
ENFORCEMENT OF LEGISLATION ON GENETICALLY MODIFIED ORGANISMS IN THE NETHERLANDS

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SUMMARY

In this paper some data will be presented on the enforcement of the legislation on genetically modified organisms (GMO's) in the Netherlands. So far many offenses have been encountered which are not always easily enforced. The problems with enforcement arise, for instance, from complex procedural aspects of the legislation and several properties of the notification system. From the experience with the Dutch legislation, we think that for the development of future enforceable genetically modified organisms legislations simple procedures, strictly defined notifications or permits and used terminology are of great importance.

1 LEGISLATION ON GENETICALLY MODIFIED ORGANISMS IN THE NETHERLANDS

1.1 General concerns with genetically modified organisms

Genetic modification of organisms is a technique which is widely used to alter the genetic constitution of organisms for, for instance, research purposes, the production of proteins used in the food or pharmaceutical industry and the improvement of agricultural breeds, varieties or strains. Using this technique new organisms may arise which have potential hazards for man or the environment. In order to reduce or manage such potential hazards, specific legislation has been formulated by some competent authorities. The Genetically Modified Organisms Decree pursuant the Chemical Substances Act Genetically Modified Organisms Decree was enacted by the parliament in 1990 and modified in 1993.

However, formulation of legislation does not mean that it's obligations are automatically being observed. Thus the question arises whether the regulations are being fulfilled. And, if they are not, are they enforceable? This article means to give an answer to these questions and to give some recommendations towards those countries that mean to develop regulations on activities with genetically modified organisms.

1.2 Current administrative framework

The objective of the Genetically Modified Organisms Decree is to manage the potential risks associated with activities with genetically modified organisms. The management of potential risks has been enacted by:

- The obligation to apply for a permit for the release of a genetically modified organism into the environment.

- The obligation to notify one's activities with genetically modified organisms under contained use to the authorities. Contained use of genetically modified organisms involves activities with genetically modified organisms within the physical containment of a laboratory, animal facility, glass house or process installation.

A notification or a permit application for working with genetically modified organisms involves highly detailed information on the combinations of genes, vectors and host organisms which are going to be used. Following notification or the appliance for a permit, a risk assessment of potential hazards associated with the activities with these genetically modified organisms is being executed. This risk assessment leads to a set of special precautions that should be taken to lower the risks associated with the use of the genetically modified organisms. As a consequence of this system, the allowed activities are restricted by the gene/vector/host combinations notified. Therefore it is not allowed to use any other gene/vector/host-combination than those notified, even in the case when an unnotified combination could be safely used under the particular safety regime.

So far 28 different companies in the Netherlands have applied for 83 permits to release genetically modified organisms into the environment. Most of these releases involve transgenic plants. For the contained use of genetically modified organisms 175 institutions have done over 1800 notifications. The permitted activities for the contained use of genetically modified organisms deal with very diverse organisms like microorganisms, mammals such as mice or cattle, fish, insects, frogs etc. (See tables 1 and 2)

Table 1. Institutions with Releases of Genetically Modified organisms (GMO's)

Institutions	Contained use of GMO's	Release in the environment
Universities	yes	yes
Hospitals	yes	yes
Research institutes	yes	yes
Polytechnic schools	yes	no
Companies for the improvements of breeds and seed cultivation	yes	yes
Companies with medical or laboratory applications	yes	yes
Large industrial companies	yes	yes
Biotechnological companies	yes	no

Table 2. Permits Issued for Genetically Modified Organisms (GMO's)

Organisms released	Number of permits	Type of permitted activities
Plants:		
• Potato	- 36	- field trial
• Carnation	- 1	- field trial
• Cabbage	- 1	- field trial
• Chrysanthemum	- 2	- field trial
• Cichory	- 5	- field trial
• Swedish turnip	- 1	- field trial
• Rapeseed	- 6	- field trial
• Maize	- 7	- field trial
• Sugarbeet	- 11	- field trial
• Tomatoes	- 2	- field trial
• Carrot	- 1	- field trial
• Sunflower	- 1	- field trial
Other organisms:		
• Human bone-marrow cells	- 1	- gene therapy
• Human somatic cells	- 1	- gene therapy
• Cattle	- 1	- field trial
• Aujeszki virus	- 2	- field trial
• Pseudomonas fluorescens	- 1	- field trial
• GMO waste	- 3	- transport and destruction of waste

2 ENFORCEMENT OF LEGISLATION ON GENETICALLY MODIFIED ORGANISMS IN THE NETHERLANDS

The Main Department Enforcement Environmental Legislation of the Inspectorate for the Environment of the Ministry of Housing, Spatial Planning and the Environment has the responsibility to enforce the Genetically Modified Organisms Decree. So far two scientifically trained people are involved fulltime in the enforcement of the Genetically Modified Organisms Decree.

2.1 Implementation of enforcement activities

Inspections of permits for releases of genetically modified organisms are relatively simple and involve inspection of all enforceable regulations of the permits.

Inspections of institutions, in which contained use of genetically modified organisms take place, is much more complex. This complexity leads to a rather long time which is necessary to prepare the inspector for one inspection. One way to tackle this problem to some extent, is to perform short inspections in which only one small topic of the legislation is inspected.

