper functioning of the internal market.

[15] First, the Directive is adopted as a continuum of the approximation achieved by the old Directive 90/220 which aimed *inter alia* at removal of unequal conditions of competition and barriers to trade between Member States. (35) Thus, the pre-harmonisation situation might have created obstacles to free movement and led to distorted competition. Those were the economic reasons underlying the adoption of the old Directive and the establishment of a one harmonised authorisation procedure. It provides that once a GM product was authorised on the market it may circulate freely within the whole Community. But nowadays, when safety of GMOs and gene technology causes much more concerns the situation might have changed. The new Directive introduces a new provision that authorisation of GMO is issued for a fixed time up to ten years and after this period it may be renewed through the renewal of consent procedure, (36) but the further positive outcome cannot be taken for granted. Moreover, the Directive states explicitly that forum shopping is allowed (37) what can cause not truly equal conditions for competition. It means, that the rejection of a GMO by one national authority is without prejudice to any future decision about this GMO by another competent authority. (38) One may easily imagine that competent authorities in some states will be more eager to take favourable opinions on GMOs even though the authorisation procedure may have the Community centralised level. The distortion of competition may also occur because of the different national administrative provisions and the possibility of ethical consultations which are not harmonised under the new Directive. Within the procedure Member States may consult any committee they have established to obtain advice on the ethical implications of biotechnology. (39) In theory, it is possible that some states will take the opportunity to impede authorisation processes by establishing five different ethical instances. All these somehow restrictive solutions do not really smooth functioning of the internal market.

[16] Still, the second argument which needs to be considered, is that the new Directive harmonises labelling and packaging rules for GMOs placed on the Community market. It moves the act towards being an internal market measure if the Dashwood test is applied. (40) Yet, the purpose of the harmonised detailed labelling rules for GMOs in the new Directive seems to be, again, the protection of consumers rather than the removal of obstacles hindering trade. (41) In the end, the "internal market" arguments do not appear entirely convincing.

[17] Nevertheless, some authors stand in favour of Art. 95 EC as the legal basis for all product-related measures which ensure the environmental protection (like in their view the new GMOs Directive). They claim that this Article should prevail e.g. over Art. 175 EC as it is believed to lead to a greater degree of integration. (42)

[18] The question arises only whether there is a desire in Member States for greater integration with respect to GMOs when taking into account their varying views on the safety of GMOs and their potential risks. (43) It is not easy to state unequivocally which legal base should indeed prevail.

[19] The answer needs to be sought in the case law of the ECJ. The case Titanium Dioxide indicates that for the new Directive 2001/18 Art. 95 constitutes a proper legal basis. (44) The Court was then satisfied that a Directive harmonising rules for the disposal of waste could be regarded as an internal market measure and did not refer directly to the theory that when there are two objectives of a directive, the principal should prevail. (45) On the other hand, it held in the later case that a Directive establishing rules for waste disposal had only incidental effect on the market and shall be treated as environmental measure. Hence, the Court applied the centre of gravity approach. (46) The situation is even more blurred after the ECJ's *Biotech* decision. (47) The consequence of this judgement is, on one hand, that any act approximating rules between Member States to prevent even future obstacles to trade may be properly based on art. 95 (like the new Directive). (48) On the other hand, the Court still says that the legal basis for an act should be determined according to its main object (essential purpose). Yet, defining the main object of a

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directive and determining if the harmonisation has an incidental or a direct impact on the functioning of the internal market is necessarily subjective process. (49)

[20] There is, however, last but not least argument in favour of the assessment that the main object of the Directive is the protection of the environment. In the recent opinion 2/00 on the Cartagena Protocol on Biosafety (50) the Court considered the similar issue with regard to the external Community competence. (51) After the analysis of the content and aim of the Protocol the Court came to the conclusion that it is

"an instrument intended essentially to improve biosafety and not to promote, facilitate and govern trade. … the broad interpretation of the concept of common commercial policy under the Court's case law are not such as to call into question the finding that the Protocol is an instrument falling principally within environmental policy, even if the preventive measures are liable to affect trade relating to LMOs". (52)

[21] Since the harmonisation achieved at Community level in the form of all GMOs Directives cover a part of the Protocol's field (53) it would be advisable to adopt the new GMO Directive also within environmental policy framework for the sake of coherency in EU law. If the Court considers the Protocol to be the environmental protection measure, it is arguable that the new Directive 2001/18 primarily aims at the environmental protection when regulating almost the same matters, namely control of release and trade of GMOs. Thus, it is mainly fulfilling the objectives of the Community environmental policy and not having as its object and effect the improvement of the conditions for the establishment and functioning of the internal market.

[22] Consequently, the result of such an analysis should be statement that Art. 95 EC was not a proper legal basis, even though, admittedly, the adoption of Directive 2001/18 on the basis of Art. 175 EC would mean a complete reformulating of the Community GMOs' regime and would necessarily lead to a lesser degree of integration. (54) It would make possible the introduction and maintainance of more stringent environmental protective measures after simply notifying the Commission on the ground of Art. 176 EC. Therefore, it would place the Member States in a much more powerful position with regard to deliberate release of GMOs. (55) Maybe it would satisfy the needs of these Member States which are not convinced about safety of GMOs, provide for greater flexibility and the possibility of protecting their environmental interests not necessarily by using purely political instruments, e.g. declaring the moratorium for any GMO approval on the EU market.

[23] At this point, we are in a position to see a sort of paradox unfolding: the Member States (through the Council) have not contested in any way the legal basis for the act in question. (56) This implies that, generally speaking, the Member States are in favour of a well functioning trade of GMOs and the maintenance of the new Deliberate Release Directive within the framework of the Community's internal market legislature. Moreover, they seem to accept the Community powers in the field, especially with the whole procedure's possible future centralisation and the current unifying legislative developments in mind. (57) All of this might be seen, however, as being slightly inconsistent with their political blocking of GMOs authorisations and their turning to other available measures (e.g. safeguard clauses) to impede the free circulation of GM products within the whole Community market. How can this be explained?

III. Power to allow deliberate release of GMOs

[24] The decision which allows a concrete GM product to be placed on the Community market is the outcome of an authorisation procedure often involving the national competent authorities as well as Commission and Council. (58) Hence, both the EU and Member States powers are represented within the decision–making process. In the following sections, we shall explore how these powers are exercised in the framework of the new Directive 2001/18.

