

Directive 2001/18/EC on the Deliberate Release into the Environment of GMOs: an Overview and the Main Provisions for Placing on the Market

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Public and political views on the regulation of genetically modified organisms (GMOs) and on the role of biotechnology continue to be extremely polarised in Europe. The EU started legislating on the authorisation and use of GMOs in the early 1990s. Despite the early regulation of this complex field, agricultural applications of biotechnology continue to be very controversial. In order to address public concerns and strengthen its regulatory framework, the EU reviewed its legislation on GMOs between 1997 and 2003. The cornerstone of the regulatory framework is Directive 2001/18/EC on the deliberate release into the environment of GMOs, whose provisions for placing on the market are the main focus of this article. The implementation of the Directive to date and the difficulties encountered will be briefly analysed.

I. Introduction

The regulation of genetically modified organisms (GMOs) and the debate on the role of biotechnology continue to be highly polarised in Europe and beyond. GMOs can be defined as organisms, 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.¹

Although genetic modification technology was first applied in the 1970s, it was only in the 90s that the first genetically modified (GM) crops were commercialised for food use. At the same time, the EU, in the early 1990s, started developing legislation to regulate the use of GMOs. Whilst other medical or environmental applications of biotechnology are widely accepted, agricultural applications remain highly controversial.

The complexity of the technology, the lack of data about the long-term effects of a relatively new field of application and, notably, a special sensitivity as regards food policies in Europe following repeated food scares, have influenced the opposing views in the debate. In addition, ethical and socio-economic concerns play a key role in the GMO debate, contributing to a decline in the public's trust in scientific knowledge as a guide for policy decision-making.

In this context, the EU undertook a comprehensive review of its regulatory framework between 1997 and 2003 in order to improve and strengthen its provisions. This article presents an outline of the review of the EU regulatory framework and of the main provisions of Directive 2001/18/EC on the deliberate release into the environment of GMOs, focusing on their placing on the market.

II. Policy context: the revision of the EU regulatory framework

The EU has been legislating on the authorisation and use of GMOs since the early 1990s, when it adopted the first directives on the contained use of

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¹ Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ 2001 L 106/3, Article 2(2).

genetically modified micro-organisms (GMMs)² and on the deliberate release of genetically modified organisms (GMOs),³ 90/219 and 90/220, respectively. The placing on the market of novel food, including GM food, was governed by the 1997 Novel Foods Regulation.⁴

The cornerstone of this initial regulatory framework was Directive 90/220/EEC, which has been applicable since October 1991. Under this Directive, eighteen authorisations were granted for the commercial release of GMOs in the EU, for uses including cultivation, import and processing as well as feed and food.⁵ Prior to the entry into force of the Regulation on Novel Foods, one GM soy and one GM maize variety had been approved for use in food products under Directive 90/220/EEC.

In addition, there was no Community legislation governing feed derived from GMOs before the introduction of Regulation 1829/2003.⁶ As a result, eight GMOs for use in feed, mostly maize and rape varieties and one soya variety, were authorised under Directive 90/220/EEC. No consent was granted under this Directive since October 1998 when the last product was authorised.

In order to strengthen its existing regulatory framework, the EU started a revision of both its horizontal and its sectoral legislation on GMOs in 1997. In parallel, various food scares (e.g. BSE) eroded the public's faith in governments' abilities to protect consumer and environmental interests in Europe.⁷ In this context, the revision of the regulatory framework was also aimed at addressing the loss of public trust in the regulation of the use of GMOs.

In February 1998, the Commission presented its legislative proposal for the revision of Directive 90/220/EEC, subject to the co-decision procedure (Article 251 of the EC Treaty). The main objectives were to extend and clarify the scope of the Deliberate Release Directive, to improve the administrative procedures and their efficiency and to introduce common principles of risk assessment.

