

**Dr. Sándor Németh and Stefan Moldovan**

## **THE REGULATION OF GENETICALLY MODIFIED ORGANISMS IN THE EUROPEAN UNION**

### **A) INTRODUCTION**

This article tries to explore the circumstances and conditions under which so-called genetically modified organisms (hereinafter referred to as "GMOs") are dealt with in the European Union. First, the framework under which GMOs are regulated on an EU-level is examined. The EU has adopted Directive 2001/18/EC (hereinafter referred to as the "Directive") in that regard which is based on Article 95 EC and which sets out the preconditions of releasing GMOs into the environment.

It should be noted that, according to Article 2 of the Directive, "organism" means any biological entity capable of replication or of transferring genetic material, whereas "genetically modified organism" means an organism, 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.

In regulating the release of GMOs into the environment, the Directive differentiates between placing genetically modified organisms on the market as or in products within the Community on the one hand and the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community. After setting out the general objectives and some general obligations that the Directive imposes upon Member States, this article will largely follow the structure of the Directive. It is understood that the process of handling GMOs in the European Union are highly technical in nature and that the Directive contains, apart from its Annexes, mostly procedural aspects of the usage. It is therefore not possible to provide a detailed overview in this article, which can by its nature only scratch on the surface of the topic.

Following from the above, it is under the Directive not possible for a member state to generally and entirely prohibit the release of GMOs into the environment. An Austrian state (the Land Oberösterreich) nevertheless attempted to do so by passing legislation to that effect, invoking certain provisions of the EC Treaty as the primary source of EU law. A short abstract of the judgment with the main arguments of the parties and a conclusion shall be provided below.

### **B) THE DIRECTIVE ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS (DIRECTIVE 2001/18/EC)**

#### **I. The objectives and general obligations of the Directive**

The Directive is arranged in three major parts (Parts A, B and C) and the final provisions (Part D). The scientific preconditions and provisions governing the usage of GMOs on the merits are governed by Annexes at the end of the Directive. After the general obligations in Part A (Articles 1-4), Part B sets out the preconditions for the deliberate release

of GMOs for any other purpose than for placing on the market (Articles 5-11). Part C (Articles 12-24) finally contains the more detailed rules governing the placing on the market of GMOs as or in products before concluding with Part D comprising the final provisions.

The aim of the Directive is, pursuant to Article 1, to approximate the legal provisions of the Member States and to protect human health and the environment when carrying out the deliberate release of genetically modified organisms into the environment or when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment. All provisions of the Directive have to be construed in the light of this broadly defined objective when applied to a particular case.

Article 2 contains a host of definitions, importantly the definition of "organism" and "genetically modified organism (GMO)" described above. Pursuant to Article 4 (1), the general obligations of Member States include ensuring that all appropriate measures are taken, in accordance with the precautionary principle, to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs.

Any person shall, according to Article 4 (2), before submitting a notification under part B or part C (the two parts governing the preconditions of placing GMOs on the market or their deliberate release into the environment for any other purposes than placing on the market), carry out an environmental risk assessment. The potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, have to be accurately assessed on a case-by-case basis pursuant to Article 4 (3). This assessment precedes the notification and authorization regime established by the Directive. Some special provisions with respect to genes expressing resistance to antibiotics or gene transfer from GMOs to other organisms which transfer may have adverse effects on human health and the environment are set out in other parts of Article 4 of the Directive.

It is true that the Directive places the Part on the "deliberate release into the environment of GMOs for any other purposes than placing on the market" prior to the Part governing the "placing on the market of GMOs as or in products". For the sake of logic and simplicity, this order shall be reversed in this article.

## II. Placing GMOs on the market as or in products within the Community

The definition "of placing on the market" can again be found in Article 2 of the Directive which contains an array of definitions. Pursuant to Article 2, it means making available to third parties, whether in return for payment or free of charge. This provision contains also a few exceptions to this definition which shall not be discussed at this stage.

The placing of genetically modified organisms on the market is regulated by Articles 13 - 24 of the Directive. Prior to releasing GMOs into the environment, a notification procedure has to be passed through according to Article 13 which contains mostly procedural provisions. Among other things, it sets out that a notification shall be submitted to the competent authority of the Member State where the GMO is to be placed on the market for the first time. This Member State has to examine, without delay, whether the notification is in

accordance with Art 13 (2) of the Directive (regulating what kind of information such notification has to contain) and, once certain conditions are fulfilled, to forward it to the Commission which in turn has to forward it to the competent authorities of the other Member States within 30 days of its receipt. Other minor aspects of the notification procedure shall not be considered here.

The notification referred to above has to contain specific information set out in Annexes III and IV of the Directive which are mostly of scientific nature, for example in connection with the release, the characteristics of the donor, recipient, parental organisms, the vector and the modified organism, interaction with the environment, etc. The details of these Annexes are highly scientific in nature and are not subject to further consideration of this script.

Alongside with the information set forth in Annexes III and IV, Art 13 (2) provides that the notification of the applicant has to contain more elements, for example the conditions for the placing on the market of the product, including specific conditions of use and handling, a proposed period for the consent which should not exceed ten years, a plan for monitoring in accordance with Annex VII of the Directive, a proposal for labeling, etc.

