Manual of European Environmental Policy

The following pages are a section from the Manual of European Environmental Policy written by the Institute for European Environmental Policy.

The Manual was published by Earthscan/Routledge from 2010 to 2012. It was designed as an on on-line interactive reference work and annual printed versions were also produced.

This section is the text of the Manual as published in 2012. It is therefore important to note the following:

- The contents have not been updated since 2012 and no guarantee is given of the accuracy of the contents given potential subsequent developments.
- The sections include links to external websites (e.g. to legal texts). These links continue to work as long as those links are not broken by those websites.
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The Manual should be cited as follows:

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Genetically modified micro-organisms – contained use

Formal references 90/219/EEC (OJ L117 8.5.90)	Directive on the contained use of genetically modified micro-organisms
proposed 4.5.88 – COM(88)160	
91/448/EEC (OJ L239 28.8.91)	Commission Decision adopting guidelines for classification of GMMOs
94/51/EC (OJ L297 18.11.94)	Commission Directive adaptation to classification of GMMOs – expired
96/134/EC (OJ L31 9.2.96)	Commission Decision amending Decision 91/448/EEC and revising guidelines for classification of GMMOs
98/81/EC (OJ L330 5.12.98)	Council Directive amending Directive 90/219 on the contained use of genetically modified micro-organisms
2001/204/EC (OJ L73 15.3.2001)	Council Decision supplementing Directive 90/219/EEC as regards the criteria for establishing the safety, for human health and the environment of types of GMMOs
Regulation (EC) No 1882/2003 (OJ L 284 31.10.03)	Regulation adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty
2005/174/EC (OJ L 59/20 5.3.2005)	Commission Decision of 28 February 2005 establishing guidance notes supplementing part B of Annex II to Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms
2009/41/EC (OJ L 125 6.5.2009)	Recast of Directive 90/219/EEC
Legal base	Article 192 TFEU (originally Article 130s EEC Treaty)
Binding dates	
Report to the Commission on notification	31 December annually
Formal Compliance 90/219/EEC	23 October 1991
Formal Compliance 98/81/EC	5 June 2000
Formal Compliance 90/219/EEC	23 October 1991
Formal Compliance 98/81/EC	5 June 2000
Report to the Commission on experience with the Directive	1 September 1992 and then every three years
Commission report	1993 and then every three years

Purpose of the Directive

The original Directive 90/219/EC was one of the earliest instruments within a broader system of Community measures regulating the use of genetically modified organisms (GMOs). It was recast as Directive 2009/41/EC, which consolidated all previous amendments but otherwise made no change to the content of the legislation. The Directive primarily involves the use of GMMOs in laboratories for the purpose of teaching, research, development, or non-industrial or non-commercial purposes, etc. It includes the process of genetic modification itself and operations in which such GMMOs are cultured, stored, used, transported, destroyed or disposed of. The Directive establishes a system of risk assessment and control, notification, consent and accident emergency measures. In particular, it is designed to keep workplace and environmental exposure to any GMMO to a minimum.

Summary of the Directive

Under Directive 2009/41/EC, a general obligation is placed on Member States to 'ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the contained use of GMMOs'. Competent authorities must be designated.

'Contained use' and 'GMMOs' were redefined in the amending Directive 98/81/EC. Directive 90/219/EEC divided operations involving the use of GMMOs into type A (small-scale operations for research, teaching, development and non-industrial or non-commercial purposes) and type B (all others); while GMMOs themselves were classified as Group I or Group II according to inherent hazard. Notification procedures were based on the type of the activity and the Group of the GMMO. However, this system was deemed too complex and insufficiently risk-based, and was thus amended by Directive 98/81/EC. The new system removed the Type A/Type B and Group I/Group II classifications and based notification on the outcome of a full risks assessment. GMMOs are exempt from the Directive if they are obtained through certain techniques listed in Annex II (Part A); or where the contained use involves only those types of GMMOs which meet the criteria which are to be listed in Annex II (Part B) before 5 October 2000. Subsequently, these types of GMMOs are to be listed in Annex II (Part C).

