

LEGAL ASPECTS AT THE EU LEVEL

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‘Safety Regulation of Transgenic Crops: Completing the Internal Market?’

A study of the implementation of EC Directive 90/220

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Contents

1	Introduction	3
1.1	Main legal acts	3
1.2	Horizontal and sectoral legislation	4
1.3	Overview	4
1.4	Effectiveness and interpretation	5
1.5	Direct application of EC law	5
2	The internal market and its barriers	6
2.1	Introduction	6
2.2	Limits of comitology: the Austrian ban on the Ciba/Novartis maize	8
2.3	France's U-Turn on the PGS oilseed rape	11
2.4	France's court decision on the Ciba/Novartis maize	14
2.5	"Commercial" barriers	16
2.6	Monitoring	16
2.7	Labelling	18
3	Moratoria	18
3.1	Limited bans	18
3.2	Court bans by reviewing or restricting the consent	19
3.3	"Voluntary" moratoria	19
4	US exports to the EU of genetically modified maize and soya beans – segregation	20
5	Possible invoking of WTO rules by the US	20
5.1	Approval procedures and labelling under the SPS agreement	20
5.2	Labelling under the TBT agreement	21
5.3	Multilateral environmental agreements as a way to comply with WTO rules	22
6	Summary	22
	Appendix	24
	Abbreviations	24
	References	25

1 INTRODUCTION

The European Commission's (EC's) regulatory framework on genetically-modified organisms (GMOs) and GMO products consists of various legal measures, including Council (and Parliament) decisions and recommendations as well as Commission directives and regulations. The EC is not empowered to enact a law on GMO safety as such; its task is to harmonize rules in the internal market and, in that process, to protect human health and the environment and to inform the consumer. The protection of human health and the environment as well as consumer interests are not the primary reasons for EC action.

1.1 Main legal acts

In 1990, the Council enacted the Deliberate Release Directive (90/220 – DRD) ⁱ. It applies to:

- the deliberate release of GMOs into the environment
- the placing on the market of products containing, or consisting of, GMOs intended for subsequent deliberate release into the environment.

Article 2 of the DRD defines a GMO as “any biological entity capable of replication or of transferring genetic material”, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Annex I A supports this definition insofar as “genetical modification” is concerned; Article 3 and Annex I B exclude genetical modifications achieved by certain (more traditional) techniques from the scope of the DRD.

The DRD has been (under its Article 20) amended by Commission Directives 94/15 ⁱⁱ and 97/35 ⁱⁱⁱ. Directive 97/35 – which does not have retrospective effect – provides labelling requirements not covered in the original DRD.

Articles 5 to 9 DRD refer to the “deliberate release”, i.e. any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment, with the exception of placing GMOs and GMO products on the market. This issue (market release) is dealt with in Articles 10 to 18 DRD.

The Novel Food Regulation, 258/97 (NFR) ^{iv}, concerns the placing on the market of novel foods or novel food ingredients. There are two categories of novel food which are related to GMOs and the DRD:

1. foods and food ingredients containing or consisting of GMOs within the meaning of Directive 90/220.
2. foods and food ingredients produced from, but not containing, GMOs (as defined in the DRD). This includes novel food still containing genetically altered material which is not viable.

The scope of application of the NFR partly overlaps with that of Article 10 to 18 of the DRD (category 1), partly it is wider (category 2). Therefore Article 9 NFR states that Article 11 to 18 of the DRD shall not apply to foods or food ingredients which contain or

consist of GMOs (novel food made from GMOs would not be under the scope of the DRD insofar as it does *not contain* GMOs).

Furthermore, the Council has enacted Regulation 1139/98^v on labelling requirements for foodstuffs produced from genetically modified maize and soya beans already approved by the EC which otherwise would not have been affected by the labelling requirements of the NFR. Regulation 1139/98 has repealed Commission Regulation 1813/97 which had already foreseen similar requirements.

1.2 Horizontal and sectoral legislation

The regulation of GMO products (including the categories of novel food just mentioned) is dealt with by both horizontal and sectoral legislation. The central piece of horizontal legislation is the DRD. The central piece of sectoral legislation is the NFR. Additives, flavourings and extraction solvents are dealt with under their respective sectoral legislation (which does not, however, require GMO labelling). Feedingstuffs and seeds will in future be covered by special sectoral legislation. Sectoral legislation deals with *certain uses* of GMOs (in that respect it is narrower than the DRD), but may also cover uses beyond the DRD.

Regulation 1139/98 is a special case of sectoral legislation supposed to close gaps regarding GMO maize and soya beans.

A Commission proposal to amend the DRD is currently being considered by the European Parliament and the Council (DRD amendment proposal).^{vi}

1.3 Overview

The purpose of these provisions is to harmonize the respective national laws; for the placing on the market of GMO products and novel food, they also seek to give EC-wide effect to approval in one member state, to achieve a one-stop-shop procedure for the entire EC while safeguarding the protection of human health and the environment and providing information for consumers. These legal acts shape EC regulation of GMOs in the following manner:

- Deliberate release, i.e. any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment, with the exception of placing GMOs and GMO products on the market – Articles 5 to 9 DRD. Approval for the release is required in the respective member state; approval does not have EC-wide effect.
- The placing on the market of products containing, or consisting of, GMOs intended for subsequent deliberate release into the environment, with the exception of foods and food ingredients containing or consisting of GMOs – Articles 10 to 18 DRD. Consent in one member state following the procedure under the DRD has EC-wide effect; under certain circumstances, decision making power for the Commission.
- The placing on the market of two categories of novel food

1. novel food containing or consisting of GMOs within the meaning of Directive 90/220/EEC
 2. novel food produced from, but not containing, GMOs
- NFR. Consent in one member state has EC-wide effect; under certain circumstances, decision making power for the Commission.
 - Labelling requirements for foodstuffs produced from certain genetically modified maize and soya beans approved before the NFR came into effect; Regulation 1139/98.

In addition, other EC legal acts may be applicable, like the general labelling requirements under Directive 79/112 ^{vii} as last amended by Directive 97/4 ^{viii}.

