

## **EU Legislation on Genetically Modified Organisms**

The following is a summary with comments of the EU legislation that governs all aspects of genetically modified organisms.

### ***Directive 2001/18 on the deliberate release into the environment of genetically modified organisms***

Directive 2001/18 on the deliberate release into the environment of genetically modified organisms is the main legislation which governs experimental releases and placement on the market. This Directive repealed the earlier Directive 90/220 which had been in place since the early 1990s. The changes made to the Directive tightened up considerably on the manner in which permission for commercial releases of transgenic organisms into the environment could be given, including limiting the life of permits and requiring monitoring of the impact of the organisms on the environment. The Directive provides a step by step approval process on a case by case assessment of the risks to human health and the environment.

### ***Directive on the Deliberate Release into the Environment of Genetically Modified Organisms (2001/18/EC)***

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l\\_106/l\\_10620010417en00010038.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf)

### ***Directive on the Deliberate Release into the Environment of Genetically Modified Organisms (90/220/EEC)***

<http://www.biosafety.be/GB/Dir.Eur.GB/Del.Rel./90.220/PR.html>

### ***Read Articles on Directive 2001/18***

<http://www.shef.ac.uk/bioethics-today/agbiotech/files/agarticles200118.htm>

### ***Directive 98/81 on the contained use of genetically modified micro-organisms***

Directive 98/81 on the contained use of genetically modified micro-organisms regulates the contained use of genetically modified micro-organisms for research and industrial purposes. This Directive repealed the earlier Directive 90/219 on the contained use of genetically modified micro-organisms which was put in place in the early 1990s.

### ***Directive on the contained use of genetically modified micro-organisms (98/81)***

[http://europa.eu.int/comm/environment/biotechnology/pdf/dir98\\_81.pdf](http://europa.eu.int/comm/environment/biotechnology/pdf/dir98_81.pdf)

### ***Directive on the contained use of genetically modified micro-organisms (90/219)***

<http://www.biosafety.be/GB/Dir.Eur.GB/Cont.Use/90.219/PR.html>

### ***Regulation 258/97 on Novel Foods and Novel Food Ingredients governing the marketing of GM foods.***

The Regulation lays out the rules for authorisation and labelling of novel foods including products containing, consisting or produced using GMOs. This current legislation requires that all food in which there are detectable levels of genetically modified DNA or protein must go through the full authorisation procedure before

being placed on the market. Regulation 258/97 requires mandatory labelling to indicate the presence of GMOs. After October 2002, Directive 2001/18 requires that Member States should ensure labelling of GMOs as or in products. Foods produced from GMOs but no longer containing GMO DNA or protein do not have to be labelled if they are "substantially equivalent". Council Regulation 1139/98 concerns the labelling of food or food ingredients from one GM soya and one GM maize variety which were authorised under Directive 90/220, before Regulation 258/97 was in place.

*Regulation 50/2000* lays down the requirements for labelling of food and food ingredients containing additives and flavourings from GM sources.

*Regulation 49/2000* introduces a 1% threshold for the adventitious presence of DNA or protein from GM material in conventional food.

*Regulation 258/97 on Novel Foods and Novel Food Ingredients*

[http://www.biosafety.be/GB/Dir.Eur.GB/FF/258\\_97/258\\_97.html](http://www.biosafety.be/GB/Dir.Eur.GB/FF/258_97/258_97.html)

[http://europa.eu.int/eur-](http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31997R0258:EN:HTML)

[lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31997R0258:EN:HTML](http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31997R0258:EN:HTML)

*Read articles on Regulation No 258/97*

(<http://www.shef.ac.uk/bioethics-today/agbiotech/files/agarticles25897.htm>)

***Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.***

The aims of the Regulation are:

- To ensure a high level of protection of human life and health, animal health and welfare, the environment and consumers' interests in relation to genetically modified food and feed, whilst maintaining the effective functioning of the internal market;
- To lay down Community procedures for the authorisation and supervision of genetically modified food and feed;
- To lay down provisions for the labelling of genetically modified food and feed.

The Regulation lays down procedures on traceability and labelling of GMOs and products produced from GMOs. The labelling legislation extends the labelling requirements to all food and food ingredients produced from GMOs regardless of the detectable presence of DNA or protein within the final food product. The Regulation will require business to transmit and retain information about products that contain or are produced from GMOs at all stages of being placed on the market. The Regulation covers the labelling provisions to all genetically modified food or feed which consist of, contain or are produced from GMOs. It would not matter whether modified DNA or protein was detectable in the food or feed.

*Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.*

([http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexplus!prod!DocNumber&lg=en&type\\_doc=Regulation&an\\_doc=2003&nu\\_doc=1830](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2003&nu_doc=1830))

*Guidelines on the new rules on genetically modified food and feed*  
(<http://europa.eu.int/scadplus/leg/en/lvb/l21154.htm>)

***Regulation 1829/2003 on genetically modified food and feed***

The Regulation covers the labelling provisions to all genetically modified food or feed which consist of, contain or are produced from GMOs. It would not matter whether modified DNA or protein was detectable in the food or feed. There will be a 0.9% threshold for the accidental presence of GM material, below which the labelling of food or feed is not required to declare the presence of GMO's. There will be a 0.5% threshold for the unavoidable presence of GM material not approved for use in the EU, provided it has received a favourable opinion from the EU Scientific Committee.

*Regulation 1829/2003 on genetically modified food and feed*

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_268/l\\_26820031018en00010023.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf)

***Regulation 1946/2003 on transboundary movements of genetically modified organisms***

The Regulation transposes the Cartagena Protocol on Biosafety into EC law. The Regulation requires Member States to take the necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol. The Regulations cover the procedures necessary for the transboundary movement of GMOs, including notification of parties of import, information to the BCH and identification and accompanying documentation standards.

*Regulation 1946/2003 on transboundary movements of genetically modified organisms*

([http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_287/l\\_28720031105en00010010.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf))

***Recommendation 2003/556/EC***

On 23 July 2003 the EC issued guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming. The main objectives behind the Recommendation were:

- No form of agriculture, be it conventional, organic or agriculture using genetically modified organisms (GMOs), should be excluded in the European Union.
- The European Commission considers that measures for coexistence should be developed and implemented by the Member States.

The recommendation introduced the concept of coexistence - that in principle farmers should be able to cultivate the types of agricultural crops they choose, subsidiarity – recognition that European farm are extremely diverse, that decisions must be science based - management measures for coexistence should reflect the best available scientific evidence on the probability and sources of admixture between GM and non-GM crops, proportionality - measures for coexistence should be efficient, cost-effective and proportionate and defined Adventitious presence as: In the context of transgenic crops, the term describes the inadvertent presence of transgenic seeds or other material in conventional and organic crops. In addition, the

Recommendation required member States to look at existing liability regimes and explore the possibility of setting up new specific schemes.

*Recommendation 2003/556/EC*

[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_189/l\\_18920030729en00360047.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_189/l_18920030729en00360047.pdf)