Risk assessment and classification
Users are required to carry out an assessment of risks following the principles outlined in Annex III (sections A and B). The assessment is to include consideration of potential harm to human health and the environment and should take account of the severity and likelihood of such effects. Guidance notes to supplement Annex III are to be completed by the Commission by 5 June 2000. A record of the risk assessment must be kept by the user and made available to the competent authority on request or as part of the notification required for that activity.

The risk assessment is to result in a final classification of the contained uses into one of four classes linked to four classes of containment (Article 5). Class 1 covers activities of no or negligible risk, while class 4 comprises high-risk activities. An appropriate level of containment and protective measure is required for each of the four classes as set out in an Annex. The aim is to keep the workplace and environmental exposure to any GMMOs to the lowest reasonably practicable level, so as to ensure a high degree of safety. The containment

and protective measures are to be reviewed both periodically and in the event that they are no longer deemed adequate, or the class assigned to the containment is no longer correct, or if there is any suspicion that the assessment is no longer appropriate in the light of scientific and technological development.

Notification

The notification conditions are set out in Table 1.

The competent authorities are required to examine the notifications for conformity with the Directive's requirements and may ask the user to provide further information or modify the conditions of contained use, including its intended duration.

If users become aware of relevant new information or modify the contained use, they must inform the competent authority and modify their notification(s). Similarly, if the competent authority becomes aware of new information it may require a user to modify the conditions of, suspend or terminate the contained use. Member States may consult groups or the public on aspects of contained use at their discretion.

Table 1. Notification conditions

	First use of premises	**Subsequent use of premises**
Class 1	Notification required, containing information listed in Annex V, Part A.	No notification required but a record of each risk assessment is to be kept and made available to the competent authority on request.
Class 2	Notification required, containing information listed in Annex V, Part B. Use may proceed 45 days after submission of the notification unless the competent authority indicates otherwise, or earlier with the agreement of the competent authority.	Notification required, containing information listed in Annex V, Part B. Use may proceed immediately following notification in the event that previous consent requirements have been satisfied, or applicant may request formal authorization from the competent authority, which must respond within 45 days.
Class 3 and 4	Notification required, containing information listed in Annex V, Part C. Use can only proceed with the written consent of the competent authority which must respond within 90 days.	Notification, containing information listed in Annex V, Part C, and prior written consent required. When the premises have been subject to a previous notification for the same or higher class of use and associated consent requirements have been fulfilled, the competent authority must respond in writing within 45 days.

Emergency and accident provisions

In instances of contained use where failure of containment measures could lead to serious

danger, the competent authority is obliged to see that an emergency accident plan for the protection of human health and the environment is drawn up and the emergency services notified, and that safety information is made available to the public and supplied to 'persons liable to be affected by the accident'. An exception to this is where such an emergency plan has been drawn up under other EC legislation. Member States must also make this information available to 'other Member States concerned'.

In the event of an accident, the user must inform the competent authority immediately and provide essential information. Member States must alert other Member States that could be affected by the accident, and are obliged to collect information for an analysis of the accident and make recommendations for avoiding similar accidents in the future or limiting their effects. The Commission must be informed of any accidents within the scope of the Directive, and is to set up and maintain a register of accidents. Member States must also consult with other Member States likely to be affected by an accident in drawing up and implementing emergency plans, under a procedure which is to be established by the Commission. Member States must ensure that the competent authority organizes inspections to ensure compliance with the Directive by the users.

Reports and information

Member States are to send to the Commission an annual report on the year's notified Classes 3 and 4 contained uses at the end of the year, and a summary report every three years on 'their experience' with the Directive, the first of which was due on 5 June 2003. In turn, every three years starting on 5 June 2004, the Commission is to publish a summary based on the Member States' three-year reports.

The Commission and competent authorities must not divulge confidential information to third parties and must protect intellectual property rights. If notifiers wish to claim confidentiality for any notified information, they must base such a claim on the grounds set out in Article 3(2) of Directive 90/313/EEC and provide full justification. In no case can confidentiality be claimed for the general characteristics of the GMMO, the notifier's name and address, the location of the contained use, its class, the containment measures, or the evaluation of foreseeable effects.