The proposal took into account the experience gained in the implementation of Directive 90/220/EEC, which was analysed in a Commission report of 1996.⁸ Accordingly, it introduced a number of elements such as mandatory monitoring after the placing on the market, differentiated administrative procedures and the obligation to formally consult a Scientific Committee when considering the placing on the market of GMOs. The intro-

duction of common principles of risk assessment, combined with the consultation of a Scientific Committee, was intended to separate the responsibility for risk assessment from the responsibility for risk management decisions.⁹

In order to strengthen the role of the Member States in the decision-making process, the proposal included the application of the Regulatory Committee procedure,¹⁰ giving the Council the possibility to reject a Commission decision on authorisation by a simple majority. The Commission also proposed to introduce further and detailed labelling requirements, complemented by traceability provisions.

The Commission's legislative proposal envisaged greater transparency in the authorisation process by making available to the public the content of the notification, the assessment reports and the opinion of the scientific committees in relation to the placing on the market of GMOs as or in products.¹¹

The Environment Council, at its meeting in June 1999,¹² reached political agreement on a common position on the aforementioned proposal to amend Directive 90/220/EEC – with abstentions by France,

2 Council Directive of 23 April 1990 on the contained use of genetically modified micro-organisms (90/219/EEC), OJ 1990 L 117/1, as amended by Directive 98/81/EC of 26 October 1998, OJ 1998 L 330/13.

3 Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (90/220/EEC), OJ 1990 L 117/15, as last amended by Council Directive 97/35/EC of 18 June 1997, OJ 1997 L 169/72.

4 Regulation (EC) No 258/1997 of 27 January 1997 on Novel Foods, OJ 1997 L 43/1.

5 See http://europa.eu.int/comm/environment/biotechnology/authorised_prod_1.htm.

6 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ 2003 L 268/1. This Regulation amended the 1997 Novel Foods Regulation (Regulation 258/97) which originally governed the placing on the market of novel food, including GM food.

7 Hill, 'Decision-making on biotechnology: developing new principles for regulation', *Journal of Environmental Assessment, Policy and Management* 1999, pp. 61-79.

8 European Commission, Report on the review of Council Directive 90/220/EEC of 10 December 1996.

9 See Levidow/Carr/Wield, 'European Union regulation on agri-biotechnology: precautionary links between science, expertise and policy', *Science and Public Policy* 2005, p. 263.

10 Provisions in Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred by the Commission, OJ 1999 L 184/23 (the so-called comitology Decision) govern the regulatory procedure.

11 European Commission, proposal to amend Directive 90/220/EEC, initial legislative document of 23 February 1998.

12 Council of the EU, conclusions of the Presidency, 2194th Council of Environment Ministers of 24 June 1999.

Ireland and Italy. During this Council meeting, a declaration was made by the Danish, Greek, French, Italian and Luxembourg delegations of their intention to suspend any new authorisations for the growing and placing on the market of GMOs.

In their declaration, the five delegations asked for a tighter and more transparent framework, in particular for risk assessment, in order to restore public and market confidence. They also asked for draft rules on traceability and labelling to be adopted in order to re-start the authorisation process. In February 2001, the five countries, now joined by Austria, re-stated their intention to continue with the standstill concerning new authorisations, pending the adoption of provisions on traceability, labelling and environmental liability.¹³ The need for precise rules on traceability and labelling before re-starting the authorisation process was again reiterated at the Environment Council meeting of October 2001.¹⁴

In parallel, in February 2001 the European Parliament and the Council of the European Union endorsed the text repealing Directive 90/220/EEC, after agreeing on a compromise package in December 2000. The compromise reached at conciliation was endorsed by the Parliament by 338 votes to 52 with 85 abstentions. At the Council, the text was adopted with Italy and France abstaining. The legal text was formally adopted in March 2001 as Directive 2001/18/EC.

Directive 2001/18/EC introduced a number of innovations when compared with its predecessor Directive 90/220/EEC, in order to clarify and tighten the authorisation procedure. Principles and criteria to be considered when performing an environmental risk assessment, which is a fundamental part of the application for a GMO release, were set out in the Directive.

The Directive has made the consultation of the Scientific Committee(s) and the provision of information to the public mandatory. Post-market monitoring requirements were also introduced, including of the long-term effects associated with the interaction with other GMOs and the environment. Contrary to the initial Commission proposal, the Council can only reject a Commission decision for authorisation by qualified majority.