[25] As regards the national ‘stage', the following can be observed. With regard to both commercial and non-commercial releases of GMOs into the environment the decision-making process reflected in the authorisation procedure starts at a national stage. (59) Art. 6 and 13 of the new Directive require that any planned release must be first notified to the Member State's competent authority where it is to take place. For example, in England it will be the Department of the Environment, Transport and the Regions or the Ministry of Agriculture, Fisheries and Food, in France the Ministry of Environment or Agriculture, Fisheries and Food. (60) At this stage the Member States through competent authorities fully exercise the power of assessment concerning risks which the release of GMO entails for human health or the environment. (61) It is their role to examine if all information provided in an applicant's notification is compatible with the requirements of the new Directive.

For non-commercial releases, the Member State that has received a request for authorisation is left to take whatever decision it deems appropriate, (62) either positive or negative. The decision–making process ends here.

[26] In the case of placing GMOs on the market the procedure varies substantially, this being due to greater safety concerns. The authorisation process may take place on both the national as well as on the EU level. The Community

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role is therefore much more extensive. (63) The comitology regulatory procedure applies and the Commission exercises implementing administrative powers in close cooperation with Member States (64) (although it is generally the obligation and right for the latter to implement directives) (65) . After the competent authority carries out an initial environmental risk assessment concerning GMOs it issues an assessment report which is circulated among all Member States. Again deciding an outcome of the report is a matter for the Member State competent authority, but the other Member States authorities may raise objections. Therefore, even a favourable opinion in the report will trigger the EU procedure if it is followed by the reasoned objections from one or more Member States as to the placing on the market of a GMO. (66) So far, out of eighteen GMOs authorised on the Community market there were a mere three cases where Member States' authorities did not raise certain objections. (67)

[27] The so-called mediation stage is entered when there are controversies over placing the particular GMO on the market, and the competent authorities from all Member States and the Commission may „discuss any outstanding issues with the aim of arriving at an agreement within 105 days from the date of circulation of the assessment report" . (68) This phase takes place before the comitology procedure starts. This is a novel mediation provision in comparison to the old Directive 90/220 to provide for a forum where informal discussions may take place in the hope for consensus between States. It is hard to assess at this point whether such solution will be efficient and help to resolve GMOs' disputes which anyway cannot be resolved in the regulatory committees and the Council during the whole procedure. (69) If there are no objections from other Member States and/or the Commission or in the case they have been, the mediation resolves problematic issues, the competent authority which first prepared the positive assessment report decides that a GMO may be placed on the market. On the other hand, where the Member State competent authority maintains its original negative position, the application is rejected and a GMO is not placed on the market. In both cases the decision–making process ends here. (70) In such event, the competent authority of a Member State that carried out the initial assessment has decisive power at this point and it is ultimate in this Member State. Still, the new Directive allows the applicant to further apply for later authorisation in other States (when it is rejected by the first competent authority). And the next application is not conditional upon e.g. new scientific evidence that the product is safe due to changed circumstances.

[28] Finally, the EU stage. When Member States raise reasoned objections and do not reach agreement through mediation the inter–institutional regulatory committee procedure starts. (71) The Commission submits a proposal for a decision authorising or not authorising a GMO on the market to the so-called regulatory (standing) committee that is composed of Member States representatives and chaired by a representative of the Commission. (72) The content and outcome of the proposal is based on the opinion of the Scientific Committee which must be consulted. (73) The general observation is that the Commission follows the scientific committee's opinion almost "blindly", thereby granting it enormous influence on the Community's decision making. (74)

[29] The Standing Committee delivers its opinion within the time-limit determined by the chair and the approval must be issued by qualified majority of the Member States. When the Member States agree by qualified majority on the favourable proposal the decision authorising a GMO may be adopted. However, it has already happened that the Commission has withdrawn its draft measure from the Committee before voting occurred in the aim of avoiding a negative outcome. Such has been the case under the impression of the impossibility of a political agreement concerning the placing on the market of a GMO. (75) When there is no consensus towards authorising a GMO at this stage of procedure the Member States may politically influence the Commission even though there is no legal provision providing for withdrawal.

[30] If the opinion of the Standing Committee differs from the Commission proposal or no qualified majority of countries opts for any solution and no opinion is delivered, the Commission must submit a proposal to the Council. It shall decide on a measure by qualified majority within three months. (76) If within that period the Council indicates by a qualified majority opposition of the proposal, the Commission must re-examine the proposal. It may then submit the amended proposal to the Council or re-submit the original draft proposal for the second time. (77)

[31] This provision increases the decision-making power of disagreeing Member States in comparison to the old regime where unanimity was needed to oppose Commission proposals. (78) This led to the situation that the Commission was seen to authorise GMOs against the will of almost all Member States. There was at least one such case of genetically modified maize which, after notification by Novartis, sought authorisation but found France to be its single supporter in the Council. (79) When the Council, after three months, had neither adopted the proposal nor opposed it, it was adopted by the Commission.

[32] The Commission's decision is legally binding on the Member State to which it is addressed. (80) The competent authority in this State is under obligation to issue its written consent for placing GMO on the market to circulate freely if the Commission decision has been positive. (81)

[33] Under the new regime, the ultimate authority of the Commission, when the Council does not act, remains intact.

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Now however, the qualified majority voting provision (as opposed to unanimity voting) would make it possible to reject the authorisation of GMOs on the market giving more decisive power to the Member States. It is even said that the new procedure provides for greater protection of citizens' preferences, at least to the extent that these may be translated into votes in the Council. (82) On the other hand, the Member States generally opposed to GMOs do not possess a qualified majority voting power (provided they express uniform position), while they will usually have enough votes to block a qualified majority decision supported by other States. (83) It is therefore still likely to happen that the Council will not reach the agreement by required majority and the Commission will decide exercising the function of dispute-resolving administrative organ. (84) Unless it refrains from any action, not eager to act clearly against political will of the Member States. Like the present situation, when 14 notifications for approval of GMO have been pending for years without any final decision. (85)

[34] Furthermore, the new Directive states that a decision reached through the comitology process shall be adopted and published within 120 days. (86) It is envisaged to remedy the current situation of "never–ending" authorisations and limit the Member States' political impediments of the authorisation processes. Under the new Directive the Commission is obliged to take the decision within the time-limit although it does not mean that the decision must be positive. Failing to do so, it places itself in clearly illegal situation of failure to act.

[35] Although in formal terms the Commission is empowered to make the final choice with regard to the deliberate release of a concrete GM product within the framework of the authorisation procedure, it is often so strongly influenced by the Member States' political pressure that it does not fulfil its tasks. This causes serious impasses in the regulatory process.