1.4 Effectiveness and interpretation

Short of simply being ignored, every law is subject to different interpretations, often influenced by political, ethical and social paradigms, sometimes to a point where interpretation is used to “twist” a law into a desired direction. Therefore modern legal systems rely heavily on procedures aimed at defining a single authority to give a final and binding decision.

As EC law is in most cases applied by national authorities, a variety of interpretations is inevitable, not least due to genuine language barriers. However, the European Community Treaty (ECT) entrusts the European Court of Justice (ECJ) with the role of final arbiter; in addition, the Commission and the Council of Ministers may also have decision-making power. The problem of differing interpretations is often addressed by the ECJ; it stresses the need to apply and interpret EC law in the same way throughout the EC so as to fulfill the goals of the ECT, among others to establish and maintain the internal market.

The practical problem is that until a final and binding interpretation is given, significant delays may occur, and during that time, the internal market may be distorted. The problem becomes worse if legislative shortcomings lead to an impasse between national authorities and the Commission. The problem of achieving the goals of the ECT by EC legislation is therefore not so much the problem of different interpretations arising, but rather of an effective procedural means to sort out the differences.

1.5 Direct application of EC law

A directive such as the DRD is addressed at member states. To make a directive’s obligations apply to individuals, for example, to impose on companies a requirement to apply for approval for releases, the directive has to be implemented at the national level through legislative measures (parliamentary or administrative). The same applies to Decisions based on a Directive. The ECJ has no reservations regarding this legislative approach ^{ix}.

The Commission Decisions foreseen under the DRD are therefore addressed to the member states – not to the company or other entity which has applied for the approval (for example, Commission Decisions under the DRD such as 97/98, and also 98/292, 98/293 and

98/294^x). This is why the national competent authority (CA) has to “rubberstamp” the Commission decision to transfer it, in a way, into applicable law (by “signing part C”; in this case EC law is applied “indirectly”, i.e. via national implementation).

The failure of member states to implement legislation and Decisions may amount to additional delays or blockages. Directives (and Decisions addressed at member states) may, however, be invoked by individuals for whom the *direct application* thereof would be favorable. Additional requirements for direct application are the sufficient precision of the Directive and the passing of the implementation deadline. If these conditions are met, a Directive or a Decision has to be applied by national authorities and courts if invoked by an individual, regardless of national implementation measures. The details of direct application with regard to the DRD are complex but they are relevant, for example, in court cases like the one before the French Conseil d’État discussed in Section 2.4.

2 THE INTERNAL MARKET AND ITS BARRIERS

2.1 Introduction

The meaning of the term “internal market”

Regarding GMO products, the term “internal market” can mean two things. First, it can mean the removal of legal barriers; this is the main objective of the DRD. It creates a single legal framework, achieved by a case-by-case approval of GMO products. (An alternative would be to set out requirements only and allow placing on the market without approval). In other words, the internal market for a GMO product is, in a legal sense, established by the DRD and by the approval of that product.

Second, it can mean the establishment of consumer and retailer trust, which helps to eliminate non-legal barriers. Such barriers cannot, however, be directly eliminated by EC law. Therefore the term “internal market” in the following sections refers to the first meaning, the removal of legal barriers.

This single framework requires mutual trust among member states since they are expected to accept each other’s safety assessments. If EC legislation fails to achieve this mutual trust, different regulatory approaches and assessments may re-emerge as differing interpretations of EC law.

Free movement of goods among member states

The free movement of goods among member states is a fundamental principle of the European Community Treaty (ECT), namely its Articles 30 and 36. Goods produced in one member state are free to circulate within all member states. This free circulation may only be restricted for the reasons given in Article 36 ECT, in particular for reasons of public safety and health. Measures based on those reasons must not directly, or in their effect, discriminate between national and foreign products.

There are several reasons why this principle falls short of establishing an internal market. For production, different standards may apply, so that when products are sold in other member states, the consumer may be confronted by up to 15 possible standards for one product. Furthermore, member states may apply Article 36 ECT in different ways. If member states consider measures to be justified under Article 36 ECT, a product may be placed on, for example, only 12 of the 15 national markets. Article 36 ECT may be used to justify an (additional) approval procedure (common in the case of pharmaceuticals), so that a producer has to undergo different procedures in different member states, and may be granted approval only in some of those member states.

While Article 30 ECT may provide market “clearance” for the majority of products, measures taken for the reasons set out in Article 36 ECT can cause serious differences and thereby obstacles to an internal market. Even if those measures turn out not to be justified under Article 36 ECT, it will often take lengthy legal disputes to clarify this.

In essence, these problems are referred to in the recitals of the DRD, which read:

“Whereas disparity between the rules which are in effect or in preparation in the Member States concerning the deliberate release into the environment of GMOs may create unequal conditions of competition or barriers to trade in products containing such organisms, thus affecting the functioning of the common market; whereas it is therefore necessary to approximate the laws of the Member States in this respect”.

Secondary legislation

Secondary legislation may go beyond Article 30 and 36 ECT by seeking harmonization (approximation) of national legal frameworks. Harmonization measures incorporated into the DRD try to solve the problems remaining under Articles 30 and 36 ECT and include the following:

- many (possible) different standards are replaced by a single standard of safety, labelling etc.
- many (possible) different approval procedures are replaced by one procedure (one-stop-shop, though in controversial cases this procedure may be long-winded or even ineffective)
- the ambiguity of Article 36 ECT is limited by a more specific provision in Article 16 of the DRD (though many ambiguities remain, as experience with controversial GMO cases has shown)
- long legal disputes should be avoided by the notification requirements and Commission (or Council) decisions about measures under Article 16 DRD. Under the ECT alone, such measures would not have to be notified and might therefore exist “in hiding” until challenged in national courts (and finally before the ECJ under Article 169 or 177 ECT).

While these harmonization measures may not always work as intended, they can at least prevent or help to resolve the most serious market barrier problems.

The limits of harmonization

Two key questions arising under the DRD need to be mentioned:

- whether a directive under Article 100a ECT (such as the DRD) establishes one single standard (“floor” and “ceiling”) for national measures or just a minimum standard (“floor”), and
- whether measures regarding considerations not addressed in the directive are ruled out by that directive or left open.

