

# Genetically Modified Micro-Organisms: the EU regulatory framework and the new Directive 2009/41/EC on the contained use

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This paper outlines the current European Union legislation regarding biotechnology and specifically the contained use of genetically modified micro-organisms. The first regulation was issued in 1990 and has constantly been updated during the last 20 years. Considering that the act has successively been modified several times, loosing in clarity, the European Union Commission released the new Directive and, following the recast procedure, merged all the previous modification in a unique (and univocal) act. The Directive does not actually represent a legislative innovation, but re-orders the existing matter in a single act. The relevance of the Directive for the industrial and environmental activities is discussed, linking it in the context of the other regulations applicable to the biotechnology research and business.

## 1. Structure of the EU biotechnology legislation.

The European Union regulated, since 1990, four main areas of biotechnology:

- contained use;
- environmental release;
- intellectual property protection;
- transboundary movements.

The legislative initiative is considered by the Commission as part of the policy response to the challenges coming from a new technology. The declared objectives of the policy are an high degree of protection for public health and the environment and to create an unified market for biotechnology (European Commission, 2002, 2006).

The European legislation on biotechnology shows the clear intent to regulate biotechnology as a peculiar “process”, regardless of the specificity of “products”, often under a regime of authorization. Benefits, risks, development opportunities and concerns have been seen, since from the initial stage of legislation definition, in the second half of eighties, as specifically related to the application of a new technology.

### 1.1 Contained use of genetically modified micro-organisms (GMMs)

All the research, industrial and even simple storage activities involving GMMs in which the contact with the population and the environment is avoided, due to a condition of containment (i.e. closed environment), are regulated as “contained use”.

The matter was initially ruled by the Council Directive 90/219/CEE (Council Directive, 1990). Scientific and technical progress, as well as the experience in the application, led to several amendments, mainly represented by the Council Directive 98/81/CE (Council Directive, 1998). The whole matter has recently been resumed in an unique comprehensive text as “DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 on the contained use of genetically modified micro-organisms” (Directive, 2009) . This act cannot be considered a truly new rule, as it simply re-orders the existing ones for clarity and for providing an unique reference.

### **1.2 Deliberate release into the environment of genetically modified organisms (GMOs)**

When a GMO is introduced into the environment, without any precise confinement measure being taken to restrict the contact between this GMO and the population or the environment, the “DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC” (Directive, 2001) applies. As apparent from the title, the directive follows and substitutes a previous one, contemporary of the initial regulation of contained use.

The Directive forecasts the possibilities of “placing on the market genetically modified organisms as or in products” or “carrying out the deliberate release [ ...] for any other purposes than placing on the market within the Community” (actually applied to experimental small scale releases).

Several regulations were added to the Directive to complement it with rules regarding authorizations as food and feed, traceability and labeling, identification, risk assessment, mandatory public information and post market monitoring. The whole matter of this legislation is highly complex and continuously subject to additions and amendments; its adoption is controversial and constantly under scrutiny.

### **1.3 Intellectual property protection.**

The “DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions” (Directive, 1998) is the reference for patenting biotechnological innovation. The European Union here states that the legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of national patent laws, while they must be adapted in order to take adequate account of technological developments involving biological materials. As well as the environmental release of GMOs, both the development and the adoption of the Directive, suffering from long delays in the member states, were very controversial.

### **1.4 Transboundary movements of genetically modified organisms (GMOs)**

Formally derived from the Directive 2001/18, the “REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 July 2003 on transboundary movements of genetically modified organisms“ (Regulation, 2003) represents a transposition of the Cartagena Protocol on Biosafety, entered into force in 2003. The Protocol provides a framework, based on the precautionary principle, for the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and

sustainable use of biological diversity, or pose risks to human health. The Protocol focuses specifically on transboundary movements. In practice, the Regulation applies on any movement of GMOs from the Union to third countries and viceversa.

## **2. The Directive 2009/41/EC on the contained use of genetically modified micro-organisms.**

The legislation on the contained use is founded on the 1990 Directive, as already mentioned above, and since there the basic structure of the whole regulatory matter has never been changed. The reason for issuing a new act can be found in the first “whereas” on the new directive, where it is considered that the initial document has been substantially amended several times and further amendments were to be made. The modality followed is the “recast”, which has led to the repealing of all the previous and indeed numerous, related acts. The recast procedure is based on the “Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts” (Interinstitutional Agreement, 2001), requiring the adoption of a new legal act to incorporate in a single text both the substantive amendments and the unchanged provisions of an earlier act. It applies when substantive amendments were introduced, while the new act should not introduce substantive amendments. In consideration of the recast procedure, member states will probably not need to adopt relevant measures of transposition.