Technical Progress Committee

The Directive provides for the establishment of a committee of national representatives chaired by a Commission representative. The committee is to give its opinion on draft measures submitted by the Commission, which may then adopt them if approved by the committee. These measures include:

- issuing guidance notes on risk assessment;
- adapting the annexes to the Directive to technical progress; and
- including additions to the list of exempted GMMOs at Annex II (part C).

Development of the Directive

Research and development work and operations involving GMOs grew during the 1970s and by the mid-1980s many Member States had established biotechnology advisory committees and guidelines or legislation on the contained use of GMOs. In 1985, the Commission established its Biotechnology Regulation Interservice Committee. The Commission and the Member States

took part in the preparatory work which led to the OECD Council adopting a Recommendation on safety considerations for applications of recombinant DNA. Also in 1986, the Commission published its Communication '*A Community Framework for the Regulation of Biotechnology*' (COM(86)573), which indicated that the Commission would develop Community measures on containment. A draft Directive was published alongside that on deliberate release in May 1988, drawing on the OECD's work for the technical annexes.

The Economic and Social Committee was generally supportive of the proposal, but did urge that 'serious consideration ought to be given as to how to involve the public at large and the social partners and experts in the consultative procedures'. The European Parliament adopted amendments to make the Directive stricter, particularly in the areas of risk assessment and environmental assessment and proposed the introduction of absolute liability for installations undertaking contained use.

The Commission had proposed the Directive under Article 100a of the EEC Treaty but the Council decided in June 1989 that the Directive should be based on Article 130 of the Treaty because 'the main objective was to protect and improve the environment, rather than to achieve the internal market'. The Council thus adopted a 'common orientation' based on Article 130s. The change of legal base meant that the cooperation procedure did not strictly apply but the Council felt that this amendment affected 'the very substance of the proposal' and that the Parliament should therefore be consulted. The Parliament proposed a return to Article 100a and restated some of its earlier amendments, but these were not included when the Directive was agreed by Council in March 1990. The final version included only minor changes to the proposal, including provisions on public consultation, more precise confidentiality parameters and the committee procedure for amending Annexes II–V.

Commission Decision 91/448/EEC adopted guidelines to be used in interpreting the criteria contained in Annex II of Directive 90/219/EEC for classifying Group I GMMOs. Annex II of Directive 90/219/EEC was subsequently amended by Commission Directive 94/51/EC which updated and simplified the criteria used to classify GMMOs in the light of technical progress. Explanatory guidelines to accompany the Directive 94/51/EC were adopted by Commission Decision 96/134/EC.

In 1995, the Commission proposed an amending Directive in the light of scientific experience, with the aim of increasing the flexibility of Directive 90/219/EEC, decreasing bureaucracy and strengthening links between the legislative requirements and the different grade of risks inherent in different activities. The European Parliament put forward a number of amendments to the proposed Directive on both its first reading in March 1997, and its second on 16 June 1998. In particular, Parliament wanted the legal base of the amending Directive changed from Article 130s to 100a and the decision making procedure from cooperation to co-decision under Article 189b in order to give the Parliament greater influence. Although the Commission did not incorporate these amendments to the proposal, it accepted many of the Parliament's other amendments. Council Directive 98/81/EC was finally adopted on 26 October 1998, to be implemented by 5 June 2000. Regulation (EC) No 1882/2003 subsequently amended the Committee procedures introduced in the original Directive.

In February 2005, the Commission adopted Decision 2005/174/EC on establishing guidance notes supplementing part B of Annex II to Directive 90/219/EEC, with the aim to help Member States ensure compliance by users of GMMOs with the EU regulations.

In November 2007 the Commission published a new proposal for a Directive on the contained use of GMMOs (COM(2007)736). The intention of the proposal was to recast Directive 90/219/EEC in order to allow the incorporation of necessary amendments and consolidate the earlier amended texts. Thus inclusion of the adjustment of the comitology procedure was the only new element in the recast Directive 2009/41/EC, which was published in May 2009.

Implementation of the Directive

Information on national legislation transposing Directive 90/219/EEC can be found in the Member States' national execution measures.