The revised Deliberate Release Directive introduced general provisions on traceability and labelling, but did not include rules on environmental liability. The Commission presented a proposal on traceability and labelling of GMOs on 25 July 2001, leading to its final adoption in September 2003.¹⁵ Last but not least, the Directive on environmental liability, which also covers damage caused by GMOs, was finally adopted in 2004.¹⁶

III. EU regulatory framework for GMOs

Following the revision of the legal framework for GMOs, Directive 2001/18/EC on the deliberate release into the environment of GMOs¹⁷ replaced Directive 90/220/EEC as the backbone of this regulatory area. The Directive regulates the intentional introduction into the environment of GMOs, either for research or commercial purposes, through a case-by-case prior authorisation system based on an environmental risk assessment. As regards the use of GMMs under conditions of containment, they are regulated by Directive 90/219/EEC.

These two Directives took a horizontal approach to the technology, addressing GMOs and GMMs as such, regardless of their use.¹⁸ At the same time, both Directives paved the way for their gradual replacement by sectoral legislation geared to the product and its use.¹⁹ The cross-cutting provisions on traceability and labelling in Regulation 1830/2003 complete the main framework of horizontal legislation in force after the review.

13 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, p. 310.

14 Brosset, 'The prior authorisation procedure adopted for the deliberate release into the environment of Genetically Modified Organisms: the complexities of balancing Community and national competences', *European Law Journal*, VOL. 10, No. 5, September 2004, p. 573.

15 Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ 2003 L 268/24.

16 Directive 2004/35 on environmental liability with regard to the prevention and remedying of environmental damage, OJ 2004 L 143/56. See JEEPL 4/2005.

17 Directive 2001/18/EC, supra note 1.

18 See Barling, 'Environmental sustainability or commercial viability? The evolution of the EC regulation on genetically modified foods', *European Environment*, 1996, p. 48; Levidow et al., 'Regulating agricultural biotechnology in Europe: harmonisation difficulties, opportunities, dilemmas', *Science and Public Policy*, 1996, p. 135; and supra note 14.

19 See supra note 14.

As mentioned above, the revision of the EU regulatory framework on GMOs covered vertical legislation as well. A key example is Regulation 1829/2003 on genetically modified food and feed, which regulates the placing on the market of GMO food and feed or food and feed products containing or consisting of GMOs. A single application for a GMO and all of its uses may be filed under this Regulation provided one of its uses concerns food or feed. Regulation 1829/2003 also lays down specific labelling requirements for genetically modified food and feed. However, as regards environmental risk assessment it relies on the provisions of the horizontal Directive 2001/18/EC.

Despite the gradual introduction of vertical legislation on GMOs, Directive 2001/18/EC remains a point of reference as regards its provisions on environmental risk assessment for the purpose of placing on the market, risk management, labelling, monitoring, information to the public and safeguard clause.²⁰ GMOs as or in products authorised by other Community legislation should be subject to a specific environmental risk assessment, to be carried out in accordance with the principles set out in the Directive, without prejudice to additional requirements introduced in the sectoral legislation.

IV. Directive 2001/18/EC on the deliberate release into the environment of GMOs

1. Main elements of Directive 2001/18/EC

On 17 April 2001, Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms, entered into force. The Directive became applicable as of 17 October 2002, the deadline for transposition by Member States and the date as of which Council Directive 90/220/EEC was repealed.

The objective of Directive 2001/18/EC²¹ is to approximate the legislative and administrative provisions of the Member States and to protect human health and the environment,²² when a GMO is deliberately released into the environment, including for placing on the market as or in products. This objective is to be pursued in accordance with the precautionary principle.²³

Even though the previous Directive 90/220/EEC made no specific reference to the precautionary principle, its application in implementing this Directive was acknowledged by the European Court of Justice (ECJ) in March 2000.²⁴ The ECJ stated that the principle had been incorporated in the various steps of the authorisation procedure, notably in the case-by-case assessment prior to a release, as well as in the safeguard clause.

Directive 2001/18/EC explicitly incorporates the precautionary principle, going one step further than the previous Directive. The precautionary principle is now a central element of the Directive, which notes in its recital eight that the principle was taken into account during the drafting and 'must be taken into account when implementing it'.