### **2.1 Scope, definitions and field of application.**

The reasons for adopting a Directive and the concerns it should cope with are extensively recorded in the “whereas” of the act. Assuming that the development of biotechnology is such as to contribute to the economic expansion, it is necessary to limit its possible negative consequences for human health and the environment. Appropriate measures, based on a case by case approach, should be adopted to fulfill those goals.

The formal scope of the Directive, as stated in the Article 1, is to lay down “common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment”.

The critical definitions are reported in the article 2. Directly quoting from there:

- “‘micro-organism’ means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture”;
- “‘genetically modified micro-organism’ (GMM) means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination” (details provided in the Annex I);
- “‘contained use’ means any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment”; Articles 3 further defines the field of application by exclusion of certain modification techniques, as stated in the Annex II of the Directive.

## **2.2 Measures and procedures**

The Directive invites member states to ensure that all the appropriate measures are taken to avoid adverse effects on human health and the environment, by assessing the risks that those contained uses may pose. The assessment shall result in the final classification of uses in four classes, from no or negligible risk to activities of high risk. As a consequence, the user shall apply the general principles and the appropriate containment and other protective measures set out in the Annex IV, corresponding to the class of the contained use.

A notification to the competent authorities is required before commencing to use the premises for the first time; this “premise” notification should include detailed technical description of the site, with specific emphasis on measures of containment.

While class 1 contained use may proceed without further notification, first and all subsequent class 2 contained uses need to be notified supplying the information listed in the Annex V. For the first and all subsequent class 3 or class 4 contained uses is compulsory a notification containing the information as above, but the notifier may not proceed without the prior consent of the competent authority, communicating its decision in writing. Two Decisions establishing guidance notes for risk assessment and safety evaluation are available to integrate the Directive (Commission Decision, 2000, 2005).

In any case an emergency plan to cope with possible accidents should be drawn up by the user and the competent authority should organize inspections and other control measures. The competent authority should also take care of an high level of information circulation (other member states, local authorities, public); the Commission shall publish a summary every three years (Commission of the European Communities, 2007).

## **2.3 Interplay with other rules.**

The Directive does explicitly not apply to GMMs which have been placed on the market in accordance with Directive 2001/18/EC. Anyway genetically modified plants and animals which are managed under containment are included in the Directive itself, as evident from the Annex IV, where protective measures for glasshouses and growth-rooms and for activities in animal units are forecasted. About plants, a Working Group was set up in 2008 to address new techniques which are applied in plant breeding and modification of organisms in general, with reference to their attribution to the contained use or the environmental release directives (European Commission Directorate, 2008).

The most relevant and not yet resolved problem of interpretation regards the question whether clinical trials with GMOs fall within the scope of to the contained use or the environmental release directives. In facts some Member States treated trials with GMMs in clinical settings as deliberate release of GMOs, while some others considered the GMM clinical trials as contained use (Commission of the European Communities, 2007; Perseus, 2006).

## **3. Relevance to the industry of the Directive 2009/41/EC**

According to the Commission “Biotechnology brings cleaner and sustainable process alternatives for industrial and agri-food operations. It will for example allow the progressive replacement of non-renewable materials currently used in various industries with renewable resources, however the scope of applications is just at the beginning;” (European Commission, 2006). At the same time “The contribution of industrial biotech to EU economic performance is currently modest, but growing rapidly. In a recent OECD study, it is estimated that biotechnology’s share of chemical production will

increase from under 2% in 2005 to between 9 and 13% in 2010, accounting for \$130-180 billion in value. This implies annual growth rates in the range of 40-50% for bio based chemicals compared to 3% for overall chemical production” (Commission of the European Communities, 2009).

The Directive appears a consolidated and widely applied regulatory tool to support such a development. The Commission states: “The number of contained use activities in the EU is steadily increasing. Most activities belong to risk class 1 or 2 and serve research purposes. On the whole, the Member States apply the Directive in a similar fashion. Different approaches exist with regard to inspection, public consultation during the authorization procedure and emergency plans“ (Commission of the European Communities, 2007). Its rapid and smooth transposition in Member States legislation testifies that the adoption is not raising up the concerns and the often irrational discussion generated by the Directives on environmental release and on protection of biotechnological inventions.

The situation outlined here above applies to contained uses only. A possible further development of industrial biotechnologies in Europe, in terms of environmental releases, like bioremediation, sludge treatments, in field production of chemicals by plants, will be likely to suffer the same problems and the de facto moratorium currently concerning the well established – in the rest of the world – agricultural biotechnologies.

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