In general inspections for the contained use of genetically modified organisms deal with compliance to:

- the obligation of notification;
- the obligation of having a biosafety officer;
- rules on furnishing of — or the working procedures; and
- general biosafety rules.

2.2 Enforcement of offenses of the Genetically Modified Organisms Decree

During practically all inspections done so far, offenses have been encountered. Severe offenses are enforced immediately by means of criminal or administrative law. Other offenses are initially enforced by a notification. Upon negligence of this notification or reiteration of the offence, enforcement occurs by means of the criminal or administrative law.

The frequency of offenses of release permits is relatively low, probably due to the conditions of the permits which are easy to fulfil.

The frequency of offenses of the legislation for contained use is much higher. During almost all inspections one to several offenses were identified. Most of these offenses dealt with incomplete notification of activities with genetically modified organisms. A minority of the offenses were observed on the rules concerning furnishing, the working procedures or the availability of a biosafety officer.

So far three criminal lawsuits have been pursued. Two for the release of genetically modified organisms into the environment and one for the contained use of genetically modified organisms. The recording for the release lawsuits were relatively easy, due to the fact that the offenses involved actions that could be checked visually.

The recording for the contained use lawsuit encountered several difficulties in demonstrating the offence. These difficulties arose mainly from:

- the complexity of the procedural aspects of the legislation;
- the lack of administrative obligations;
- the unclear definition of terms used in notifications; and
- the vague delimitation of notifications.

The exact nature of these difficulties are described in the next paragraph. Due to the lack of adequate administrative obligations 16 interrogations had to take place. The lawsuit has cost about half a year of labor of one person and is still under surveillance.

Administrative law is so far considered to be less effective for the enforcement of offenses of the Genetically Modified Organisms Decree. This is due to the relatively long time which is necessary for the execution of the administrative law procedures compared to the time which is needed for execution of the procedures of the Genetically Modified Organisms Decree.

2.3 Problems encountered with inspections and enforceability of the legislation

Although offenses of the Genetically Modified Organisms Decree are frequently detected, the legislation possesses several enforceability problems. There are several causes for the complexity of the inspections and these problems with the enforceability. One of these problems is intrinsic to the topic: genetic modification. The others lie within aspects of the

legislation, such as: the procedures of the legislation, the notification system and the history of the development of genetically modified organism legislation. These causes will be discussed below.

2.3.1 Genetic modification

It is intrinsic to the topic that it is usually impossible to see or measure whether an organism is a genetically modified organism. As a result the inspection whether a permit holder is working within the borders of his license, is a complex task. It involves interviews with researchers, literature research and administrative research. However, for a great deal of information the inspectors are dependent on the cooperation of the permit holder. Therefore, in order to enable inspections genetically modified organism legislation needs specific qualities compared to other legislation.

2.3.2 Complex procedures of the legislation

The legislation means to assess and manage potential risks involved in activities with genetically modified organisms. This risk is determined by use of technical and scientific data and criteria. Different levels of risk involved in activities with genetically modified organisms lead to a different procedure for obtaining a permit. This means that the procedure for working with a "high risk genetically modified organism activity" is more profound than one in case of a "low risk genetically modified organism activity". This has led to a very complex system of procedural categories of genetically modified organism activities with very diffuse and overlapping boundaries and with different obligations per procedural category.

As a result, during inspections much time is used for determining which procedure of the genetically modified organism decree is relevant and whether an offense has occurred or not. Furthermore, if offenses are determined they are often difficult to enforce by criminal law. This is due to the loosely defined procedural categories and the necessity to demonstrate precisely which obliged procedure has been offended.

2.3.3 Properties of the Dutch notification system

The notification system bears at the moment three main problems with enforceability. First of all, notifications are done by (part of) a research project. Hence, an institution may have done over 50 notifications. For enforcement by criminal law one needs to demonstrate that the offense activity with genetically modified organisms does not fall under one of the other notifications done by the institution. One can imagine that this is a very laborious task.

Secondly, the terminology used in notifications is often poorly defined or unclear. As a result, encountered offenses often lead to much debate with the permit holder about whether or not a term gives consent for the offense as seen by the inspectors. As an example, permits often refer to a vector and its derivatives. However, it is not defined when a vector is still considered to be a derivative or when it should be considered as a new vector (and thus a new (changed) license should be applied for).

Thirdly, the notifications result in consent for a very limited range of activities which is a combination of described hosts with certain vectors and inserts. This means that for a good inspection, the inspector has to ascertain that no other than the permitted combinations are being used. However, as stated before, a genetically modified organism can neither be seen, smelled or measured. Thus, in order to be able to inspect whether a permit holder is working within the limits of his permit, there should be very precise administrative conditions in the regulation or permits. These kind of detailed conditions are lacking at the moment in the Dutch

legislation. Such conditions should consider all activities which are being performed within a laboratory and which should be administrated in accordance with a very strict format. This way the inspector will be relatively easily able to see whether there is an illegal situation.