Article 14 of the Directive contains some other provisions with respect to further proceeding once the notification has been received. Upon receipt and acknowledgement of the notification, the competent authority shall examine it for compliance with the Directive and prepare a report on the issue within 90 days. In case the assessment report indicates that the GMO in question should be placed on the market, the competent authority sends its report, together with other specified information, to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States. Likewise, if the assessment report indicates that the GMO in question should not be placed on the market, such report has to be disseminated to the Commission and the competent authorities of the other Member States, albeit under slightly different time schedules.

Some other procedural provisions are included in Article 15 - 24 of the Directive. The standard procedure of the assessment report is laid out in Article 15 of the Directive. Importantly, the consent shall generally be given for a maximum period of ten years starting from the date on which the consent is issued (Article 15 (4)). The other Articles of Part C govern further procedural issues which shall not be considered here.

### III. Deliberate release into the environment of GMOs for any other purposes than placing on the market within the Community

The release of GMOs into the environment for any other purposes than placing on the market is regulated by Articles 5-11 of the Directive (Part B). Article 5 starts off by excluding the applicability of Part B to medicinal substances and compounds for human use consisting of, or containing, a GMO or combination of GMOs. This exclusion stands with the proviso that their deliberate release for any purpose other than that of being placed on the market is authorized by Community legislation which provides - among other things - for a specific environmental risk assessment in accordance with certain Annexes to the Directive, for a specific consent prior to release and some other required elements outlined in Article 5.

The standard authorization procedure is set forth in Article 6 which provides that any person must submit a notification to the competent authority of the Member State within the territory of which the release is to take place before undertaking a deliberate release of a GMO or of a combination of GMOs. This notification shall include a technical dossier supplying the information specified in Annex III necessary for carrying out the environmental risk assessment of the deliberate release of the GMOs, the environmental risk assessment and the conclusions required in Annex II which contains principles for the environmental risk assessment.

The following provisions contain further procedural rules, e.g. differentiated procedures which apply if sufficient experience has been obtained of releases of certain GMOs in certain ecosystems and specific requirements are met. Article 8 refers to the case that the deliberate release of a GMO or of a combination of GMOs is modified or unintentionally changed which could have consequences with regard to risks for human health and the environment after the competent authority has given its written consent. In this case, the notifier shall immediately

- Take the measures necessary to protect human health and the environment;
- Inform the competent authority in advance of any modification or as soon as the unintended change is known or the new information is available; and
- Revise the measures specified in the notification.

The same is applicable if new information has become available on such risks, either while the notification is being examined by the competent authority of a Member State or after that authority has given its written consent.

Finally, the rest of Part B refers to various matters that are mainly of procedural nature, such as consultation of and information to the public, reporting by notifiers and releases, and exchange of information between competent authorities and the Commission. The rest of the Directive (Part D) contains final provisions which are not the subject of this article.

**C) THE JUDGMENT OF THE EUROPEAN COURT OF JUSTICE IN THE CASE LAND OBERÖSTERREICH AND REPUBLIC OF AUSTRIA V COMMISSION OF THE EUROPEAN COMMUNITIES (JOINED CASES C-439/05 P AND C-454/05 P)**

As we have seen above, the Directive contains provisions that subject the release and placing of GMOs on the market to certain conditions. An Austrian state (the Land Oberösterreich) attempted to prohibit certain uses of GMOs by way of legislation which led to the above mentioned judgment of the ECJ rejecting the arguments of the Land Oberösterreich and the Republic of Austria (hereinafter referred to as the "**Appellants**").

**I. Background of the case**

A draft law of the Land Oberösterreich was notified to the Commission, which aimed at prohibiting the cultivation of seed and planting material composed of or containing GMOs and the breeding and release, for the purposes of hunting and fishing, of transgenic animals. A derogation from Directive 2001/18 was supposed to be secured by way of this notification pursuant to Article 95 (5) EC.

Under Article 95 (5) EC, a Member State shall notify the Commission of the envisaged provisions as well as the grounds for introducing them if, after the adoption by the Council or by the Commission of a harmonization measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonization measure. Scientific evidence is therefore the crucial aspect of this provision and is a question of fact to be determined by scientists.

It is submitted that the fulfillment of the conditions of Article 95 (5) EC (and the ability of a Member State to depart from the harmonizing measure) depends on the following elements:

- Existence of new scientific evidence;
- This new scientific evidence relates to the protection of the environment or the working environment;
- Existence of a problem specific to the Member State;
- This problem arose after the adoption of the harmonization measure; and
- The new national provisions have to be based on the new scientific evidence, the Member State introduced such provisions on grounds of the specific problem mentioned above and the Member State has to deem their introduction necessary.