The scope of application of the Directive excludes the transport of genetically modified organisms by rail, road, inland waterway, sea or air, which is governed by the relevant transport legislation. Organisms that have been genetically modified through techniques listed in Annex IB are also exempted from the application of the Directive in accordance with its Article 3.

The provisions for the placing on the market of GMOs do not apply to medicinal products for human and veterinary use covered by Council Regulation (EC) No 726/2004,²⁵ provided that it includes an environmental risk assessment equivalent to that laid down in Directive 2001/18/EC.²⁶

20 Directive 2001/18/EC, *supra* note 1, recital 27.

21 *Ibid.*, Article 1.

22 The Directive is based on Article 95 EC.

23 See Communication from the Commission on the precautionary principle (COM(2000) 1 final), where it is acknowledged that the scope of the precautionary principle covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.

24 ECJ, Case C-6/99 – Association Greenpeace France and Others v. Ministère de l'Agriculture et de la Pêche and others [2000] ECR I-6031, para. 41 and next. See as well Hill, 'The precautionary principle and release of Genetically Modified Organisms (GMOs) to the environment', in *Interpreting the precautionary principle*, London 1994.

25 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ 2004 L 136/1, repealing Council Regulation (EEC) No 2309/93 of 22 July 1993, OJ 1993 L 214/1.

26 Directive 2001/18/EC, *supra* note 1, Article 12.

The Directive provides for the introduction of GMOs into the environment to be carried out according to the 'step by step' principle. This means that the containment of a GMO is gradually reduced and the scale of the release increased, step by step, but only if the evaluation of the earlier steps in terms of the protection of human health and the environment indicates that the next step can be taken.

According to the definitions in Article 2, the deliberate release of a GMO into the environment means its intentional introduction without any specific containment measure to limit the contact between the GMO or combination of GMOs and the population or environment in general. Experimental releases of GMOs for the purposes of research and development of novel varieties are subject to the provisions of Part B of the Directive.²⁷

After studying the behaviour and interactions of the GMO with other organisms and the environment, the company may decide to place the GMO on the market, i.e. make it available to third parties, either in return for payment or free of charge. The GMO may be placed on the market for purposes of importation, cultivation or transformation into different products. The provisions of Part C of the Directive²⁸ govern the placing on the market of a GMO. GMOs may only be deliberately released or placed on the market in conformity with Part B or Part C, respectively.

Notably, the revised Directive introduces a general obligation to gradually phase out Antibiotic Resistant Marker (ARM) genes from GMOs, in line with differentiated timetables for commercial and experimental releases.²⁹ Genes expressing resistance to antibiotics in use for medical or veterinary treatment, which may have adverse effects on human health and the environment, have to be phased out by 31 December 2004 in GMOs to be placed on the market and by December 2008 for GMOs authorised under Part B.

The first stage in the authorisation procedure is the submission of a notification by the interested

party or notifier to the relevant competent national authority. A person or company applying for the deliberate release of a GMO or combination of GMOs into the environment for experimental purposes, must submit a notification to the competent national authority of the Member State where the experimental release is to take place. This authority subsequently plays a central role in the decision-making process under Part B.

The notification should contain a technical dossier including a full environmental risk assessment as well as a monitoring plan and appropriate safety measures.³⁰ The decision-making process takes place through a national procedure, where the competent national authority has exclusive responsibility for granting the authorisation. Nevertheless, the other Member States may present observations through the Commission or directly.

The eventual authorisation of an experimental release is only valid in the Member State where the notification was submitted. The notifier may proceed with the release only when he has received the written consent of the competent authority and must act in conformity with any conditions required in this consent.

Part B of the Directive provides for differentiated procedures with shorter timetables for the approval of releases of certain GMOs. These procedures have to be applied – subject to certain criteria being met – when sufficient experience has been obtained of releasing specific GMOs in certain ecosystems.