In principle, a harmonisation directive under Article 100a ECT (such as the DRD) leaves member states without much room to manoeuvre. Its aim is to achieve harmonization for the internal market, i.e. one set of rules. Therefore Article 15 of the DRD prohibits member states from introducing conditions on the marketing of a product based on concerns already dealt with under the consent procedure. The placing on the market of a GMO product complying with the DRD may not be restricted “on grounds relating to the notification and written consent” under the DRD (Article 15).

The case law of the ECJ ^{xi} is not entirely clear on those issues and depends upon the individual harmonization measure in question.. Therefore the following considerations are only one possible way of interpreting the DRD.

While the DRD sets out rules regarding several aspects (namely safety, labelling) of a GMO product, it is silent on considerations such as social or agricultural effects. The silence of the Directive could be interpreted in two ways: such considerations are not relevant and must not affect (prohibit, restrict etc.) the placing on the market (“full harmonization”), or such considerations are beyond the scope of the DRD and may therefore be applied by member states in ways which affect the placing on the market. The following point indicates a full (“floor and ceiling”) harmonization: the DRD establishes a single procedure for GMO product market approvals, only one provision allowing for member state measures (Article 16 DRD) and no provision allowing for stricter member state rules. However, a definitive answer to these questions can only be supplied by the ECJ.

2.2 Limits of comitology: the Austrian ban on the Ciba/Novartis maize

Comitology procedures

Under Article 16 DRD a member state may impose provisional safety measures (restricting or banning the commercial use of a GMO product on its territory). These measures must be notified to the Commission, which will then initiate a procedure under Article 21 DRD, called a “comitology” procedure. The usual phrase that the Article 21 Committee shall “support” the Commission is only a euphemism for “control”. While such powers are transferred to the Commission, member states want to retain some influence on the way in which such powers are used. Not surprisingly, comitology procedures often involve significant delays.

Nevertheless, the comitology procedure is used to limit the authority of the Commission as a legislative instrument by the EC legislation for the following reasons.

The DRD takes away discretion from member states and the ECJ and vests it in the Article 21 procedure. Without the Directive, member states would have some discretion under Articles 30 and 36 ECT within a stricter control by the ECJ. With the Directive, member state discretion is transferred to the Article 21 procedure, and as the ECJ applies less scrutiny to EC measures than to national measures (as the EC measures are the same for the entire community and EC organs are involved), discretion is wider for the Article 21 procedure than it would be for member states. If these powers were transferred to the Commission alone, it would gain these powers at the expense of the ECJ as well as of the member states. Where such a transfer of power is deemed necessary, comitology is used to limit the transfer of authority to the Commission.

The comitology procedure is open to various uses, from obstructing the Commission's views, to influencing Commission's views, to supporting the Commission's views. The framework is also open to support for one particular account, or to negotiation. There are legal limits to what the committee can do (for example, it cannot completely ignore every scientific aspect), but in essence, comitology voting is a reflection of Council voting, since the committee is a reflection of the Council of Ministers. As with Council voting, there may be various outcomes. Within the legal framework, the mechanics of politics and/or scientific discussion apply. The potential of trade law to speed up the process would be by shortening the deadlines and giving more detailed definitions for Article 16 measures.

Measures under Article 16 DRD

Once one member state has given final consent to the placing on the market of a product under Part C of the DRD, this consent applies to the entire internal market.

Under Article 16 DRD a member state may impose provisional safety measures (restricting or banning the commercial use of a GMO product on its territory) based on "reasonable" grounds. The basis for this clause is Article 100a paragraph 5 ECT:

"The harmonization measures [...] shall, in appropriate cases, include a safeguard clause authorizing the Member States to take, for one or more of the non economic reasons referred to in Article 36, provisional measures subject to a Community control procedure."

The safety clause of Article 16 DRD is necessary only if in its absence, national measures would contradict Article 15 DRD and as a consequence would be inapplicable or at least could be challenged before (national) courts (if the DRD was directly applicable). The DRD, however, entails such a clause only with regard to safety. Measures for other reasons are not justified under Article 16 DRD.

Measures under Article 16 DRD must be notified to the Commission, which will then initiate a procedure under Article 21 DRD. Article 16 DRD allows such a national measure to stand on a provisional basis.

As a next step, the DRD then seeks to sort out the problem by reviewing the national measure under the Article 21 procedure. For that purpose, the national measure has to be notified to the Commission. The legal consequences of non-notification are not entirely clear; the measure would be inapplicable or could be challenged before national courts.

If notification has taken place, the problem is reduced to the question of whether or not the national measure is *justified*. Justification has to be determined under Article 21 DRD. Until that procedure is concluded, even unjustified measures (or more exactly, measures finally deemed unjustified by the Commission or the Council under Article 21 DRD) remain in effect.

For this reason, the effectiveness of the Article 21 procedure is crucial for ensuring the effective working of the internal market. Currently, the controversy about GMO products means that the procedure is being used to further political ends rather than as an effective tool for the internal market.

The EC reaction to the Austrian ban on maize

Invoking Article 16 of the DRD, Austria enacted a ban on EC-approved Ciba/Novartis maize and notified it to the Commission. The Commission came to the conclusion that the measure was not justified. It therefore submitted a proposal to the Article 21 committee to overrule the Austrian measure. The committee failed to come to a decision. In such circumstances (or if the committee does not agree with the Commission), the proposal is submitted to the Council of Ministers. As the committee decides on the basis of a qualified majority vote, a member state only has to find a blocking minority in that committee to avoid being overruled at that stage.

The same qualified majority requirement applies to the Council vote. If the Council does not decide (as in the case of the Austrian ban), the decision is left with the Commission. This may not be desirable for the member state which is defending its measure, since to succeed at this stage, it would have to find a qualified majority for its position, which did not happen in this case.

So far, we could state that the procedure has been slow, but working. The various stages had been run through, and it remained for the Commission to decide. At this point, however, the Commission withdrew its proposal – in other words, it backed down. The consequence of this is that the Austrian ban remains in effect and is likely to stay.