[36] Accordingly, the next part of the paper will consider if Member States might employ any lawful means in order to protect their interests and differentiate from the Community provisions and EU level decisions.

IV. May the Member States still lawfully act?

[37] The harmonisation achieved at the Community level in form of Directives on contained use and deliberate release of GMOs (87) covers but a small part of a biosafety field. (88) Yet, through the adoption of the Directives the Community legislation pre-empted national provisions which now would have to be harmonised in line with secondary law. Instead, the Member States are obliged to transpose the measures into national legal orders. (89)

[38] The new Directive aims at total, complete harmonisation (90) and optimally Member States shall not maintain or enact any provisions making it ineffective. The Community measure sets the standards for all GMOs and after meeting the requirements of the authorisation process they may circulate freely in all Member States. (91) This is confirmed by Art. 22 of the Directive which provides that without prejudice to the safeguard clause contained in the Directive

„Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive".

[39] In case of conflict such legislation of a Member State would be subject to the supremacy and direct effect doctrine and the Community law should then prevail. (92) Any Member States' legislation attempting to introduce a general prohibition of GMOs or to anyhow hinder their trade will, in principle, be incompatible with Community law.

[40] However, Member States competence to deal with deliberate release does not end once and for all with the adoption of the new Directive. First, the national competence is superseded by the Community act only to the extent covered by the Directive, for example it does not cover ethical issues. (93) Therefore, in this particular area Member States preserve their competences. Second, both the Treaty and the new Directive provides for the opportunity to derogate from the Community provisions notwithstanding the harmonisation. Since, the new Directive is based on Art. 95 the future Member States' freedom to opt out from the Community measure is governed by the Art. 95 paras. 4 and 5. (94) Moreover, the new Directive includes a safeguard clause in Art. 23 which may also allow for differentiation.

[41] We shall now explore the possibility for differentiation under Art. 95 EC. An extensive analysis of the specific conditions and their interpretation under Art. 95 would, however, exceed the scope of this paper. (95) Therefore, it is enough to state, that under Article 95 para. 4, Member States may *maintain* differing national legislation *after* the adoption of a harmonisation measure, when they deem it necessary on grounds of major needs referred to in Art. 30, or relating to the protection of the environment or the working environment. Under Art. 95 para. 5 Member States are empowered to *introduce* differing national provisions, but the conditions are more detailed. The necessity of national legislation must be based on *new scientific evidence* relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of a harmonisation

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measure. Both provisions provide for the authority of the Commission to approve or reject the national provisions.

[42] So far, there has not been a case of applying Art. 95 in the field of deliberate releases of GMOs. Yet, during the Council of Environment meeting held in June 1999, the Austrian, Belgian, Finnish, German, Netherlands, Spanish and Swedish delegations took a note of possibility for Member States to introduce national measures in conformity with the new provisions of Art. 95 paras. 5 to 7. They did so

"being aware of the increasing public concern about the potential risk to health and environment linked to the release of GMOs". (96)

[43] It is hard to foresee a possible decision of the Commission and, likewise, the thrust of Art. 95 in this context. Approval to the national *Sonderweg* has to be given if the national legislative act does not constitute arbitrary discrimination or erect obstacles to free movements within the internal market (Art. 95 para. 6). The outcome may be difficult as banning GMOs by one or more Member States can always hinder trade, so the Commission will again have to weigh the protection of environment and public health grounds against the proper functioning of the internal market. (97) At the same time, Member States' powers to derogate from the provisions of the new Directive are restricted by the condition of new scientific evidence. In the context of other Art. 95 cases also related to the safety of human health and the environment, the Commission attached high importance to the scientific evidence presented by the national authorities. (98) This may cause hardship as it is already known that there is no agreement between the Commission and some Member States concerning the scientific evidences with regard to GM products. (99)

[44] On the other hand, Art. 95 para. 5 may be a proper legal instrument for the situation when indeed new scientific evidence appears and a Member State introduces some specific provisions to apply and enforce it. This may improve the general Community safety rules, because of the requirement from Art. 95 para. 7 EC which says that the Commission, if it authorises a derogating measure, shall immediately examine whether to propose adaptation of that measure. (100) When a Member State enacts such legislation this may provide necessary impetus for the Commission to exercise its tertiary-rule making (101) . The provisions may concern e.g. labelling of GMO or any matter specified in the Annexes to the Directive e.g. techniques regarded as genetic modification and not only direct prohibition of use or sale of GMOs. The Member States' derogation can become a proper incentive for adaptation of the new Directive to technical progress in the realm of better protection of the environment. (102)

[45] For instance, the new Directive lays down the obligation to include on a label the information that a product contains GMO. In theory, it is possible that new research proves it necessary to change the requirement for a label containing the information to a label with an explicit warning that product contains a GMO. This leads us to the question concerning the conditions for invoking safeguard clauses.

[46] As mentioned above, in addition to the opportunities provided in Art 95 Member States may restrict deliberate release of GMOs by applying directly the provisions of the new Directive.

[47] With regard to non-commercial release of GMOs the suspension or termination of a release resides in the power of competent authorities in the individual Member State. They may decide whether or not there is unintended change in the release or whether new information has become available whereafter a GMO may cause risk on human health or environment. (103)

[48] If Member States wish to restrict or prohibit the use and/or sale of GMOs on their territories with respect to GMOs that have been placed on the market they must invoke the safeguard clause. (104) As Ellen Vos rightly observes, Member States use such provisions to achieve the results which they were not able to obtain within the Community legislation. According to the ECJ it is generally an appropriate measure to adopt after or even before the final consent approving GMO was issued. (106)

[49] Under Art. 16 of the old Directive, eight safeguard measures have been invoked by the Member States. (107) According to the legal conditions, a Member State wishing to restrict trade of GMOs had to prove „justifiable reasons to consider that GMO constitutes a risk to human health or the environment". (108) It has been pointed out, that what constitutes a "justifiable reason" is not entirely clear nor whether it includes a simple suspicion of danger posed by a GMO in the absence of unequivocal scientific proof or in case of conflicting scientific opinions. (109)

[50] For example, Austria has invoked the Art. 16 safeguard clause to prohibit the GM maize (Bt-176 maize). It was a high-profile political case, as the resistance to placing the GMO with antibiotic resistant markers (as b-t) on the market has been backed by popular actions gathering more than one million signatures against such product. (110) However, according to the Scientific Committee opinion Austria based its prohibition of Bt-maize on „unoriginal" information, which was well-known before the consent was given. Therefore the Commission took the view that due to the lack of any new evidence the Austrian prohibition was not justifiable. (111) Since, the legality of a safeguard

