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.

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The Manual should be cited as follows:

Farmer, A.M. (2012) (Editor). Manual of European Environmental Policy. 1043pp. Routledge, London.

Genetically modified organisms: traceability and labelling

Formal references Regulation (EC) No 1830/2003 (OJ L268 18.10.03) proposed 25.7.2001 – COM(2001)182	Regulation concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products from genetically modified organisms and amending Directive 2001/18/EC
Regulation (EC) No 65/2004 (OJ L10 16.1.04)	Commission Regulation establishing a system for the development and assignment of unique identifiers for genetically modified organisms
2004/787/EC (OJ L 348 24.11.04)	Recommendation on technical guidance for sampling and detection of genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003
Legal base 1830/2003	Article 95(1)
Binding dates	
Entry into force 1830/2003	7 November 2003
Entry into force 65/2004	16 January 2004
Articles 1 to 7 and Article 9(1)	16 January 2004
Notification on penalty measures	18 April 2004
Commission report on the implementation of the Regulation, and in particular with regard to Article 4(3)	18 October 2005

Purpose of the Regulation

Within the context of the wider regulative framework on genetically modified organisms (GMOs), this Regulation seeks to provide a framework for the traceability of products consisting of or containing GMOs, and food or feed produced from GMOs, given concerns about their potential impact. The aim is to create a sound basis for the protection of human and animal health, consumer choice and the environment as regards GMOs, by facilitating accurate labelling and monitoring of the effects on the environment and, where appropriate, on health. It also requires the monitoring of appropriate risk management measures including, if necessary, the withdrawal of products. In particular, the Regulation is to build on rules on GM food and feed and on the transboundary movement of GMOs.

Summary of the Regulation

Regulation (EC) No 1830/2003 serves as a harmonization measure and is one of a group of measures regulating GMOs in the Community. It regulates the traceability and labelling of food and feed produced from or with GMOs, as defined in Directive 2001/18/EC, on deliberate release with the view to creating fair and equal conditions for marketing across the Community. Moreover, the harmonized Community framework on labelling is to ensure that accurate

information is available to ‘operators’ and consumers to enable them to exercise their freedom of choice in an effective manner, as well as to enable control and verification of labelling claims. The Regulation also amends Directive 2001/18/EC on the deliberate release into the environment of GMOs.

Labelling and traceability requirements apply to three types of products, if placed on the market in accordance with Community legislation:

- products consisting of, or containing, GMOs;
- food produced from GMOs, that is derived, in whole or in part, from GMOs, but not containing or consisting of GMOs; and
- feed produced from GMOs.

The requirements do not apply to medicinal products for human and veterinary use authorized under Regulation (EC) No 2309/93.

Likewise, the provisions do not apply to adventitious or technically unavoidable traces of GMOs in products intended for direct use as food, feed or for processing below the thresholds established under Articles 12, 24 or 47 of Regulation (EC) No 1829/2003 on genetically modified food and feed.

Traceability under the Regulation means ‘the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market and through the production and distribution chain’. Any measures taken under this Regulation should be established in accordance with Regulation (EC) No 1829/2003.

Before the measures relating to traceability and labelling can be applied, a system for the development and assignment of unique identifiers for GMOs has to be established, taking account of developments in international fora. This has been put in place by Commission Regulation (EC) No 65/2004. A unique identifier is a simple numeric or alphanumerical code which serves to identify a GMO on the basis of the authorized transformation event from which it was developed, and provides the means to retrieve specific information pertinent to that GMO.