The next question is whether there exists another way to restore the internal market. First, in the absence of a decision under Article 21 DRD, it is highly unlikely that the DRD would be directly applicable against a possibly unjustified, but notified, national measure. Challenges to the national measure before national courts do not look a promising option and seem not to have been attempted. Second, there is the question of a violation of the ECT. The member state could be brought before the ECJ. There are however two problems: as long as the matter is pending in the Article 21 procedure, it is questionable whether there can be a violation of EC law. Regardless of this, a treaty violation procedure can only be initiated by other member states (a step prohibited by an unwritten law of courtesy) or by the Commission (unlikely as it would be much simpler for the Commission to decide under Article 21 DRD). Third, state liability (damages) for a qualified (i.e. severe) violation of EC law may be an indirect means to do away with the ban but, as already mentioned, it is questionable whether a violation is present is all.

All that appears to be feasible at this stage is a new proposal from the Commission to “restart” the Article 21 procedure; the company desiring to place the GMO product on the

market may attempt to force the Commission to take action by Article 175 ECT, i.e. by bringing the Commission before the ECJ for lack of a decision it is required to make. Whatever the chances of success of such an action may be, it would be time consuming.

The accumulation of a broad – or even “twisted” – interpretation to justify a measure under Article 16 DRD and the slowness (or open-endedness) of the Article 21 procedure may tempt member states to obstruct unwanted commercial uses of GMOs. The problems of the DRD framework described above make this a promising approach to pursue national concerns or even obstructions. If the Commission lacks the political will to overrule Article 16 measures, the “provisional” (i.e. until a decision under Article 21 DRD is reached) measures may become a permanent barrier to the internal market.

The legal framework does not provide other means to resolve the conflict. It sets out the procedure and foresees a decision. It provides a forum for negotiations (whether this is used is another question) and, if the conflict is still unresolved, there remains the possibility of a court case before the ECJ. In general, the EC legal system is based on resolving appearing conflicts by means of administrative and court decisions, not, for example, by mediation. The scope of the legal response is a rather narrow one.

The role of the European Court of Justice

The criteria under Article 16 DRD are quite ambiguous. The member state which wants to impose such a measure is, in a way, putting forward a certain interpretation of Article 16 DRD. As this measure stands, provided it is notified to the Commission, the problems of interpretation are concentrated at the EC level. The comitology provision decides the final interpretation, whereas under the ECT the ECJ would be the final arbiter. In a case like this, however, only a few questions of interpretation are left to be decided by the ECJ. First, if the member state puts forward an obviously wrong interpretation in abuse of Article 16 DRD or if a member state’s interpretation is finally found to be wrong, that is not a problem as the whole system takes this into account under Article 21 DRD. Second, the ECJ does not review EC decisions in detail where the decision involves wide discretion, as under Article 16 DRD; it only reviews the question of whether the legal limits to that discretion have been respected and whether the procedural provisions have been followed (in a way, the final interpretation is thereby legitimated by the procedure, which allows reduced scrutiny by the ECJ).

One might say that there is no violation until a case is brought to the ECJ. If the Article 16 measure has been notified by the member state to the Commission and the measure is not an obvious abuse, the member state is acting legally. If notification has taken place and no decision is reached under Article 21, then there is no violation even if a case is brought before the ECJ, as it is up to the Article 21 procedure to determine the relevant interpretation of Article 16 DRD in this case.

2.3 France’s U-Turn on the PGS oilseed rape

In the case of the DRD, as in the case of most directives, EC law is applied by national authorities and courts. EC law does not, however, provide a complete set of rules on procedure. This is provided by national law, with the restriction that the procedure must not be less favorable than those for comparable national law, and it must not render EC law

ineffective. Not surprisingly, this incorporation of non-procedural EC law (such as the requirements for an approval, the conditions for granting approval, and safety requirements) into national procedural law (such as the choice of competent authority and legal remedies) raises many questions. As some procedural issues (content of the notification; referral to and under certain circumstances decision by the Commission) are dealt with in EC law, these problems can become even more difficult to resolve. These questions are currently an ever-growing issue in ECJ case law; definitive statements are difficult to make.

As the national CA has to deal with an application under the DRD, it may be able to block the consent for the placing on the market of GMO products. There are three scenarios whereby this can occur:

- The CA rejects an application

Under Article 12 paragraph 2.b) DRD, the national CA can reject an application. The DRD does not provide further procedures in that case. Such a case is not dealt with under Art 21 DRD.

This does not, however, mean that the national CA can reject applications at will. In the absence of specific provisions in the DRD, the general rules of EC law apply. The negative decision of the CA can be challenged before national courts according to national law; the courts may be required to refer the case to the ECJ if the legal questions involved are not sufficiently clear. It is therefore possible to reject the decision of the national CA and to “restart” the procedure.

- The CA refuses to process a dossier

If the national CA remains silent (without forwarding the dossier to the Commission and without rejecting the application) for more than three months (calculated according to Article 12 paragraph 5 DRD), it violates Article 12 paragraph 2.a) DRD. In this case, the Article 21 procedure cannot be applied (for lack of a notification). Legal remedies have to be sought within national law; moreover, the Commission may already at this stage (i.e. before a judicial decision) take the respective member state to the ECJ under the treaty violation procedure. In 1998, the Commission sent a warning to France as the French CA had refused to acknowledge new applications.^{xiii}

- The CA refuses to “sign” a Commission decision, i.e. refuses to implement the Commission decision

For example, the French CA has refused to approve GMO oilseed rape already cleared by the Commission by Decision 97/393 (PGS herbicide-tolerant oilseed rape). The Commission has taken the first steps of the treaty violation procedure under Article 169 ECT. Beyond that, action by the notifying company in national courts would be possible, but does not seem to have been taken. If the CA does not want to implement a Commission decision because of safety concerns, it cannot rely directly on Article 16 DRD as this provision only refers to measures after a consent has been granted. One might consider using Article 16 DRD by analogy in such a case (see Section 2.4).

All those scenarios have in common that the entire internal market is blocked, thereby imposing a *de facto* EC-wide moratorium in violation of EC law.