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clause is decided, again, via the regulatory committee procedure, the Commission submitted the proposal for committee decision asking for withdrawal of the national ban. Certainly, Member States in the regulatory GMO committee have not reached any agreement and apparently the final decision on the matter has not been yet taken. (112) The Austrian government has been still prohibiting the marketing of this GMO, and so have done Germany and Luxembourg. (113)

[51] The unresolved disputes between the Commission and the Member States with regard to the justifiable reason and conflicting scientific evidence show, first, that the legal provisions are not precise, second, that the Member State are again able to politically influence the Commission. And that such influence is so far strong enough to achieve the satisfying results. Even though, it is claimed that all the safeguard measures, up to date, constitute violation of Member States obligations under the present biotechnology regime. (114)

[52] The safeguard clause in the new Directive (Art. 23) is expected to remedy the situation. Hence, recourse to Art. 23 should be provisional, temporary and conditional upon certain material requirements:

a) „new" or „additional" information available (since the date of consent)
b) which affects the environmental risk assessment or requires reassessment of existing information; and which arises
c) on the basis of „new" or „additional" scientific knowledge
d) as a result of this new information a Member State has detailed grounds for considering that GMO constitutes a risk to human health or environment;

and procedural requirements:

a) Member State inform the Commission and the other States of action taken
b) Member State give reasons for its decision and indicate how consent shall be amended or terminated.

[53] In comparison to the old Directive these conditions are much more precise and scientific knowledge is "officially" integrated into the whole decision-making process. (115) New conditions demand the evidence which is based on *new scientific knowledge* and there must be a link to risk-assessment which is affected by this new knowledge. The safeguard clause has been tightened. Now, in clear legal terms it restricts the Member States' power to ban GMOs whenever they call it "justifiable" even without direct relation to the scientific findings. (116) Such detailed conditions are not directly imposed under old regime.

[54] According to the procedure, somewhat like before, the final acceptance of invoking of safeguard clause is taken at the Community level again through comitology procedure („a decision shall be taken on the matter within 60 days" (117)). In case of an absent QM consensus between Member States regarding the measure, the Commission decides on its approval. Although the political controversies still exist the conditions for invoking safeguard clauses are more precise now and therefore more restrictive. This has made it easier for the Commission to take legal action against the Member State (under Art. 226 EC) which introduces or maintains an illegal ban of a GMO. (118) This formally places the Member States in a weaker position with regard to unjustifiable introduction of measures based on purely political concerns. Action by the Commission may be more frequent and better-founded, especially, when concerning present practice of the Member States.

[55] Is the governing norm Art. 95 EC or safeguard clause? In order to answer this question it must be noted that Member States may still lawfully act in the field of deliberate release of GMOs. Moreover, the conditions for *introducing* national legislation aiming e.g. at the prohibition of GMOs after harmonisation has taken place are similar both on the basis of Art. 95 para. 5 or with regard to the safeguard clause in the new Directive.

[56] Decisively, under both procedures a measure must be based on *new scientific evidence*. Yet, in the former, it is the Commission which decides on approval. In the latter, the approval is issued through the comitology procedure where each Member State has an opportunity to expound its views and express its reservations in the committee appointed to assist the Commission and then, possibly, in the Council. (119) This procedure gives part of the decision-making power to the Member States. Applying the safeguard clause can, in the end, be preferable for Member States simply because they may attempt to enforce their views.

V. Conclusions

[57] In this concluding section, we shall summarize our findings in contrasting them with some alternative routes or provocations. The answer to the question who really possesses most of the powers concerning GMOs could well be: "the consumer". This, at least, seems to be the opinion of interest groups and lobbyists which give particular concern to the protection of the environment, the safeguard of public health and a secured safety of food, all of which is likely

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to influence politicians in the Member States. (120) Accordingly, governments behave and act "in public" as if they were neither ready nor willing to transfer too much power regarding GMOs to the EU. The mission to maintain a high level of consumer protection might then be equated with a rally for safeguarding national sovereignty. This is, certainly, in stark contrast to the level of integration which has already been achieved.

[58] Respectively, Member States agreed to adopt the new Directive 2001/18 on deliberate release as an internal market measure, even though, as was argued above, it is mainly an environmental protection act. (121) This allows the Commission to claim this field to mainly fall within exclusive Community competence (112) And introducing or maintaining differentiating, national provisions may only be achieved by Member States under the specific conditions provided by Art. 95 EC instead of minimum harmonisation technique from Art 176 EC.

[59] Still, the general resistance and opposition of European citizens towards GMOs is an important factor to be taken into account. In consequence, it may be proposed, that the regulators consider it more carefully and seriously when establishing the division of powers between the EU and the Member States with regard to deliberate release and use of GMOs. So the consumers' voices will not only influence the political declarations and actions (e.g. the GMOs moratorium), but could be expressed in legal terms as well.

[60] The system of division of powers between the EU and the Member States under the new Directive 2001/18 continues to be very complex as it involves various levels and surfaces of analysis and a lot of different bodies where the powers reside and are being exercised. Thus, it is hard to give an unequivocal answer to all the questions we have raised. Certainly, Member States received more decision–making powers through the new provisions on the comitology procedure (rejection of the Commission's proposals by the qualified majority). In this respect, all the issues to be decided via comitology procedures may be better influenced by Member States' interests. (123)

[61] On the other hand, there are some new restrictions of the Member States' powers in the GMOs area such as precise conditions for invoking safeguard clauses, the obligation to follow scientific evidence at all stages of the procedure, or strict, procedural time-limits for various actions. Additionally, it is the Commission which possesses ultimate authority for GMO authorisations, even against political positions of Member States, which often may not have been expressed in a formal vote, because of the failure to reach consensus. The same is applicable to all matters where the comitology procedure is envisaged and the Commission may finally decide. Plus, the Commission has decisive power under Art. 95 EC to approve or reject Member States derogating national provisions.

[62] This means that in procedural and formal legal terms the Commission, acting on the behalf of the EU, has relatively a lot of powers vis-à-vis Member States, even if, of course, it can always be subject to judicial review by the ECJ.