Public consultation on all proposed releases of GMOs, whether for experimental or commercial purposes, is a mandatory requirement under the Directive. For Part B releases, Article 9 requires Member States to consult the public and, where appropriate, interested groups, on the proposed deliberate release. The Directive only states that arrangements for this consultation are to be laid down at national level, leaving the definition of the specific arrangements to the Member States in line with the subsidiarity principle.³¹

2. Focus on provisions for the placing on the market of GMOs as or in products

Part C of the Directive governs the authorisation of the placing on the market of GMOs or products consisting of or containing GMOs. In contrast with authorisations for research purposes, an authorisa-

27 Ibid., Articles 5-11.

28 Ibid., Articles 12-24.

29 Ibid., Article 4(2).

30 Ibid., Article 6 and Annexes II and III.

31 Report from the Commission to the Council and the European Parliament on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC and incorporating a specific report on the operation of parts B and C of the Directive, COM(2004) 575 final of 31 August 2004, Annex IV.

tion for a commercial release is valid for the whole of the Community territory, in order to ensure compliance with the principle of the free movement of goods. Accordingly, the decision-making process involves all Member States.

The first step in the authorisation starts with the notification procedure to the relevant competent authority, which in this case will be the competent authority of the Member State where the GMO is to be placed on the market for the first time. The notification must comprise a dossier of information on the GMO, the receiving environment, interactions between the GMO and the environment, as well as the conditions of release and monitoring, control, waste treatment and emergency control plans. This detailed dossier must include the results of research and development releases concerning the impact on human health and the environment.³² The notification must also include an environmental risk assessment,³³ carried out by the notifier.

The environmental risk assessment should identify and evaluate any potential adverse effects of the GMO. In contrast with the former Deliberate Release Directive, Directive 2001/18/EC sets out the methodological basis for carrying out the environmental risk assessment including its objective, elements to be considered and general principles and methodology to be followed.³⁴

The assessment should not only address the possible direct and immediate effects of releasing the GMO, but also any indirect and delayed effects on human health and the environment, as well as cumulative long term effects. The evaluation of potential adverse effects will examine the characteristics of the GMO, its potential allergenic or toxic effects and the possibility of gene transfer (e.g. of antibiotic resistance genes).

The national authority receiving the notification will examine it for compliance with the requirements of the Directive and prepare an assessment report³⁵ to be sent to the notifier, indicating its opinion on the placing on the market of the GMO(s) in question. In the event of an unfavourable report, the notification must be rejected, whilst stating the reasons for the refusal.³⁶ The company may submit a new notification for the same GMO to the competent authority of another Member State, which may eventually issue a different report.

In the event of a favourable assessment regarding the placing on the market of the GMO con-

cerned, the competent authority will inform the other Member States via the European Commission, which will examine the assessment report and may issue observations and objections. In line with the standard procedure as presented in Article 15, in the absence of objections or if outstanding issues are resolved in the conciliation phase,³⁷ the competent authority that carried out the original assessment may then authorise the placing on the market of the product. The consent for the placing on the market is to be given in writing and for a maximum period of ten years.

If at the end of the conciliation phase the objections raised by a competent authority or the Commission are maintained, the Community procedure³⁸ involving all competent authorities is to be applied for adopting a decision. The European Food Safety Authority (EFSA)³⁹ has to be consulted for an opinion on the objection(s) as regards the risks of GMOs to human health or to the environment.⁴⁰ In line with this opinion, the Commission will then prepare a draft decision.

A regulatory committee composed of the representatives of the Member States and chaired by the representative of the European Commission would assist the Commission according to the provisions of Article 30(2). This inter-institutional procedure is laid down in Decision 1999/468/EC and provides for the adoption of the decision by the Commission when the Committee gives a favourable opinion by qualified majority.⁴¹

32 See Directive 2001/18/EC, *supra* note 1, Article 13 and Annexes III and IV.

33 *Ibid.*, Article 13(2).

34 *Ibid.*, Annex II.

35 The assessment reports shall be established in accordance with the guidelines laid down in Annex VI of Directive 2001/18/EC.

36 Directive 2001/18/EC, *supra* note 1, Article 15(2).

37 The standard procedure provides for a conciliation phase among the Member States and the European Commission in order to resolve outstanding questions when objections are raised.

38 See Article 18 of Directive 2001/18/EC on the Community procedure in case of objections.

39 EFSA was created in 2002 following Regulation 178/2002/EC of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 L 31/1.

40 EFSA is also consulted, in accordance with Article 28, when the assessment report indicates that the GMO should not be placed on the market.