As part of its changed position on GMOs, and in addition to its refusal to grant consent or process applications, France has also enacted bans under Article 16 DRD against GMO products which had been approved by the Commission and the CA of the United Kingdom (Commission Decisions 96/158 and 98/291^{xiii}). As both consents are quite limited in scope (96/158 – obtaining seed; 98/291– handling during import and before and during storage and processing), it is difficult to see possible safety concerns regarding the two consents.

2.4 France's court decision on the Ciba/Novartis maize

A particularly interesting topic is the French stance on the Ciba/Novartis maize for which France had been the initial rapporteur. With Decision 97/98 of January 23rd 1997, the Commission required France to give final consent for the Ciba/Novartis maize. In the follow-up to this decision, France implemented that Commission decision, but this implementation may be partly revoked by the French *Conseil d'État*.

The French procedure

On 4 February 1997, France granted consent for the placing on the market of the Ciba/Novartis maize as foreseen in the Commission Decision. The French authorities approved cultivation on 5 February 1998 by authorising national list certification. This certification, however, has only been granted for a period of three years. Such a time limit was not foreseen under the DRD or in Commission Decision 97/98. This national time limit is a restriction on the GMO product in the meaning of Article 15 DRD, and it is also based on safety grounds (precautionary principle) which are dealt with under the DRD procedure. Implementing such a time limit is at least questionable with regard to Article 15 DRD.

The next step, however, did not come from the Commission or the notifying company. A challenge to the national list certification was brought before the French *Conseil d'État* by Greenpeace and others, aimed at a complete ban on cultivation. The *Conseil d'État* issued an injunction at the end of September 1998 prohibiting cultivation^{xiv}, without addressing EC law (with the exception of citing the DRD at the beginning as one of the acts it had regard to). The French Ministry for the Environment has informed Greenpeace about its intention to separate and store the 1998 GMO maize harvest.^{xv} This adds a new and unforeseen aspect to the problems of segregation.

From the perspective of EC law, this injunction raises several questions. Is the *Conseil d'État* competent for this matter (and beyond the injunction)? The *Conseil d'État* has not invoked Article 16 DRD; most likely, this would not be a proper argument anyway. It would be a very odd situation where a court would have to notify a decision with the possibility of it being overruled under the Article 21 procedure. The consequence of Article 16 DRD and Article 21 DRD would be that there is no competence for national courts to enact Article 16 measures.

Could it review the national consent? This is ruled out by Article 15 DRD insofar as the argument relates to concerns dealt with in the Commission decision (97/98). The directive and the Commission decision are addressed to the member states and therefore only directly applicable before the courts if additional criteria are met (see Section 1.5). The *Conseil d'État* seems to consider those acts to be directly applicable though it does not consider the topic (see its referral to the ECJ below).

A (*de facto*) review of a directly applicable Commission decision by a national court is only allowed if, among other requirements, it refers the matter to the ECJ. The ECJ alone would have the final say on the legality of the Commission decision (including the question of the completeness of the notifier's dossiers).

The referral to the European Court of Justice

In December 1998, the *Conseil d'État* decided to refer two questions to the ECJ for a preliminary ruling under Article 177 ECT.^{xvi} Although the act under review was the national list certification, the *Conseil d'État* stated that the legality of this act depends upon whether the earlier procedure under the DRD (conducted by the French CA) had been irregular. Therefore, the questions referred to the ECJ dealt with matters of the DRD. In short, the questions were:

1. If no objection has been raised against the consent or the Commission has decided that a consent shall be granted, does the national CA which has been the rapporteur have to grant the consent (sign Part C), or does it retain a power of discretion allowing it not to grant the consent ?
2. Is Commission Decision 97/98 to be interpreted as obliging the French CA to grant the consent (sign Part C) ?

Though the *Conseil d'État* has not addressed this, two conclusions can be drawn from its referral:

- that the *Conseil d'État* considers the DRD and Decision 97/98 to be directly applicable. A court can only refer questions to the ECJ regarding provisions it has to apply in its proceedings.
- that there is a strong link between the consent under the DRD and national list certification (with national list certification being essentially a mere formality). Otherwise, there would be no need to ask questions about the interpretation of the DRD and Decision 97/98.

The most likely answers to the questions referred to the ECJ are that the CA has to sign Part C following the Commission decision and that the DRD does not allow discretion (namely, regarding the precautionary principle) as safety aspects are dealt with under the DRD (see the considerations about Article 16 of the DRD and Article 100a ECT under Section 2.2 “Measures under Article 16 DRD”).

The implications for EC authority on GMO regulation are ambiguous. On the one hand, the ECJ procedure involves another significant delay. On the other hand, the ECJ may clarify some of the controversial issues, especially as it feels free to rephrase the questions put to it by a national court to answer the questions the ECJ sees as relevant.

Remaining possibilities for national CAs

These restrictions on the CA raise the question of what a CA can do if it comes to the conclusion that a Commission decision does not deal appropriately with safety aspects. The following possibilities can be considered:

- To sign Part C and subsequently enact a ban under Article 16 DRD. This ban, however, would only apply to the territory of the respective member state.

- To act under Article 16 DRD before signing Part C of the consent. While the text of Article 16 DRD refers only to bans enacted after a consent has been issued, it could be argued that the provision could be used before a consent has been issued as well. The measure would be not to sign Part C for the reasons given in Article 16 DRD and to notify this to the Commission.
- To “restart” the procedure by forwarding an enhanced dossier to the Commission.

Only the first possibility has a firm legal basis.

2.5 “Commercial” barriers

When retailers, namely large supermarket chains, seek non-GMO sources of products and refuse to sell products where the absence of GMOs cannot be guaranteed, trade blockages may arise. This is, however, beyond the scope of EC law. The rule of free movement of goods is, in principle, directed at member states. Under the case law of the ECJ, namely the *Bosman-judgement*^{xvii}, only entities with regulating powers comparable to that of the state (such as “monopolistic” sports organisations) are bound by the fundamental freedoms of the treaty. Only a binding non-GMO policy of an association of food retailers might meet that criterion, but not single retailers.