Exemptions from the traceability and labelling scheme will apply for the adventitious or technically unavoidable presence of traces of GMOs. The thresholds for these exemptions are introduced in this Regulation by way of reference to two other legal instruments. The first comprises the Regulation (EC) No 1829/2003, where the threshold level has been set at 0.9 per cent and can be lowered through a Regulatory Committee. The second is Directive 2001/18/EC, where the level has also been set by way of amendment by this Regulation at 0.9 per cent. These exemptions generally cover only GMOs that have been authorized in the EU. However, the adventitious or technically unavoidable presence of GMOs that have not been authorized but have benefited from a favourable risk evaluation will be permitted below a threshold level of 0.5 per cent, or lower as set by the Regulatory Committee in accordance with Regulation (EC) No 1829/2003, for a transitional period of three years after the Regulation entered into force.

The Regulation distinguishes between:

- products consisting of or containing GMOs; and
- products produced from, but not actually consisting of, GMOs.

Traceability of products consisting of or containing GMOs

At the first stage of the placing on the market of a product consisting of or containing GMOs, the operator, that is the natural or legal person who places the product on the market, has to ensure that the following information is transmitted in writing to the receiving party:

- that the product contains or consists of GMOs;
- the unique identifier(s) assigned to those GMOs.

At all subsequent stages, operators, that is those receiving the product and passing it on, have to ensure that this information is transmitted in writing to subsequent parties.

In the case of products consisting or containing mixtures of GMOs to be used only and directly as food or feed or for processing, this information may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

Systems and standardized procedures have to be put in place by operators to allow the holding of information and the identification, for a period of five years from each transaction, of the operator by whom and to whom the products have been made available. This does not apply in cases where Community legislation provides for specific identification systems, such as lot numbering for pre-packaged products, as long as the lot number is clearly marked and information about lot numbers is held for the required period of five years from each transaction. It does, however, always apply to the first stage of placing on the market or primary manufacture or re-packaging of a product.

Traceability of products produced from GMOs

When placing products produced from GMOs on the market, operators have to ensure that the following information is transmitted in writing to the receiving party:

- an indication of each of the food ingredients which is produced from GMOs;
- an indication of each of the feed materials or additives which is produced from GMOs; and
- in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

As with products consisting of or containing GMOs, operators have to provide for standardized procedures and information and identification systems, unless other specific identification systems apply.

Labelling

Labelling is required only for products consisting of or containing GMOs, whether pre-packaged or not. It does not apply to products produced from GMOs.

Labels for pre-packaged products have to state that the ‘product contains GMOs’ or ‘contains genetically modified [Name of organism(s)]’. For products which are offered to consumers without pre-packaging, the same words must appear on, or in connection with, the display of the product. These label requirements are independent of other specific requirements on labelling in Community legislation.

Amendment to Directive 2001/18/EC

Regulation 2001/18/EC puts in place the measure on traceability and labelling foreseen under Articles 4(6) and 21(1) of Directive 2001/18/EC on the deliberate release into the environment of GMOs. It thus amends the Directive accordingly and adds the following paragraph on thresholds to Article 21:

'*For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in a proportion no higher than 0,9 % or lower thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable'.*

Unique identifiers

Under Commission Regulation (EC) No 65/2004, which was adopted pursuant to Article 8 of Regulation (EC) No 1830/2003, applicants for the placing on the market of GMOs have to include in their application a 'unique identifier' to be developed for each GMO in consultation with the OECD BioTrack product database, and the Biosafety Clearing-House. This should avoid duplication. The requirement for unique identifiers also applies for all GMOs for which consent for marketing has been granted prior to the Commission Regulation. Consent holders, or where appropriate competent authorities, have 90 days after entry into force of the Regulation to communicate to the Commission, in writing, the details of the new identifier. The unique identifiers have to be communicated to all relevant registers and Clearing-Houses.

Inspection and control measures

Member States have to ensure that inspections and other control measures, including sample checks and testing of a qualitative and quantitative kind, are carried out to ensure compliance with Regulation (EC) No 1830/2003.