[63] But on the other hand, again, in reality the Member States influence outcomes of legal decisions and various behaviours of the Commission by using their political power. They can successfully do so either in the regulatory committees or in the Council. Both the present moratorium and disagreement concerning the safeguard clauses are clear examples of it as they are not based directly on legal provisions.

[64] Thus, what can be the final conclusion? It may be to express the hope that, ideally, the EU institutions and the Member States work on ensuring a well-functioning, coherent and far integrated European legal framework regarding deliberate release of GMOs. If only possible, both sides shall take into consideration the consumers' preferences, and at the same time, obey the legal rules and conditions they themselves have created. Otherwise, the conclusion would have to be that inspite of which legal provisions apply, the Member States would prefer to impose their current political will and that changing political opinions may effectively prevail over the binding law. Such conclusion should especially be avoided in view of the establishment and the proper functioning of the new European Food Authority. This seems particularly important when one thinks about the possibility of a complete centralisation of GMOs authorisation procedure (as oreseen in the Preamble to the new Directive) which can lead to further limitation of the Member States powers in this field.

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(1) Council Directive 219/90/EEC on the contained use of genetically modified micro-organisms (hereinafter the Contained Use Directive) OJ 1990 L117/1 as amended by Directive 98/81/EC [1998] OJ L330/13; Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (hereinafter the old Directive) OJ 1990 L117/15. The old Directive 90/220 will be repealed by Directive 2001/18/EC on 17 October 2002.(hereinafter the new Directive), OJ 2001 L106/1, 17 April 2001.

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(2) The last approval dates from 20 October 1998; see Annex 1, MEMO/01/277 Revised, .*Questions and Answers on the regulation of GMOs in the EU*., Brussels, 29.10.2001; http://www.europa.eu.int/comm/dgs/health_consumer/library/press/press208-en.pdf.

(3) Cf. Explanatory Memorandum for the proposal for a Council Directive 2001/18, COM (1998), 85 final, 2. Deliberate release include commercial releases (placing on the market) and non-commercial (experimental) releases. With regard to the situation under the Contained Use Directive see Report from the Commission, .*Based on the reports of Member States concerning their experiences with Directive 90/219/EEC on the contained use of genetically modified micro-organisms, for the period 1996-1999*., COM (2001) 263 final.

(4) See Art. 2 of the new Directive, cf. as well the glossary included in the Communication from the Commission, *Towards the strategic vision of life sciences and biotechnology: consultation document*, COM (2001) 454 final, 29ff.

(5) MEMO/01/277 Revised, *supra* n. 2, 4; see further the European Commission website on GMO Research at http://europa.eu.int/comm/research/quality-of-life/gmo.html.

(6) Cf., Communication from the Commission, *Towards…, supra* n. 4, 3, 7; Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions, *Life sciences and biotechnology – A Strategy for Europe*, COM (2002) 27 final, 3-5ff; S. Francescon, *The New Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment: Changes and Perspectives*, RECIEL 10 (3) 2001, 309.

(7) European Parliament resolution on the Future of Biotechnology Industry, OJ C 343/292, 5 December 2001, 293.

(8) Cf. Communication from the Commission, *Towards…, supra* n. 4, 17ff; Communication from the Commission…, *Life sciences…, supra* n. 6, 11, 16, 31; European Parliament resolution…, *supra* n. 7, 295ff.

(9) Cf. N. McNelis, *EU Communication on the Precautionary Principle*, Journal of International Economic Law, 2000, 545; M. Matthee, D. Vermersch, *The International Integration of European Precautionary Measures on Biosafety*, European Environmental Law Review, June 2001, 183ff.

(10) Especially, GM foodstuffs cause extended public debates, therefore, the food safety , including GM products, was made one of the priorities during the Belgian Presidency in the EU, the European Commission press releases, 2 July 2001.

(11) Explanatory Memorandum for the proposal for a Council Directive 2001/18, *supra* n. 3, 3ff; cf. S. Francescon, *supra* n. 6, 310ff; M. Matthee, D. Vermersch, *supra* n. 9, 192; D. Lawrence, J. Kennedy and E. Hattan, New controls on the deliberate release of GMOs, European Environmental Law Review, February 2002, 51-52.

(12) Cf. MEMO/01/277 Revised, *supra* n. 2, 4.

(13) Namely Denmark, France, Greece, Italy and Luxembourg (later joined by Austria); cf. Draft Minutes of the 2194 Council meeting (Environment) held in Luxembourg on 24 and 25 June 1999, 9433/1/99 REV 1, annex III, 14; cf. J. Kioussi, The evolution of the EU regulatory system for GMOs, Proceedings of 6th International Symposium on the Biosafety of GMOs, University of Saskatchewan, 2000, 3, http://www.ag.usask.ca/isbr/Symposium.

(14) B. Sheridan, EU Biotechnology Law and Practice, Palladian Law Publishing Ltd, 2001, 2, 81, 87; cf. AG Opinion, case C-377/98, The Netherlands v European Parliament and Council, ECR [2001] I-07079 , par. 106.

(15) Statement 12/01, Monthly summary of Council Acts, February 2001, 7191/01, 5; cf. S. Francescon, *supra* n. 6, 310 – 311; M. Mann, Biotech groups despair at EU attitudes, Financial Times, 10 November 2001.

(16) G. de Burca and B. de Witte, The Delimitation of Powers between the EU and the Member States, in: A. Arnull and D. Wincott (eds), Legitimacy and Accountability in the European Union after Nice, Oxford University Press, forthcoming, 2002, 5.

(17) A. Dashwood, The Limits of European Community Powers, 21 ELRev. 1996, 116.

(18) Cf. L. Krämer EC Environmental Law, 4th edition, Sweet & Maxwell, 2000, 74; Art. 2, 3 (l),6 and title XIX EC ensure the importance of environmental protection within the Treaty framework.

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(19) Cf. e.g. D. Geradin, Trade and Environmental Protection: Community Harmonization and National Environmental Standards, 13 YBEL 1993, 161; C. von Kameke, Gemeinschaftliches Gentechnikrecht: Die Freisetzungsrichtlinie 90/220/EWG, Duncker & Humblot, 1995, 30-32; see as well in the slightly different context T.K. Hervey, Community and National Competence in Health after Tobacco Advertising, 38 CMLRev. 2001, 1421.

(20) Cf. AG Opinion, case C-6/99, Association Greenpeace France and Others v Ministere d l'Agriculture et de la Peche and Others, ECR French edition [2000] I-1651, par. 67, this case was decided under the old Directive 90/220, but the citations remain applicable.