Current EC law does not directly tackle such “commercial” barriers. More importantly, this shows that EC legislation, while it may be able to build trust and consensus and thereby influence retailer and especially consumer sentiment, is not able to do away with the possibly more significant blockages that arise beyond statutory barriers. Regulation 1139/98 was intended to clarify the requirements for labelling gm foods, but failed to overcome different approaches to ‘non-gm’ food as well as ‘gm-free’ labels in member states like Germany and Austria.

While it may be argued that many of these blockages stem from different national approaches towards food safety and quality standards, consumer attitudes, for example, will change slowly at best. To achieve consumer trust is the task of the interested companies. Trade law only gives them the opportunity to do so without legal obstacles.

2.6 Monitoring

The DRD as amended by Commission Directive 94/15 does not provide directly for monitoring and management obligations. Information about monitoring and management is not required for the placing on the market of products derived from genetically modified higher plants. Monitoring obligations can only be required if they are necessary for safety reasons.

Notifiers have, however, under pressure from national CAs given commitments to monitoring beyond those requirements. This leads to two questions. What is the legal standing of such commitments, and what are the consequences if those commitments are not fulfilled ?

Legal standing of voluntary monitoring commitments

As the DRD does not require or regulate such commitments, their legal standing has to be judged either under national law or under general EC law. They may be considered part of the consent, or they may be based on a contract under civil law or, more likely, on an administrative contract. The legal standing of a commitment also depends on the way in which it has been made – for example, as a pure assertion, or as a formal agreement with the CA and/or the Commission. In the latter situation, fulfilment of the commitment would be a legal obligation.

Legal consequences of a breach of the commitment

While EC law does not explicitly rule out such obligations, they are not necessary for the validity of the consent once it has been granted. There are, however, several possible legal consequences of a breach of the monitoring commitment. Some are under the DRD *and* national law, and some under national law *only*.

Article 14 DRD requires member states to ensure that GMO products placed on the market meet packaging and labelling rules; Article 15 forbids measures against *products* meeting the criteria of the DRD – but a lack of monitoring and management measures does not make *the product* non-compliant. This means that even with a breach of monitoring and management measures as laid down in the notification, GMO products and their placing on the market are not affected.

The next question is whether such a breach can lead to a ban under Article 16 DRD. While there is no direct justification, a breach of monitoring obligations may lead a member state to the conclusion that a product is no longer safe. But voluntary commitments to monitor should, by definition, only exist if safety reasons do not *require* monitoring in the first place.

What remains is the possibility of sanctions under national law for a breach of monitoring and management commitments. This, however, brings new problems. A monitoring commitment may be made for the entire internal market – but national authorities usually only act upon actions (or inactions) within their territory. Conversely, other national authorities (i.e. those to which such a commitment has not been made) would have no legal basis to act.

The effects of legally binding monitoring commitments to a national authority therefore differ from member state to member state. The lack of clear provisions for such monitoring in the DRD may therefore lead to differences within the internal market.

Company commitments have been crucial for gaining a qualified majority of member states to vote for the products. Unless a company decides to take the burden and delay challenging such a practice before the courts, the actual application of the law is more important than textual interpretations. Usually, such commitments should be respected, whether they are legally binding or just “gentlemen’s agreements”. Such voluntary monitoring should not lead to blockages within the internal market. However it might be that in member states where the sensitivity about GMOs is greater, monitoring would be more intense.

Some of these problems are dealt with in the DRD amendment proposal. As well as imposing a time limit on consents and clarifying member states rights, the proposed amendment Article 13e could include a monitoring obligation.

2.7 Labelling

From the EC perspective, regulation of labelling is first of all about harmonization of labelling. While Article 30 ECT foresees, in principle, the acceptance of labelling as regulated in one member state throughout the EC, harmonization may improve the reliability, transparency and comparability of labelling – especially in the case of novel products such as GMOs.

The question is whether the goal of harmonization is achieved in practice. While there should be no problems with labelled products, problems arise with products where it is unclear whether they need labelling. Different interpretations by member states on that question may lead to trade barriers. This difference would translate to the producer level as well: a company would have to follow the requirements of the most restrictive member state in order to be sure that the product is placed on the entire market of the community.

A different problem occurs if member states do not comply with the labelling requirements. This leads to uncertainty about the efficiency of the labelling system and subsequently undermines consumer trust or the building thereof.

Also, uncertainties may arise where the scientific evidence for the presence of viable DNA is disputed, as in the controversy over whether shipments of processed corn gluten still include viable kernels.

When member states demand negative labelling or more far-reaching “positive” labelling (for GMO-related products which do not come under the labelling requirements of EC law), this could be interpreted as imposing a restriction on the placing on the market of the product, either under the DRD or the NFR (for approved products containing GMOs, or under the NFR also for products made from, but not containing GMOs, which do not have to be labelled) or under

Articles 30 and 36 ECT (for products not covered by the DRD or the NFR at all).

3 MORATORIA

The legal status of moratoria on commercial uses of GMOs and GMO products depends upon the definition of “moratorium”. Member states may ban or restrict the use of GMOs and GMO products if they pose a threat to health or the environment. This has to be based on available information and an evaluation of the GMO or GMO product in question. These powers do not justify outright indiscriminate bans.

3.1 Limited bans

Limited bans (i.e. bans on a certain product) can be justified under these provisions. Beyond that, however, any limitation or ban on a particular use is under the regime of the respective EC law since it would affect the internal market.

Measures under Article 16 DRD and Article 12 NFR may be overruled by the Commission or the Council. The overruling requires a decision under the comitology provision of Article 21 DRD or the similar provision of Article 15 NFR. This may lead to significant delays; during that time, the ban remains in effect. Again, the Commission may bring the respective member state before the ECJ. It is not clear whether such bans may be challenged in national courts, as EC law provides special procedures in those cases. (In a similar way, national courts are not competent to decide whether a state aid (subsidy) is compatible with the internal market as this is under a special procedure which constitutes a prerogative of the Commission. It could be argued that the assessment of safety risks is a prerogative of the Commission and/or the Council as well.)