Prior to the application of the provisions on traceability and labelling, the Commission, following the procedure referred to in Article 10(3), has to develop and publish technical guidance on sampling and testing, to facilitate a coordinated approach to implementation. In developing this, the Commission is to take account of the work of national competent authorities and the Standing Committee on the Food Chain and Animal Health. The latter was established under Article 58(1) of Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority etc. The Commission also has to consider the work of the Community Reference Laboratory, established under Regulation (EC) No 1829/2003 on genetically modified food and feed.

Moreover, the Commission is to ensure that a central EU register is put in place, containing all available sequencing information and reference material for GMOs authorized for circulation in the EU. It is also to contain, where available, relevant information concerning GMOs which are not authorized in the European Union. All competent authorities in the Member States are allowed access to the register.

In its general work, the Commission is to be assisted by the Regulatory Committee, set up under Directive 2001/18/EC.

Penalties

Member States are to lay down rules on penalties applicable to infringements of Regulation (EC) No 1830/2003 and all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. They have to be notified to the Commission by 18 April 2004. Any subsequent amendment to them has to be notified to the Commission without delay thereafter.

Other provisions

The Regulation provides for a review of its provisions. The Commission has to forward to the European Parliament and the Council a report on the implementation of this Regulation no later than 18 October 2005. In particular, the report should focus on Article 4(3) on the possible replacing of the unique identifier system for certain products. Where appropriate, the Commission is to bring forward a proposal for the review of the Regulation.

Development of the Regulation

The EU recognizes the consumer's right to information and labelling as a tool for making an informed choice. Since 1997, Community legislation has made labelling of GM food mandatory under Regulation (EC) No 258/97 on novel foods and novel food ingredients and Regulation (EC) No 1139/98, later repealed through Regulation (EC) No 1829/2003. This applies to products:

- consisting of GMO or containing GMO; and
- derived from GMO but no longer containing GMO, if there is still DNA or protein resulting from the genetic modification present.

In addition, all GM additives and GM flavourings have to be labelled under Regulation (EC) No 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings. Moreover general labelling rules were set out in Directive 90/220/EEC, later replaced by Directive 2001/18/EC on the deliberate release into the environment of GMOs.

Following considerable controversy about GMOs in the food chain and wider environment, it became clear that measures to strengthen the existing EU framework were necessary to respond to opinions in the Council as well as wider public. In December 2000, the Commission released a working document outlining ways to ensure that GMOs and GM derived products, produced within the EU, are labelled and fully traceable through the supply chain. This was followed, in July 2001, by a proposal (COM(2001)182) for a Regulation laying down a harmonized framework for the traceablity and labelling of GMOs, as foreseen under the then new Directive 2001/18/EC on deliberate release.

During early discussions in the Council in October and November 2002, some of which were transmitted live to the press and public, most Member States supported the main features of the Commission proposal, with some divergence on the detail. In particular, the United Kingdom expressed concern that the proposal went too far, while Austria and Luxembourg argued that it did not go far enough. Regarding the issue of derogations to be granted in the event of adventitious or technically unavoidable traces of GMOs being found in products, opinions were divided, with most Member States preferring to limit derogations to GMOs that had already

been authorized. This issue was only addressed in the preamble of the proposal, and has remained there in the final Regulation, but in an amended form. While considering that a unique code system developed at the international level to identify GMOs would be preferable, the majority of Member States raised the possibility of taking forward the development of such a system in order to avoid excessive delay in implementing a traceability system within the Community.[1]

The same Council meeting also saw a discussion on the question of a moratorium. The President concluded that 'a majority of Member States agreed that there was a link between extending the authorizations (for the deliberate release of GMOs) and a specific regulatory framework with a traceability system and transparent labelling enabling the consumer to make a choice on the basis of clear information'. A *de facto* moratorium on GM approval had been in place in the EU since 1998.