41 Council Decision 1999/468/EC, see *supra* note 10.

If the draft decision is not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission must submit to the Council a proposal relating to the measures to be taken and inform the European Parliament. The Council of Ministers can adopt or reject the decision by qualified majority.⁴²

If the Council does not act within three months, the Commission shall adopt the decision though.⁴³ If the Council rejects the proposal by qualified majority, the Commission has the obligation to re-examine it. In this case, the Commission has three options, namely to submit an amended proposal to the Council, re-submit the same proposal or present a legislative proposal through the co-decision procedure, on the basis of the Treaty.

Where a favourable decision has been taken, the competent authority that had prepared the assessment report must give consent in writing to the placing on the market. The notifier may proceed with the placing on the market of the product only after the written consent has been received and in conformity with any conditions set out in that authorisation. Directive 2001/18/EC includes provisions for the renewal of consents, according to certain criteria.

The Community-wide approach applied to decision making under Part C involves all Member States in making an authorising decision. Every Member State is given the opportunity to prevent an authorisation for placing on the market, although subject to the control of the Community institutions. The national authority to which the initial notification was submitted plays a less important role in the decision-making process than in Part B releases. Nevertheless, this competent authority retains a significant degree of discretion in the ini-

tial stage of the process and a more marginal one at its end,⁴⁴ optimising collaboration between the various competent national authorities.⁴⁵

After a GMO has been placed on the market, Article 20 of the Directive introduces monitoring requirements in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment. A monitoring plan needs to be submitted as part of the application and be implemented in accordance with the consent. A report on the results of the monitoring must also be provided as part of the consent renewal procedure.⁴⁶

Notably, the Directive introduced the requirement that GMOs placed on the market as or in products must be labelled with a statement that 'this product contains genetically modified organisms'. For products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, a minimum threshold may be established below which labelling obligations would not apply. In addition, Article 4 requires Member States to ensure the traceability of GMOs at all stages of their placing on the market. The horizontal Regulation 1830/2003 addresses these requirements in detail, and amends Directive 2001/18/EC.

The Directive tightens the safeguard clause in Article 23, as compared with the former Directive, allowing for limited discretion. A Member State may provisionally restrict or prohibit the use or sale of a GMO on its territory if there is new or additional information affecting the environmental risk assessment on the basis of new scientific knowledge after the consent has been given. Accordingly, the Member State would have to have detailed grounds to consider an authorised GMO to pose a risk to human health or the environment.

Part C of the Directive also introduces mandatory consultation of the public. During the notification process, the public should be informed and have access to the summary notification format, the assessment reports of the competent authorities and the opinions of EFSA. The public can provide comments concerning the summary notification and the assessment report.

3. Supplementary legislation

Over the past few years, the EU has adopted a number of implementing measures to support the opera-

42 Under Directive 2001/18/EC Member States are given more influence as compared to the former procedure envisaged in Council Decision 87/373 (previous comitology decision), where the Council had to act unanimously to amend the Commission proposal, see Francescon, *supra* note 13.

43 Council Decision 1999/468/EC, see *supra* note 10, Article 5.

44 See ECJ, Case C-6/99, *supra* note 20, where the Court of Justice affirmed that the Competent Authority having issued a favourable assessment report to the Commission must issue the consent in writing, allowing the product to be placed on the market. This may not be the case if new information on risks of the specific GMO to human health and the environment becomes available.

45 See *supra* note 14, p. 563.

46 See Lawrence/Kennedy/Hattan, 'New controls on the deliberate release of GMOs', *European Environmental Law Review* 2002, p. 51.

tion of the regulatory framework for GMOs. Two of these measures are specific to Part B of the Directive, (1) a standard format for summary notifications⁴⁷ and (2) a standard format for reports on releases.⁴⁸

Three additional implementing measures are specific to Part C of the Directive, (1) a standard format for summary notifications,⁴⁹ (2) guidelines for monitoring,⁵⁰ and (3) the establishment of a register to record information related to genetic modifications.⁵¹ The sixth measure provides guidelines for environmental risk assessment concerning both Part B and Part C of the Directive.⁵² This latter measure gives guidance on the objectives, general principles and methodology of environmental risk assessments.