2.3.4 History

Finally, in the period from 1982 until 1993 it was common that institutions with genetically modified organism activities were obliged to notify their activities to an Advisory Board. With the enactment of the modified Genetically Modified Organisms Decree in 1993 the notifications to the advisory board together with the advise on safety precautions which had to be taken, received the status of permits drawn in accordance with the Genetically Modified Organisms Decree. In the period before 1993, however, enforcement of these notifications was virtually absent and compliance was more or less voluntary. As a result these notifications were not established in consideration of possible enforcement and delimitation of the 'old' notifications is poor. To inspect and enforce an undelimited project is a very complex (sometimes impossible) task.

3 CONCLUSION AND RECOMMENDATIONS

The legislation on release as well as contained use of genetically modified organisms is energetically enforced since the modification of the Decree in October 1993. The experiences so far show that enforcement of this law is possible but very difficult. It must be stated that enforcement of intended illegal activities is virtually impossible. Furthermore, enforcement activities require a great amount of expertise and experience with the subject of genetic modification.

Most countries of the world, so far, lack legislation for activities with genetically modified organisms. Due to expansion of activities of biotechnology companies, more and more countries are coming into contact with activities with genetically modified organisms. To avoid possible risks of these activities development of some sort of specific legislation is inevitable. As described earlier, the enforcement difficulties of the Genetically Modified Organisms Decree in the Netherlands are connected with several aspects. These aspects involve the legislation itself, the way it's been implemented and the history from which it descends. Based on our experience we would like to bring the following points of interest and recommendations under the attention of those who want to develop a genetically modified organism legislation.

3.1 Whether to have formal legislation or voluntarily observed guidelines

The problems with enforcement of the Genetically Modified Organisms Decree may partially result from the fact that compliance of the contained use legislation in the years before 1993 has been regarded as more or less voluntary. As a result issues concerning enforceability of the contained use legislation have until then not been taken into consideration.

First of all, we would like to suggest that one should make a very clear decision on the desirability of enforcement of the genetically modified organism regulations to be developed. The actual choice one has to make is whether a formal enforceable legislation will be enacted or a voluntarily observed guideline will be developed. Legislation by itself has no use if it is not enforceable. The desirability of enforcement will influence the outcome of the bill of the genetically modified organism regulations to major extent.

One should bear in mind that, if one wishes to enact enforceable legislation, much effort will have to be invested both by the branch and the legislator. Only a part of this effort will be necessary in case of voluntarily observed guidelines.

If one decides for voluntarily observed guidelines, very good examples for such guidelines may be found in the Dutch legislation and in a set of guidelines which have been formulated by some cooperating countries. If one decides for the development of enforceable genetically modified organism legislation we would like to give some recommendations underneath which, we think, are of great importance.

3.2 Referencing international guidelines

One could also decide to use the internationally developed guidelines as a starting point for the development of national legislation. Such kind of transposition of guidelines for the contained use of genetically modified organisms into enforced legislation has taken place in the Netherlands. The big advantage of such transposition is, of course, that the implementation can take place within a very short time. It is, however, just plain logic that regulations or guidelines which are written from a point of view of voluntariness of the applicant, lack enforceability. One should keep in mind, therefore, that upon transposition of guidelines into formal legislation, a great deal of the guidelines needs to be rewritten into enforceable conditions.

In addition it might be possible that in first instance voluntarily observed guidelines are implemented which later on will be transposed into enforceable legislation. In that case transposition of notifications done under the guideline into formalized notifications may be attractive but will encounter the same kind of enforceability problems as we have in the Netherlands. A solution for this problem without severe administrative burden for applicants could be, for instance, transposition of the voluntary projects into permits connected with a limited validity.

3.3 Tailored administrative conditions

As a consequence of the fact that genetically modified organisms can neither be seen, smelled or measured, there is a greater need for administrative conditions in the genetically modified organism legislation compared to what is normally needed for other legislation. Such administrative conditions will, however, not be welcomed by the applicants, as it will cause a substantial administrative burden. Without those administrative conditions, however, enforcement will be very difficult.

3.4 Specifying conditions and procedures

We recommend that the procedures for notification or permit application are kept as simple as possible. This may lead to a preferable system in which only very few procedures exist which do not relate directly to the potential risks involved with the activity with genetically modified organisms.

Another point of importance is that one should decide very carefully what level of detail is really wanted or needed for permits and notifications. The high level of detail in permits and notifications lead to a rather small permitted range of genetically modified organism activities. The rapid development of new techniques and vector/host systems for genetic modification will easily and rapidly lead to a large variety of new gene/vector/host combinations wanted to be used. Thus, the limited range of permitted activities with genetically modified organisms is in conflict with the intention of science to develop and explore. We believe that the high amount of offenses connected with the notification system in the Netherlands is firmly connected to this conflict.

A solution for this problem might be the development of a system in which the notifications are being done on the level of the specific set of biosafety rules used in the laboratories. The applicant would then only have to notify that they are working under a certain set of safety rules. This would result in a high level of freedom in the activities with genetically modified organisms for which consent has been given. Again as a consequence, an extensive administrative system would be needed for inspection. However, the higher level of freedom might make the burden of the obliged administration more acceptable for the applicant.