(21) Cf. E. Vos, Differentiation, Harmonisation and Governance, in: B. de Witte, D. Hanf, E. Vos (eds), The many faces of differentiation in EU law, Intersentia, 2001, 146-147.

(22) Cf. joined cases C-164/97 and C-165/97, European Parliament v. Council, [1993] ECR I-939, par. 14.

(23) Cf. e.g. joined cases C-164/97 and C-165/97, European Parliament v. Council, *supra* n. 22, par. 12, case C-155/91 Commission v. Council [1993] ECR I-939, par. 7; case C-42/97 Parliament v. Council [1999] ECR I-0869, par.36.

(24) Cf. case C-377/98, The Netherlands v European Parliament and Council, [2001] ECR I-07079, par. 27, quoting the case C-155/91, Commission v. Council, *supra* n. 23, pars 19-21.

(25) It means giving the priority of production method (all products resulting from genetic modification must be subject to authorisation) rather than to the characteristics of the final product. It confirms precaution with regard to genetic engineering, M. Matthee, D. Vermersch, *supra* n. 9, 185.

(26) Explanatory Memorandum for the new Directive 2001/18, *supra* n. 3, 3. The current Community legislation on GMOs consists of general (horizontal) measures, Directive 2001/18 on deliberate release into environment of GMOs repealing Directive 90/220 and Directive 90/219 on contained use of GMOs, *supra* n. 1; and specific (product-related) acts, inter alia, Regulation 258/97 concerning novel foods and novel food ingredients OJ 1997 L 43/1; Regulation 2309/93/EEC laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use OJ 1993 L 214/1; cf. T.K. Hervey, Regulation of Genetically Modified Products in a Multi – Level System of Governance: Science or Citizens?, RECIEL 10 (3) 2001, 321; I.- I.-J. Sand, The legal regulation of the environment and new technologies - in view of changing relations between law, politics and science. The case of applied genetic technology, 22 Zeitschrift für Rechtsoziologie (2001), Heft 2 , 16; S. Francescon, *supra* , n. 6, 309.

(27) Cf. Art. 12 of the new Directive.

(28) Cf. D. Lawrence, J. Kennedy and E. Hattan, "The new Directive, the main aim of which is to harmonise bio – safety measures across the EU and to clarify and tighten the regime…", *supra* n. 11, 51.

(29) Cf. recitals 4, 5, 6, 8, 10, 11,18-25 of the Preamble to the new Directive 2001/18 (first three recitals refer to the amendment of the old Directive 90/220).

(30) Cf. recital 4 of the Preamble to the old Directive 90/220, *supra* n. 1; J. Sand, *supra* n. 30 , 15.

(31) Cf. Explanatory Memorandum for the proposal for a Council Directive 2001/18, *supra* n. 3; when Explanatory Memorandum for the proposal for a Council Directive 90/220 on the deliberate release to the environment of genetically modified organisms to the contrary, COM (1988), 160 final, 2.

(32) Recital 8; Cf. also Opinion 2/00 of the Court of 6th December 2001, not yet reported, par. 29; see however AG Opinion, case C-6/99, *supra* , par. 70, saying "no one dares to suggest… that it [the precautionary principle] may be disregarded in cases where Art. 95 provides legal basis".

(33) Cf. Art. 13-14, 20, 28-29 of the new Directive; cf. D. Lawrence, J. Kennedy and E. Hattan, *supra* n. 11, 51.

(34) Cf. B. Iwañska, Podstawy prawne dzia³ania Wspólnoty Europejskiej w prawie techniki genetycznej [Community competence to act in the law of genetic engineering], in S. Biernat (ed.), Studia z Prawa Unii Europejskiej [Studies on EU Law], Kraków, 2000, 537.

(35) Recital 4 of the Preamble to the Directive 90/220, *supra* n. 1; as to the disparities between Member States' legislation before adopting this act cf. Explanatory Memorandum for the Directive 90/220, *supra* n. 31, 3.

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(36) Art. 15.4. and 17 of the new Directive.

(37) B. Sheridan, *supra* n. 14, 34. The possibility is expressed in recitals 36, 38 of the Preamble but, interestingly, not stated in the text of the new Directive

(38) The first national part of the authorisation procedure takes place in the Member State where a GMO is to be first placed on the market. The producer of a GMO has the obligation of the relevant notification, cf. Art. 13 of the new Directive.

(39) Recitals 57-58 of the Preamble, Art. 29 of the new Directive.

(40) Cf. Art. 21 and annex IV of the new Directive; A. Dashwood, *supra* n. 17, 121.

(41) Due to the safety concerns the governments of the Member States make ending their opposition for approvals of GMOs conditional upon, *inter alia*, establishment of the detailed labelling rules, M. Mann, *supra* n. 15.

(42) L. Krämer, *supra* n. 18, 56, 59; I.-J. Sand, *supra* n. 30, 11.

(43) Cf. the problem of moratorium, *supra* n. 14, 15.

(44) Case C-300/89, *Commission v. Council* [1991] ECR 2867; J. Scott, *EC Environmental Law*, London and New York, 1998, 8.

(45) A. Dashwood, *supra* n. 17, 121; L. Krämer, *supra* n. 18, 58. However, J. Scott calls Titanium Dioxide case temporary aberration in the legal basis debate, *supra* n. 44, 9. Cf. as well P. Craig and G. de Burca, *EU Law. Text, Cases and Materials*, 2nd Ed., Oxford University Press, 1998, 1120.

(46) J. Scott, *supra* n. 44, 9; case C-155/91 *Commission v Council, supra n. 22; joined cases C-164/97 and C-165/97, European Parliament v. Council, supra n. 22, par.15.*

(47) See hereto M. MacLaren, Patently Unsatisfactory:? Community Legislative Competence and the ECJ Biotech Decision, 2 German L. J. No. 18 (1 December 2001), http://www.germanlawjournal.com, search Biotech, or directly at: http://www.germanlawjournal.com/past_issues.php?id=114.

(48) Case C-377/98 The Netherlands v European Parliament and Council, supra n. 24, par. 15, 20, 27 - 28; in view of such reasoning to my opinion it can always be argued that approximation of legislation is essential purpose of a directive.

(49) Cf. A. Dashwood, supra n. 17, 121.