The European Food Safety Authority (hereinafter referred to as 'EFSA') issued an opinion on 4 July 2003, in which it essentially reached the conclusion that that information did not contain any new scientific evidence which could justify banning GMOs in the Land Oberösterreich. The Commission came to the decision that the Republic of Austria had failed to provide new scientific evidence or demonstrate that a specific problem in the Land Oberösterreich had arisen following the adoption of the Directive which made it necessary to introduce the notified measure and that the conditions set out in Article 95(5) EC were therefore not satisfied. The subsequent judgment of the Court of First Instance followed the line of the EFSA and the Commission.

## II. Legal argumentation of the Parties

Apart from complaining about the violation of the right to be heard (which is not the subject matter of this article), the Appellants stated that the Commission did not carry out a complete scientific analysis of the risks, nor did it fulfill its obligation to state reasons. The Appellants further criticized the judgment under appeal in so far as it took as a basis for the absence of a specific problem the fact that it had not been proved that GMOs were present in the Land Oberösterreich. In that respect, the judgment under appeal was, according to the Appellants, inconsistent with the obligation to take as a basis a high level of protection when adopting health, safety, environmental and consumer protection measures on the basis of Article 95 EC.

Apart from referring to the Appellants' complaint about the violation of the right to be heard and certain other moot points, the Commission submitted that the existence of new scientific evidence and protection of the environment are not among the conditions which constitute a specific problem but are placed on an equal footing with that problem. According

to the Commission it follows that *the existence of new scientific evidence relating to the protection of the environment or the working environment and a problem specific to a Member State* are different elements of Article 95 EC and are therefore to be examined separately. In the Commission's view all the conditions laid down in Article 95(5) EC are cumulative, i.e. all the above mentioned elements of Article 95 (5) EC have to be fulfilled if a Member State wishes to depart from a harmonization measure. Accordingly, the Court of First Instance, the decision of which was under appeal in the above mentioned judgment, was right to dismiss the action after finding that the condition relating to the existence of a specific problem had not been fulfilled.

In a similar vein, the Commission was of the opinion that the Appellants *"failed to satisfy the burden of proof imposed on them under Article 95 (5) EC, in so far as they confined themselves to basing their argument on the small size of farms and on the importance of organic production. According to the Commission, it is the existence of an unusual or unique ecosystem, rendering necessary a risk assessment separate from that carried out under Directive 2001/18 for other similar regions in Europe, which, in the context of a specific problem, justifies the derogation from that directive"* (Land Oberösterreich and the Republic of Austria v. Commission). The Commission and, prior to that, the EFSA found that the Appellants failed to adduce the necessary evidence in that regard.

### III. Judgment of the ECJ

The ECJ dismissed the appeal, holding that the Court of First Instance did not infringe Article 95 (5). It clearly pointed out that the conditions contained in Article 95 (5) EC are cumulative in nature and must therefore all be satisfied if the derogating national measures are not to be rejected by the Commission.

With respect to the existence of a problem specific to the notifying Member State, the ECJ followed the line of the Court of First Instance, the Commission and the EFSA in holding that *"the Republic of Austria had not adduced any scientific evidence proving, in particular, the existence of 'unusual' ecosystems"*. The Commission was of the opinion that the Appellants had not shown that there was a specific problem in the territory of the Land Oberösterreich for the purposes of Article 95 (5) EC arising after the adoption of the Directive. *"That decision followed an EFSA opinion which found that there was no scientific evidence demonstrating the existence of a specific problem. That agency took the view that no scientific evidence proving the existence of unusual or unique ecosystems that required separate risk assessments from those conducted for Austria as a whole or in other similar areas of Europe had been submitted"* (Land Oberösterreich and the Republic of Austria v. Commission).

Finally, the Appellants had, by way of a report that they submitted, not furnished any new evidence that was capable of casting into doubt the provisions of the Directive. One of the conditions of Article 95 (5) EC, i.e. the existence of a specific problem, was not satisfied. As the conditions provided for in Article 95 (5) EC are cumulative pursuant to the above considerations, there is no need to further examine the other elements of Article 95 (5) EC if it has been established that one of them is not satisfied. The actions of the Appellants have therefore been dismissed by the ECJ.

## D) CONCLUSION

It can be concluded that GMOs can be released into the environment under the strict conditions specified in the Directive. It is, pursuant to the provisions of the Directive, not possible to prohibit such release altogether. Therefore, the Appellants relied on the more general provisions of the EC Treaty as primary EU law which overrides the more specific provisions of secondary EU law. As the Directive has already been adopted, the Appellants could only rely on Article 95 (5) EC.

The specific conditions of Article 95 (5) EC, pursuant to which Member States may depart from adopted harmonizing measures, are outlined above. The problem of this case was, whether a problem specific to the notifying Member State existed at all. The Appellants should have proved by way of scientific evidence the existence of unusual or unique ecosystems that required separate risk assessments from those of other areas of the European Union. What such unusual or unique ecosystems are in the first place, have to be determined by scientists who, as in many other areas of life sciences law, wield the ultimate power to determine what can and cannot be done. As the small size of farms and the importance of organic production are no sufficient arguments for proving a problem specific to the notifying Member State, the ECJ rendered judgment against the Appellants.

*The contents of this article are intended to provide only a general overview of the subject matter. Specialist advice should be sought for specific matters.*