Criticism was levelled at the proposal by the European Economic and Social Committee (EESC). In particular, they criticized the lack of clarity of some provisions, for instance with regard to differentiating products using GMOs in the manufacturing process from products manufactured from GMOs. More clarity was also needed in the case of the liability regime for damage to the environment and to biodiversity, according to the EESC. Moreover, liability for adventitious contamination of organically farmed products, for which, at present, a 0 per cent threshold applies, was still an outstanding issue, which would have to be addressed – the more so because a proposal for a liability Directive did not consider damage by GMOs. The Committee also pointed out that there was a risk that the introduction of new requirements would result in a higher final product cost, which would likely be passed on to the consumer. It, at the same time, underlined that the costs of new technologies should fall on GM producers and products rather than on the traditional products through 'GM free' labelling (2002/C-125/14).

The Parliament in its first reading, in July 2002, broadly supported the proposal. In plenary, the Parliament was not able to agree on some of the more radical amendments which had been tabled by Members of the Parliament's Environment Committee, notably the labelling of meat, milk and eggs obtained from animals fed on GM feed (despite similar if yet unsuccessful suggestions in the Council by the Danish Presidency). However, it adopted 30 amendments to the legislative package, the majority of which did not alter the general thrust of the Commission proposal. These included amendments intended to strengthen reference to the precautionary principle, human health and the environment, as well as the proposal for the drawing up of 'guides to good segregation practice'.. Importantly, the Parliament also included wording that would link the authorization procedure for GMOs with the establishment of the system of unique identifiers by the Commission. The Commission only partially accepted the Parliament's amendments, dropping changes which would rule out tolerance of minute traces of unauthorized but adventitious GM material. Similarly, it overruled an amendment which would require the precise identification (through a unique identifier) of GMOs which are not to be released into the environment. The Commission was of the opinion that these changes would represent a higher cost for the exporter without providing significant benefits in terms of risk management.

Subsequently, the Council, in its first formal reading, tightened the Commission proposal with regard to the information that is to accompany bulk shipments of products containing mixtures of GMOs, and by introducing inspection and control measures for products being held, rather than just for products placed on the market. Importantly, the Council also introduced a review clause which required the Commission to produce a report. The Council, however, disagreed

with half of the Parliament's changes, amongst these amendments extending the period for which information must be kept from five to ten years, and the link between the authorization procedure and the establishment of the system of unique identifiers. Significantly, the Council also rejected (however unsuccessfully in the end) changing the reference to the Regulatory Committee under Directive 2001/18/EC to the Regulatory Committee of the Food Chain and Animal Health established under Regulation (EC) No 178/2002. The Council also introduced, by means of an amendment to Directive 2001/18/EC, an exemption from labelling for GMOs destined for direct processing, provided they are authorized and fall within the 0.9 per cent threshold, or a lower limit established elsewhere.

From an early stage, there had been a debate about the 0.9 per cent threshold for labelling, which is stricter than the 1 per cent threshold established by the existing labelling framework. Environmentalists and the organic farming lobby were concerned that this 'leaves the door open for widespread GM contamination'[2]. Moreover, there were concerns that the coexistence of GM and conventional crops will lead to cross-contamination, allowing consumers 'to choose only between different levels of GM contamination'.

In its second reading, in July 2003, the Parliament did not propose changes to the substance of the legislative text, agreeing with the need for a timely conclusion. They also confirmed the 0.9 per cent threshold. The Commission confirmed all the amendments. On 22 July 2003, the Council finally adopted the proposal, with Denmark, Luxembourg and the United Kingdom voting against. In a statement, the United Kingdom 'maintained that existing Community legislation provides a sound basis for an ordered return to decision-making on the placing on the market of products consisting of or containing GMOs', and that 'the text agreed by Environment Council falls short of satisfactorily meeting criteria' on practicality, enforceability and consistence with international obligations under the Cartagena Protocol. In particular, it criticized the new and lower thresholds, insisting that 'the 1 per cent is the lowest level that can reliably be achieved and detected at present'. The United Kingdom further urged the Community to restart taking decisions under this legislation as soon as possible. In a similar statement, Denmark, in general support of the provisions, stressed the importance of clear compensation rules for GMO damage which include both environmental damage and conventional damage (i.e. damage to property or personal injury). Denmark had tried to obtain the Commission's agreement to submit a proposal for such compensation rules, but was refused[3]. However, in November 2005, the Commission approved a Danish five-year compensation scheme for farmers who experience economic losses due to the presence of GMOs in conventional or organic crops (see Section on GMOs- deliberative use).