(50) Cf. Opinion 2/00 of the Court of the 6th December 2001 on the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, not yet reported, The Protocol was adopted on the 29th January 2000 and signed on behalf of the European Community and the Member States on the 24th May 2000. The Protocol regulates transboundary movement of GMOs and ensures an adequate level of protection in the field of safe transfer, handling and use of GMOs that may have adverse effects on the environment, taking into account risks to human health. See further, e.g. B. Eggers and R. Mackenzie, The Cartagena Protocol on Biosafety, Journal of International Economic Law, 2000, 525 – 527ff; V. Koester, Cartagena Protocol, A new Hot Spot in the Trade-Environment Conflict, Environmental Policy and Law, 31/2 (2001), 82.

(51) The Court considered the question of the legal basis for the conclusion of the Protocol on behalf of the Community. The Commission proposed Art. 133 (Common Commercial Policy) and 174(4) EC in conjunction with the first subparagraph of Article 300(2) claiming that the Protocol essentially falls within the field of regulation of international trade; the Council adopted the decision concluding the Protocol on the basis of Art. 175(1) and 300(2) as the environmental protection measure. Further see, Ch. Pitschas, EuGH: Zuständigkeit zum Abschluss des Protokolls von Cartagena, EuZW, Heft 4/2002, 113.

(52) Cf. par. 34, 37 – 40 of the Opinion 2/00, supra n. 50; LMO is the international law notion for GMO.

(53) Cf. supra n. 1; cf. par. 46 of the Opinion 2/00, supra n. 50.

(54) Cf. also J. Scott, supra n. 44, 40.

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(55) To lawfully differentiate from the Community provisions under the present system Member States have to use either a procedure of Art. 95.4–8 or the safeguard clause from the new Directive, cf. section IV.

(56) Cf. Legislative Observatory of the European Parliament, Stages in the procedure, the new Directive 2001/18; http://wwwdb.europarl.eu.int/oeil/oeil_ViewDNL.Procedure.

(57) Cf. the centralisation envisaged in the Art. 12 of the new Directive and the Proposal for a European Parliament and Council Regulation on Genetically Modified Food and Feed, COM (2001) 425 final.

(58) Through the regulatory comitology procedure, cf. Art. 18 in conjunction with 30 of the new Directive. On the basis of Article 202 EC the Council issued decision laying down the procedures for the exercise of implementing powers conferred on the Commission (1999/468/EC), OJ 1999 L184/23.

(59) See as well, S. Francescon, supra n. 6, 311ff; T. K. Hervey, supra n. 26; M. Matthee, Greenpeace v. France, Case 6/99, (Genetically Modified Maize Case), RECIEL 9 (2) 2000, 192.

(60) H. Ross, D. Tenant, Definitive guide for GMOs, Suffolk, 2000, 12; case C-6/99, Association Greenpeace France and Others v Ministere d l'Agriculture et de la Peche and Others, ECR French edition [2000] I-1651, par. 14; T. K. Hervey, supra n. 26, 328; A. Mastromatteo, A lost opportunity for European Regulation of genetically modified organisms, 25 ELRev. 2000, 425.

(61) Case C-6/99, supra n. 60, par. 39-42; cf. T. K. Hervey, supra n. 26, 325.

(62) Opinion of AG Mischo in the case C-6/99, supra n. 20, par. 48.

(63) Ibid., par. 49.

(64) Cf. case C-6/99, supra n. 60, par. 33.

(65) J.P. Jacque, Implementing powers and Comitology, in C. Joerges and E. Vos (eds) EU Committiees: Social Regulation, Law and Politics, 1999, 59-61; G. Winter, On the Effectiveness of the EC Administration: the Case of Environmental Protection, 33 CMLRev. 1996 , 689.

(66) Cf. S. Francescon, supra n. 6, 312; M. Matthee, supra n. 59, 193.

(67) Cf. annex 1, MEMO/43/00/EC, "Facts on GMOs in the EU" , 13.07.00; http://www.europa.eu.int/comm/dgs/health_consumer/library/press/press63-en.pdf. However, Matthee states there have always been objections, supra n. 59, 193.

(68) Cf. Art. 15, 18 of the new Directive, B. Sheridan, supra n. 14, 47.

(69) Cf. below, section IV.

(70) Cf. S. Francescon, supra n. 6, 312; B. Sheridan, supra n. 14, 46–48; A. Mastromatteo, supra n. 60, 428–429.

(71) Cf. S. Francescon, supra n. 6, 312 - 313.

(72) Art. 30 of the new Directive, Art. 5, 7 of the Decision 1999/468/EC, supra n. 58. With regard to committees cf. E. Vos, supra n. 21, 170ff; E. Vos, EU Committees: the Evolution of Unforeseen Institutional Actors in European Product Regulation, in: Ch. Joerges and E. Vos (eds), supra n. 65, 24.

(73) Art. 28 of the new Directive; cf. scientific opinions on GMOs available at: http://www.europa.eu.int/comm/food/fs/sc/scp/outcome_gmo_en.html. E.g. Scientific Committee on Plants (SCP) issues opinions on GM plants, Scientific Committee on Food – opinions on GM food. Very soon, all the responsibilities of the different scientific committees relating to GMOs will be taken over by the Panel on genetically modified organisms established within the European Food Authority, cf. Art. 22.5 and 28.4 (d) of the Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Authority and laying down procedures in matters of food safety, OJ 2002 L31/1.

(74) E. Vos, supra n. 21, 174.

(75) B. Sheridan, supra n. 14, 60.

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(76) Ibidem, for more detailed description of the procedure and new possible role of European Parliament, 61ff; Art. 5.4. of the Decision 1999/468/EC, supra n. 58.

(77) Art. 5.6. of the Decision 1999/468/EC, ibid.

(78) Although the requirement of unanimity did not reflect the language of Art. 21 of the old Deliberate Release Directive, such was the interpretation of the Commission, cf. S. Francescon, supra n. 6. First, in order to increase the role of Member States in the decision-making process the Commission proposed application of IIIb comitology procedure allowing the Council to reject the Commission proposal by only simple majority, Art. 2 of the old Decision 87/373/EEC, now repealed by Decision 1999/468/EC, supra n. 58. That proposal is not valid any more as the new Decision 1999/468/EC does not provide a procedure equivalent to the old IIIb; cf. Explanatory Memorandum for the new Directive 2001/18, supra n. 3, 5-6; Opinion of the Economic and Social Committee for the new Directive 2001/18, CES 1117/1998, 2.

(79) Cf. L. Krämer, supra n. 18, 170, S. Francescon, supra n. 6, 313; T. K. Hervey, supra n. 26, 328.