Furthermore, in the framework of Regulation 1830/2003 on traceability and labelling, and in relation to Article 19 of the Directive, an additional implementing measure addressing the development and assignment of unique identifiers for GMOs was adopted on 14 January 2004.⁵³ Last but not least, a Recommendation on sampling and detection methods was adopted on 4th October 2004 so as to complete the implementing measures.⁵⁴

4. Overview of experience in implementing the Directive

As mentioned above, the deadline for the transposition of the Directive was 17 October 2002. The whole revised regulatory framework for GMOs only became fully applicable in April 2004,⁵⁵ so that to date there has been only limited experience of its implementation. It is also important to note that as of December 2005, France had not yet transposed the provisions of the Directive into national legislation and other Member States had only done so recently.

Since April 2001, when the Directive entered into force, the Commission has convened regular meetings with the competent authorities (CAs) of the Member States, normally twice a year, in order to exchange views on specific implementation issues. Working groups were established for the purpose of developing the content of the various implementing measures that have been adopted by either the Commission or the Council in the framework of the Directive.

Additional working groups of CAs, under the chairmanship of the European Commission, have been established to address specific issues related to

the implementation of the Directive.⁵⁶ These groups have focused on specific issues such as post-market monitoring, herbicide tolerance, antibiotic resistance marker genes or access to and exchange of information. Moreover, CAs use these meetings to arrive at a common understanding on the implementation of specific articles of the Directive, thus contributing to harmonising its operation across the EU.

According to the 2004 report on the experience of Member States with GMOs placed on the market under this Directive,⁵⁷ between January 2003 and March 2004, 24 Part C applications were submitted. A number of these applications were originally submitted under Directive 90/220/EEC (prior to 17 October 2002) and subsequently were complement-

47 Council Decision 2002/813/EC of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market, OJ 2002 L 280/62.

48 Commission Decision 2003/701/EC of 29 September 2003 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market, OJ 2003 L 254/21.

49 Council Decision 2002/812/EC of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products, OJ 2002 L 280/37.

50 Council Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ 2002 L 280/27.

51 Commission Decision 2004/204/EC of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council, OJ 2004 L 65/20.

52 Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ 2002 L 200/22.

53 Commission Regulation (EC) 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for GMOs, OJ 2004 L 10/5.

54 Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidelines for sampling and detection of Genetically Modified Organisms and material produced from Genetically Modified Organisms as or in products in the context of Regulation (EC) No 1830/2003, OJ 2004 L 348/18.

55 Date when the provisions of Regulation 1830/2003 became fully applicable.

56 See Report from the Commission, *supra* note 31, chapter 3.

57 *Ibid.*

ed by the notifiers as required by Article 35 of the Directive. As of January 2006, there are eight pending applications, whilst five products have been authorised under Part C of the Directive.⁵⁸ The scope of some of the pending applications is restricted to import and processing uses whilst others also include cultivation as a requested use.

Although Part C covers all commercial releases, applications for the placing on the market of GMOs for uses including food and/or feed may be filed for authorisation under Regulation 1829/2003 in line with its 'one door, one key' principle. Hence, as a consequence of this evolving legislative framework, the number of applications under Part C of the Directive has been reduced.

The approval of GMOs for cultivation raises concerns as regards the implementation of coexistence measures and the definition of seed thresholds. Due to the labelling requirements, pollen flow between GM and conventional crops may have economic implications for traditional farmers. In accordance with the subsidiarity principle, the Commission adopted a general framework for the development of national strategies on coexistence in 2003, leaving to Member States the definition and implementation of the necessary management measures.⁵⁹

National approaches to co-existence need to be based on efficient and cost-effective technical guidelines and be fine-tuned to their objective. However, a number of Member States have found the Commission Recommendation on co-existence insufficient and demanded more precise guidelines or legislation. Moreover, several national co-existence measures have been refused by the Commission as disproportionate to their objective and representing a potential barrier to free circulation of authorised GMOs.

Also, in connection with cultivation, thresholds below which adventitious traces of authorised GM seeds in conventional lots do not require labelling still need to be established by the European Com-

mission. Scientific and political consensus in connection with the level of these thresholds seems difficult to attain.