3.2 Court bans by reviewing or restricting the consent

A similar problem arises when a national consent, following a Commission decision, is reviewed by a national court. The French *Conseil d'État* is reviewing the French national list certification for planting Ciba/Novartis maize approved by Commission Decision 97/98 (see Section 2.4). Such a ban on the planting of GMO crops which have been approved for placing on the market is not outside the scope of EC law. The planting by third persons who have obtained a GMO product through the market is a question of “placing on the market”. It is not about the release for e.g. scientific purposes where national authorities do have more powers. EC law does not only provide for the free movement of goods, but also for the appropriate use of those goods. The reasoning behind the free movement of goods makes it clear that such measures are not allowed, unless they are covered by EC law (in the case of GMO products in general, Article 16 DRD and Article 12 NFR, or the national list certification may consider additional aspects).

This question goes further than the temporary injunction just mentioned: the injunction may be a measure under Article 16 DRD (though it is unclear whether such court measures have to be notified to the Commission and could be overruled); the revoking of that certification would be a permanent measure. Even more far-reaching would be the consequences of repealing the national consent for placing on the market.

3.3 “Voluntary” moratoria

Legal challenges to moratoria, bans etc. are complicated and time-consuming, but if used they might lead to state liability for damages. This may be why some member states, such as the UK, seek to establish “voluntary” agreements for moratoria with the organisations concerned. They are not legally binding, but they are very unlikely to constitute a violation of EC law.

Where member states seek to achieve legally-binding agreements, difficulties arise. Problems may arise when an organisation’s waiving of rights is not temporary or is only accepted under massive political pressure. In that case, the agreement may be void, just as in the case of any “contract” imposing an improper limitation of rights or being forced on one party.

4 US EXPORTS TO THE EU OF GENETICALLY MODIFIED MAIZE AND SOYA BEANS – SEGREGATION

The placing on the market of genetically modified soya beans and maize from the US before the GMOs and GMO products had been approved in the EC was illegal. If the imports contained GMOs, even if mixed with other soya beans or maize, they were subject to the DRD. The “new” labelling requirements under Commission Directive 97/35 and the NFR do not have retrospective effect. Regulation 1139/98 covers GMO products derived from GMOs already approved if those products enter the market after Regulation 1139/98 came into force.

New products covered by these legal acts must meet their criteria:

- Under Annex III Part C of the DRD, products for placing on the market in mixtures with non-GMO products must be labelled as well. However, “information on the possibility that the GMOs may be present, is sufficient”; this allows for “may contain” labelling.
- Under Article 8 NFR, novel food containing or consisting of GMOs must be labelled.
- The same applies under the special regime for new GMO maize and soya products covered by Commission Decisions 96/281 and 97/98.

The 20th recital of Regulation 1139/98 states that operators maintain the right to (*voluntarily*) label the presence of such foods and food ingredients in cases where it is not scientifically verifiable, but other evidence is available. This implies that the simple knowledge of a mixing with GMOs/GMO products does not constitute an *obligation* to label; where the mixture contains a not scientifically measurable amount of GMOs, or just may contain such an amount of GMOs, labelling is not required.

5 POSSIBLE INVOKING OF WTO RULES BY THE US

5.1 Approval procedures and labelling under the SPS agreement

In general, the US government’s approach to biotechnology is much more “positive” than the European one. In 1997, 10 percent of the US maize area and about 14 percent of the soybean area were planted with genetically modified varieties; in 1998, about 40 percent of the soybeans planted were GMO plants, and about 25 percent of the maize.^{xviii} The US position is well described in a statement from US Secretary of Agriculture, Dan Glickman, to the House of Representatives Committee on Agriculture on March 18 1998:

“While maintaining the rights of countries to use *legitimate measures* to protect health and safety, we want to make sure that science, not internal politics or protectionism, is the basis for public, animal and plant health rules. These last two goals should lower some of the more elusive trade barriers that range from unnecessary red tape to regulatory practices that erect *unjustified sanitary and phytosanitary barriers*. For example, the major trade disputes causing tension in the US-EU relationship – the EU hormone ban, specified risk materials, and EU

approvals for new biotech products – all demonstrate the need for greater international harmonization on the basis of more clearly defined rules on technical barriers” (emphasis added) ^{xix}.

The linking of the sentences about “unjustified barriers” and “EU approvals for new biotech products” shows the relevant legal question here. The WTO’s (World Trade Organisation’s) agreement on sanitary and phytosanitary measures ^{xx} (SPS) stresses scientific principles and scientific evidence (Article 2 SPS agreement). The reference to “unjustified barriers” and “EU approvals for new biotech products” in the Secretary of Agriculture’s statement implies these principles and evidence are not the basis of the EC decisions.

However, the SPS agreement also leaves room for precautionary measures. Under Article 5 paragraph 7, a member may adopt measures on the basis of “available pertinent information” where “relevant scientific evidence is insufficient”. Due to the possible long-term effects and lack of long-term experience with GMOs and GMO products this argument may well be invoked to justify the EC measures (and national measures beyond them). Relying on Article 5 paragraph 7 of the SPS agreement implies, however, an obligation to seek to obtain the necessary information and to review the measures accordingly.

While the SPS agreement does not entail a rule about the burden of evidence, the body enacting a measure will have to justify it. This view is supported by Article 5 paragraph 7: if safety had to be proved, this special rule for the case where safety cannot be assumed due to insufficient evidence would not be necessary – insufficient evidence for safety would already justify such measures.

SPS measures must, according to Article 2 paragraph 3 of the SPS agreement, meet a further test. They must “... not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.”

5.2 Labelling under the TBT agreement

Labelling requirements which are not related to protecting human, animal or plant life and health (such as information to serve a consumer’s right to choice) would not fall under the SPS agreement, but under other WTO law. In principle, labelling requirements can constitute a non-tariff barrier to trade, especially under the WTO agreement on Technical Barriers to Trade ^{xxi} (TBT). Article 1.5 TBT agreement states that it does not apply to SPS measures as defined in the SPS agreement; labelling requirements “as they apply to a product, process or production method” are, however, explicitly considered to be “technical regulations” and “standards” (Annex I TBT agreement).