(80) Case C-6/99, supra n. 60, par. 27-29; AG Opinion, case C-6/99, supra n. 20 , par. 65.

(81) Cf. A. Mastromatteo, supra n. 60, 428.

(82) T. K. Hervey, ibidem.

(83) Main countries behind the present moratorium for GMO together 34 votes; cf. supra n. 13.

(84) G. Winter, supra n. 65, 696.

(85) Cf. Annex 2, MEMO/01/277, supra n. 2.

(85) Art. 18.1 of the new Directive; on the contrary Art. 13 of the old Directive 90/220, supra n. 1, does not specify any procedural time-limit for adoption of decision, it says the Commission shall adopt it.

(87) Cf. supra n. 1.

(88) Cf. Opinion 2/00, supra n. 32, par. 46.

(89) Art. 249 EC, cf. Art. 34 of the new Directive 2001/18.

(90) Cf. B. Sheridan, supra n. 14, "complete harmonisation" , 87; A. R. Ziegler, Trade and Environmental Law in the European Community, Oxford, 1996, "extensive harmonisation" , 156.

(91) Cf. L.Krämer, supra n. 18, 93.

(92) Locus classicus is: Case 6/64, Costa v ENEL, [1964] ECR 1141.

(93) Consultations with European ethical committees "shall be without prejudice to the competence of Member States as regards ethical issues", recital 57 of the Preamble and Art. 29 of the new Directive.

(94) Even though some authors see derogation possibilities under Art. 95 rather in the context of minimum harmonisation only, cf. M. Dougan, Minimum Harmonisation and the Internal Market, 37 CMLRev. 2000, 855, 868; see also L. Krämer, supra n. 18, 101. S. Weatherill says that this provision subverts the traditional doctrine of pre-emption and establishes within the Treaty the legitimate importance of national regulatory measures…; shared competence, Beyond Preemption? Shared Competence and Constitutional Change in the European Community, in D. O'Keeffe, P. Twomey (eds), Legal Issues of the Maastricht Treaty, London, 1994, 22-23.

(95) For systematic analysis of conditions under Art. 95.4-5. as amended by the Amsterdam Treaty together with tests applied by the Commission in the particular cases, see above all E. Vos, supra n. 21, 150ff, 160ff; L. Krämer, supra n. 18, 98ff; B. Iwañska, supra n. 34, 545ff.

(96) Cf. Draft minutes of the 2194th Council meeting, supra n. 13, 15.

(97) L.Krämer, supra n. 18, 102.

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(98) Cf. E. Vos, supra n. 21, 166 –167.

(99) It appeared after Member States invoked the safeguard clauses under Art. 16 of the old deliberate release Directive, see below. The problem of the "objectivity of science" is not new as such and it has already caused many controversies; cf. J. Scott, E. Vos, The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO, in: Ch. Joerges and R. Dehousse (eds), Good Governance in Europe's Integrated Market, Oxford, 2002, 258ff.

(100) That is why incoherence between EU and national legislation, at least in theory, should not remain for long.

(101) Cf. G. Winter, supra n. 65 , 690.

(102) Adaptation of the Annexes to technical progress is pursued through comitology procedure, save for Annexes II AB, VII AB (general basis principles of environmental risk assessment, principles for monitoring plan) which as regulating crucial issues are subject to the full co-decision procedure. This is due to the amendment made by the Council while adopting the common position, Communication from the Commission to the European Parliament concerning the Common Position adopted by the Council, SEC/99/2180 final - COD 98/0072, comment on Article 26.

(103) Art. 8 of the new Directive.

(104) Art. 23 of the new Directive, cf. A. Mastromatteo, supra n. 81, 429.

(105) E. Vos, supra n. 21, 167.

(106) Case C-6/99, supra n. 60, par. 44-47, cf. somehow critically J. Scott, E. Vos, supra n. 99, 258.

(107) Cf. B. Sheridan, supra n. 14, 82 – Austria (3), France (2), Germany, Greece, Luxembourg (1).

(108) Cf. Art. 16 of the old Directive, supra n. 1.

(109) T. K. Hervey, supra n. 26, 323.

(110) I.-J. Sand, supra n. 30, 16; T. K. Hervey, supra n. 26, 324.

(111) Ibidem, 324.

(112) T. K. Hervey, supra n. 26, 324; E. Vos, supra n. 21, 168; cf. as well I.-J. Sand, supra n. 30, 16-17.

(113) Cf. B. Sheridan, supra n. 14 , 82, 84; I.-J. Sand, supra n. 30, 16; L. Krämer, supra n. 18,171.

(114) B. Sheridan, supra n. 14, 83; none of the opinions of the relevant Scientific Committee within the Commission confirm the reasons for GMOs ban invoked by Member States; cf. opinions at http://www.europa.eu.int/comm/food/fs/sc/scp/outcome_gmo_en.html. In the future as stated above the tasks of these committees will be taken over by the European Food Authority, cf. supra n. 73

(115) Generally on the subject, see Ch. Joerges, Integrating Scientific Expertise into Regulatory Decision-Making, EUI Working Paper, RSC No. 96/10.

(116) The same D. Lawrence, J. Kennedy and E. Hattan, supra n. 11, 52; S. Francescon, supra n. 6, 313; cf. as well T. K. Hervey, supra n. 26, 323.

(117) Art. 23.2. of the new Directive.

(118) The same B. Sheridan, supra n. 14, 82.

(119) Cf. AG Opinion, case C-6/99, supra n. 20, par. 82. The influence may be surprisingly strong, see above and cf. E. Vos, supra n. 21, 170.

(120) Cf. data showing general negative public attitude in Europe towards GMO in D. Vogel, Ships passing in the night: The Changing Politics of Risk Regulation in Europe and the United States, EUI Working Paper, RSC No. 2001/16, 11-13; T. K. Hervey, supra n. 26, 324ff.

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(121) With the abstention of the Italian and the French delegates, cf. Legislative Observatory of the European Parliament, Stages in the procedure, the new Directive 2001/18, 2; http://wwwdb.europarl.eu.int/oeil/oeil_ViewDNL.Procedure. Anyway, Statement of the Council's Reasons after adoption of the common position also does not reveal that legal base has been a matter of discussion, OJ 2000, C64/40.

(122) Although not expressly stated by the ECJ it is regarded as such by the Commission, D. Chalmers, EU Law, Vol. I, Ashgate Dartmouth 1998, 222.

(123) This is true for all the fields where the regulatory comitology procedure is applicable, not exclusively for GMOs deliberate release.

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