The implementation of the revised regulatory framework has not prevented various environmental and safety concerns to remain, which has led various Member States to invoke the safeguard clause. In relation to Directive 90/220/EEC, the safeguard clause was invoked on nine separate occasions, eight of which were maintained under Article 23 of Directive 2001/18/EC.⁶⁰

In addition, Hungary invoked the safeguard clause in January 2005 in order to prohibit the cultivation of MON 810 on its territory. In June 2005, the Environment Council reached qualified majority against eight proposals to lift the existing bans. As a result, EFSA has been consulted to obtain an updated opinion and the Commission needs to consider whether to submit the same or amended proposals back to the Council or to prepare proposals for adoption through co-decision.

Some Member States have questioned the decision-making process under Part C, considering that final decisions may go against a majority of them. The division of opinions amongst Member States, often polarised either in favour of or against the technology, is leading to the application of the Community procedure to every Part C notification. The subsequent absence of the necessary majority at Council level makes it necessary to send authorisations back to the Commission for adoption.

A Commission report on the implementation and operation of the Directive, according to provisions in its Article 31, is due in 2006. This report will allow the identification of specific areas in the operation of the Directive, where further guidance may be necessary. Moreover, and according to the provisions of the Directive, the Commission will assess the feasibility of various options to further improve the consistency and efficiency of the regulatory framework on GMOs, including a centralised Community authorisation procedure and the arrangements for the final decision making by the Commission.

V. Conclusion

The comprehensive review of the EU regulatory framework for GMOs has addressed the various concerns that had triggered it. As a result, and in

58 See http://europa.eu.int/comm/environment/biotechnology/authorised_prod_2.htm and http://europa.eu.int/comm/environment/biotechnology/pending_products.htm.

59 See Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming.

60 The GMOs, Bt 176, T25 and MON 810 maize and Ms1xRf1 and Topas 19/2 oilseed rape had been authorised for all uses, including cultivation, except for Topas 19/2 (import and processing).

relation to Directive 2001/18/EC, the administrative procedures have been improved, principles for environmental risk assessment harmonised and various operational elements, such as post-market monitoring have been introduced. In parallel, provisions to ensure the traceability and labelling of GMOs and rules on environmental liability have been put in place.

As a result of the introduction of mandatory consultation of EFSA and the establishment of common principles for undertaking environmental risk assessments, the scientific basis for undertaking risk assessments was strengthened, whilst the expert assessment has been separated from the risk management process leading to decisions on GMOs authorisations.

The implementation phase of the regulatory framework will define its performance in practice. Since the Directive only became fully applicable in October 2002 and the complete revised regulatory framework for GMOs in April 2004,⁶¹ the implementation experience is limited so far. Moreover, the transposition of the Directive by Member States has been slow and is not yet completed. In several cases, transposition into national measures has only happened very recently or incorrectly, thus preventing the proper implementation of the Directive.

Taking into account that the Directive provides for a case-by-case analysis of GMOs and introduces a number of discretionary elements in the decision-making process, the implementation phase may allow for the fine-tuning of the policy. Furthermore,

guidance on specific issues is being developed as part of the ongoing operation of the Directive.

Experience so far shows that the Directive, together with the revised wider regulatory framework, has addressed fundamental concerns that should help increase confidence in the legislative framework. Outstanding regulatory issues such as its correct transposition, addressing safeguard clauses and the definition of seed thresholds need further action.

However, decision making under the Directive continues to be very problematic and the resulting decisions have been highly contested. The implementation of the revised regulatory framework has not, so far, removed some of the existing environmental and safety objections and the review has not satisfied public concerns related to ethical and socio-economic considerations, which not only concern the regulatory framework for GMOs but the technology as such.

The ongoing analysis of the implementation of Directive 2001/18/EC and of the complete regulatory framework on GMOs will help to identify areas where additional guidance is necessary. Further improvement to the efficiency of the regulatory framework will also need to be assessed. Nevertheless, in order to address the broader concerns, a wider debate on the role of biotechnology and on how to mainstream its application in line with societal concerns is going to be necessary.

61 See *supra* note 55.

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