Labelling requirements must meet the test of general WTO rules: they must not be “prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfilment would create” (Article 2.2 TBT agreement). The phrase “risks of non-fulfilment” has to be interpreted with regard to the “legitimate objective” the measure shall

fulfill. For labelling, such objectives could be “the prevention of deceptive practices” (as mentioned in Article 2.2 TBT agreement) or consumer information.

The WTO has summed up its position on eco-labelling in the following manner:

“An important starting point for addressing some of those trade concerns is by ensuring adequate transparency in their preparation, adoption and application, including affording opportunities for participation in their preparation by interested parties from other countries. Further discussion is needed on how the use in eco-labelling programmes of criteria based on *non-product-related processes and production methods* should be treated under the rules of the WTO Agreement on Technical Barriers to Trade” (emphasis added) ^{xxii}.

The additional requirements leave much room for interpretation. So far, they do not seem to have been invoked by the US. The question of “non-product-related processes and production methods” arises when labelling is required for GMO derivative products which do not – or which very likely do not – contain GMOs. The extension of labelling requirements to a “may contain”-labelling of products where the presence of GMOs cannot be excluded (new Annex IV Part C of the DRD amendment proposal), for example, may face stiff US resistance (only labelling which is to serve consumer information falls under the TBT agreement.).

Negative commercial effects on US imports can be caused by labelling them as GM in the absence of segregation in the US, even if the presence of GMOs cannot be proved. When this is done by importers and retailers for commercial reasons, this cannot be considered a state trade barrier.

5.3 Multilateral environmental agreements as a way to comply with WTO rules

A WTO law-compliant way to ensure certain safety standards may be to implement them by means of multilateral environmental agreements (MEAs). Such agreements are usually seen as legitimate. Furthermore, the attempt to achieve MEAs is seen as a positive factor in determining whether a measure is in line with WTO law by the WTO dispute-settling bodies. The negotiations on a biosafety protocol on the basis of the Convention on Biological Diversity may be of particular relevance.

6 SUMMARY

This overview of some of the issues surrounding GMO regulation allows the identification of two main problems: legislative shortcomings and political problems.

Legislative shortcomings at the EC level include the enactment of complex horizontal and sectoral legislation with different regulatory approaches. The required criteria and possible measures are often unclear, for example, those dealing with monitoring and labelling in the notification (though some of this may change once the DRD amendment proposal becomes law). The direct effect of directives like the DRD and of decisions based on such directives are at least partially unclear. In addition, implementation by national legislation and

national authorities is a problem where national resistance arises and finds some support in the committees designed to “support” the Commission or in the Council.

Political problems can be summed up by the EC regulatory framework finding itself between the proverbial rock and a hard place. On the one side, national governments and courts as well as consumer and environmental organisations demand more safety and information. On the other side, the US is pressing, maybe by means of the WTO, for a less restrictive approach. The resistance “below” the EC level is testing the EC regulatory framework and thereby revealing all its legislative shortcomings. The same may happen in future from the other side of the fence in a procedure under the WTO.

While the political problems will not be sorted out by a more coherent regulatory approach, at least the legal problems could be reduced so as to provide a clearer background for the inevitable disputes beyond the merely legal questions of EC law. A solution for the underlying conflicts will be difficult to achieve. Agreement may be achieved by extensive discussion among CAs and their advisers or by legal measures. However, the players in both approaches (the national CAs and the Council of Ministers as the main EC legislative body) reflect the political pressures, scientific disputes, and different national regulatory traditions and approaches. While consent is hard to achieve, legal measures also face practical limitations as the current problems with GMO products show.

APPENDIX

Abbreviations

CA	Competent Authority
Council	Council of Ministers (European Community)
DRD	Deliberate Release Directive
EC	European Community
ECJ	European Court of Justice
ECR	European Court Records
ECT	European Community Treaty
EU	European Union
GMO	Genetically modified organism
MEA	Multilateral environmental agreement
NFR	Novel Food Regulation
OJ	Official Journal of the European Communities
p	page
PGS	Plant Genetic Systems
SPS Agreement	WTO Agreement on Sanitary and Phytosanitary Measures
TBT Agreement	WTO Agreement on Technical Barriers to Trade
WTO	World Trade Organisation

REFERENCES

- (i.) OJ L 117/90, p 15
- (ii.) OJ L 103/94, p 20
- (iii.) OJ L 169/97, p 72
- (iv.) OJ L 43/97, p 1
- (v.) OJ L 159/98, p 4
- (vi.) OJ C 139/98, p 1
- (vii.) OJ L 33/79, p 1
- (viii.) OJ L 43/97, p 21
- (ix.) ECJ case C-359/92, Germany/Council, ECR 1994 I-3681
- (x.) OJ L 131/98, p 28, 30, 33
- (xi.) E.g. ECJ case C-11/92, Gallaher, ECR 1993 I-3545; case C-1/96, Compassion in World Farming, ECR 1998 I-1251
- (xii.) FOEE Biotech Mailout Volume 4, Issue 7, October 31 1998
- (xiii.) OJ L 37/96, p 30 and OJ L 131/98, p 26
- (xiv.) Conseil d'État du 25 septembre 1998, No 194348 (Association Greenpeace France)
- (xv.) Ministre de l'Aménagement du Territoire et de l'Environnement, letter of October 16 1998, Ref. LR/CDV00251
- (xvi.) Conseil d'État du 11 décembre 1998, No 194348, Nos 195511,195576,195611,195612 (Association Greenpeace France et autres)
- (xvii.) ECJ case C-415/93, Bosman, ECR 1995 I-4921
- (xviii.) M. Revelt, GMO's - A U.S. Perspective (speech at the European Forum on Genetically Modified Foods, December 3, 1998), <http://www.useu.be/agri/biotech.html>
- (xix.) D. Glickman, <http://www.usia.gov/topical/econ/wto/wtxt031c.htm>
- (xx.) SPS agreement , OJ L 336/94, p 40
- (xxi.) TBT agreement; OJ L 336/94 p 86
- (xxii.) WTO, <http://www.wto.org/envIRON/eco.htm>