In September 2004, the Commission postponed a proposal to agree on a 0.3 per cent threshold referring to further economic impact assessment being required. The 0.9 threshold was also the figure which was used in a new draft Regulation on organic farming, proposed by the Commission in December 2005 (COM(2005)671). In the end, Regulation (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 applied the 0.9 threshold by referring to Regulation (EC) No 1829/2003 on GMOs – food and feed.

Implementation of the Regulation

The Commission is required to produce technical guidance on sampling and testing to facilitate a coordinated approach between Member States. Such guidance has been agreed to by Member States and is expected to enable their inspection and control authorities to operate in a

harmonized manner throughout the EU. In this regard, the Commission published Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of GMOs as or in products in the context of Regulation (EC) No 1830/2003.

The Commission is also responsible for putting in place a central register containing all available sequencing information and reference material for GMOs authorized to be put into circulation in the Community. Authorized products are entered into a public register of GM food and feed which contains detailed information on all authorized GMOs.

The Commission published its first implementation report on the Regulation in May 2006, seven months after the deadline of 18 October 2005 (COM(2005)197). The report, which takes into account views of Member States and a number of stakeholders, including EU and non-EU actors, concluded that the provisions of the Regulation appeared to have been correctly applied. A majority of Member States reported that the Regulation requirements had had positive effects on the provision of relevant information, consumer choice and safety guarantees. On the other hand, international trade in GMOs remained an issue of contention and while some Member States emphasized the need to strengthen controls of imported goods, some trading partners argued for relaxing regulations. The report emphasized that the Regulation had only been in force for a relatively short time and consequently, it was difficult to assess its implementation at that early stage.

The Commission published its second implementation report on Regulations (EC) No 1830/2003 and (EC) No 65/2004 on 17 September 2008 (COM(2008)560). Based on the contributions of 23 Member States and two industry associations, it found that the majority of Member States reported no problems with interpreting the traceability rules for GMOs and considered that they had positive effects regarding labelling and the possibility of making a more informed choice between different products. They also had an impact on the market, leading to an increase in consumer demand for products not containing GMOs. Overall, inspections and control measures were carried out without problems, but national practices varied considerably. No serious infringements were noted, with most infringements concerning non-labelling or insufficient operating procedures for traceability.

Enforcement and court cases

No relevant cases have been concluded in the European Court of Justice

Related legislation

The following legislation and policy has a strong interaction with Regulation (EC) No 1830/2003 on traceability and labelling of GMOs:

- Directive 2001/18/EC on the deliberate release into the environment of GMOs.
- Regulation (EC) No 1829/2003 on GMOs – food and feed.
- Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

Regulation (EC) No 1830/2003 sets up rules on traceability and labelling for all GMOs, including food and feed (see the Section on GMOs – food and feed) and GMOs used for cultivation (see the Section on GMOs – deliberate release). In addition, genetically modified

foodstuff is subject to the general legislation labelling, presentation and advertising of related products.

References

1. EU Council (2001) Environment Council - Luxembourg, 29 October 2001, Reference: PRES/01/372. 29/10/2001.

2. FOE (2002) *EU Agriculture Ministers Confirm GM Labelling: But Threshold Threatens Choice and the Environment*, Press release, 29 November 2002, http://www.foeeurope.org/press/GR_29_11_02_GM_labelling.htm

3 European Council (2003) *Statements to be Entered in the Council's minutes*, 11262/03 ADD1 REV1.