In 2007 the Commission released its 5th summary report based on the reports of Member States concerning their experiences with Directive 90/219/EEC on the contained use of GMMOs for the period 2003–2006 (SEC(2007)1636) The report was compiled by the Commission from individual reports submitted by all Member States, with the exception of Greece. It did not include information on the transposition of Directive 98/81/EC into national law, as this is subject of a separate conformity check carried out by the Commission. The conclusions of the report iterated that the number of contained use activities in the EU had been steadily increasing, mainly for research purposes. Though the Directive was generally applied in a similar way by Member States, often different approaches were taken with regard to inspection, public consultation during the authorization procedure and emergency plans. For example, in Denmark and Estonia all activities are inspected, while Austria only carries out spot checks. On the other hand, Cyprus, the Slovak Republic, Slovenia and the United Kingdom have appointed specialist inspectors for the contained use of GMMOs.

Enforcement and court cases

Three cases concerning Directive 90/219/EEC have reached the European Court of Justice.

- C-429/01 27.11.03. This was a judgement against France for failing to correctly transpose Article 14(a) and (b), first subparagraph, third sentence, and Article 19(2) to (4) of Directive 90/219/EEC, and for failing to transpose the provisions of that directive in respect of certain contained use by the Ministry of Defence. Regarding Article 14(a) for example, it was found that the French legislation did not satisfy the requirement of the Article that an emergency plan be drawn up before the commencement of an operation covered under the directive. Regarding Article 14(b), it was found that French legislation did not make emergency plans available to the public. The court however rejected claims that France had failed to transpose Articles 15(1) and (2) and 16(1) of the Directive.

- C-312/95 17.10.96. This was a judgement against Luxembourg for failing to transpose the directive within the required time. Luxembourg did not deny that it had failed to transpose this, but argued that the action should be dismissed due to the complexity of the subject matter. However the court found in favour of the commission.

- C-170/94 29.06.95. This was a judgment against Greece for failing to transpose Directive 90/219/EEC and Directive 90/220/EEC correctly. Greece did not contest the fact that the Directives were not transposed within the required period, but pleaded that it had set up a committee composed of representatives of all the authorities jointly

responsible and of the scientific world in order to draw up two draft decrees for implementing the Directives. However, the court ruled in favour of the Commission.

Three cases concerning Directive 94/51/EC have reached the European Court of Justice.

- C-339/97 16.07.98. This was a judgement against Luxembourg for failing to transpose the directive within the required time. Luxembourg gave the excuse that transposition could not commence until the law transposing Directives 90/219/EEC and 90/220/EEC had been adopted. However, as it is settled case law that a Member State cannot rely on provisions, practices or situations of its own internal legal order to justify its failure to respect the obligations and time-limits laid down by a directive, the court ruled in favour of the Commission.

- C-285/97 16.07.98. This was a judgement against Portugal for failing to transpose the directive within the required time. Portugal had previously argued that Portaria (Implementing Order) No 602/94 of 13 July 1994 was sufficient for transposition, but the Commission later found this not to be the case. Portugal did not deny that it had failed to fulfil its obligations.

- C-343/97 09.07.98. This was a judgement against Belgium for failing to transpose the directive within the required time. Belgium did not deny that it had failed to fulfil its obligations.

Three cases concerning Directive 98/81/EC have reached the European Court of Justice:

- C-325/02 16.10.03. This was a judgement against Luxembourg for failing to transpose part of the directive. Luxembourg claimed that a draft law transposing the Directive would enter into force shortly, but the court found that it had failed to fulfil its obligations.

- C-436/01 13.03.03. This was a judgement against Belgium for failing to transpose the directive within the required time. Belgium did not deny that it had failed to fulfil its obligations.

- C-333/01 13.03.03. This was a judgement against Spain for failing to transpose the directive within the required time. Spain did not deny that it had failed to fulfil its obligations.

Related legislation

The following legislation and policy has a strong interaction with Directive 2009/41/EC:

- Directive 2001/18/EC on the deliberate release into the environment of GMOs.
- Regulation (EC) No 1946/2003 on the transboundary movements of GMOs.
- Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products from GMOs.
- Regulation (EC) No 1829/2003 on genetically modified food and feed.
- Common Agriculture policy and related legislation.