

# **Enforcement in the European Union of Genetic Modified Micro-Organisms, Contained Use Activities, and the Efficiency.**

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## **1. Introduction**

Directive 90/219/EC of 23 April 1990 of the European Union (EU) lays down the regulations for handling genetic modified micro-organisms (GMMs) in the case of 'contained use' in the European Union. Countries within the European Union are obliged to implement this directive in their national regulations. The implementation of this European regulation has been done by all of the EU members. Since directive 90/219/EEC is a minimum directive a country may have more stringent requirements than the directive, but not less stringent. So, some countries have adopted the text literally, others have elaborated the directive more in depth, some countries has extended their regulations with other genetically modified organisms than micro-organisms. The countries outside the EU which has adapted his national legislation to the EU directive 90/219/EEC, is Switzerland and Norway.

Besides the implementation of this EU directive, Members States are obliged to enforce these regulations. It turns out to be that there is a major difference in experience of enforcement between the member states in the field of the contained use of GMMs. This article attempts to provide more insight in the efficiency of several enforcement activities and strategies with the aim to increase the efficiency in general of the enforcement activities in the field of GMMs 'contained use'.

The experience in the Netherlands with the enforcement of the national GMMs regulations, contained use, is a point of reference for this article. The dutch experience is compared with the information of the EU inspectors given by means of a questionnaire and personal contacts.

## **2. Cycle of enforcement**

In order to explain the major differences between the countries in experience of enforcement of GMMs regulations, it is important to distinguish several phases in the cycle of development, which also applies to enforcement:

### **1. Recognition of a problem:**

If there are GMMs regulations in place, there is also a need for enforcement.

Some countries nevertheless have little or no experience with the enforcement of GMMs activities or have just begun to organise enforcement in this area.

Other countries have lots of experience with GMMs enforcement and consequently have identified more specific problems that require further attention.

## 2. Formulation of a policy strategy.

In this phase the following items are important:

- I. Unambiguity. The explanation of legislation and regulations has to be consistent. Enforcement measures should be harmonised.
- II. Clearness. Companies and institutions have to know which rules they have to obey and how they have to follow these rules. Furthermore they have to know clearly the consequences in case of non-compliance. An important point is the after-care, to keep an eye on the appointments made during an earlier visit between the inspector and the responsible person.
- III. Verifiability. Companies and institutions should take greater responsibility in checking compliance themselves. This requires, however, an administration that allows verification of these efforts.

In this phase the next items are of importance:

- Analyses of the types of institutions and companies working with GMMs. Certain groups may show differences in compliance and require a different approach or extra attention;
- Analyses of the GMMs regulations. Not all laws and regulations are equally well enforceable. Sometimes further clarifications is needed before rules become enforceable;
- A Checklist. This list can be used to enforce more unambiguously and consequently, see also the general checklist prepared by Germany in the European project 'Contained Used', 1999;
- Measurement of initial compliance (zero-measurement) in order to be able after some time to measure the effect of a certain enforcement strategy.

## 3. Solving the problem.

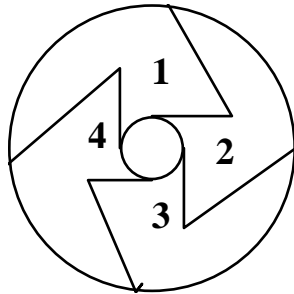
By execution of enforcement activities, compliance with the legal regulations will improve. In this phase it is necessary to use certain instruments of enforcement, for example written warnings, fines, prosecution, etc, to improve the observance of the legal regulations. Furthermore the results of enforcement leading to better compliance should be measured, or be made visible at least.

## 4. Maintenance.

The emphasis in this period is to maintain a certain level of compliance with the legal rules. Important for the Inspectorate in this phase is to check GMMs regulations. Furthermore the inspectors should be alert on new developments in order to react adequately and to find different solutions in changing circumstances. Of importance in this phase is the continuation of the regular control and the identification of new problems, what brings you back to first phase I, 'Recognition of the problem'.

In diagram 1 is expressed in graphic, the several phases of cycles of enforcement.

Diagram 1: **Cycle of Enforcement**



- 1: Recognition of the problem
- 2: Formulation of a policy strategy
- 3: Solving the problem
- 4: Maintenance

### 3. Efficiency versus effectiveness

Confusion sometimes exist about the definition of the words ‘effectiveness’ and ‘efficiency’. Effective means more to the purpose, to reach the goal. Efficiency means more the cost effective way, more suitable. For example:

If you are in sleeping in your bed at night and you get a sting from a fly, you will wake up and want to kill the fly as soon as possible with a newspaper or if need be with your pillow. At that moment you don't worry about the blood on the wallpaper or on your pillow, but your action had direct success. The fly is dead and your action has been effective. But was your action efficient? No, because the next day you have to clean the wallpaper etc. Perhaps it would have been more adequate to open the window that night and to chase the fly away. The next day you would have had no extra work. Such action would have been equally effective but more efficient.

### 4. Regulations of GMMs in the Netherlands, Participants

1) Government or government connected:

- Policy department:

The Minister of the Environment is responsible to prepare regulations and laws in relation to EU Directives on GMMs. This also includes the responsibility for licensing and judging notifications.

- COGEM:

The COGEM (Committee Genetic Modification) is a advisory board for the Minister in GMMs affairs. The COGEM gives scientific advise in matters of risk analysis relating to health and environment. This advice may be focused on individual applications.

- GMMs Office (In Dutch: Bureau GGO):

This office deals with the administrative handling of notifications and applications for a license. The office works under the supervision of the policy

department. Risk-assessment of individual notifications or applications are always checked by this office and for some notifications advice may be asked from the COGEM.

- Inspectorate for the environment:

This Inspectorate is responsible for the enforcement of the GMMs regulations in the Netherlands.

## 2) Contained GMMs users in the NL: Companies, Private research institutes, Universities, Hospitals:

- Licence holder

Though not required by 90/219/EC, in response to almost all notifications in the Netherlands a license is issued which explicitly lays down the general rules for working with GMMs.

The GMMs license is given to the notifier, called licence holder. This licence holder has the overall responsibility for the GMMs activities that are carried out. In most cases the licence holder is not a GMM expert. In the Netherlands the licence holder has to delegate some of his responsibilities to an appointed and recognised GMMs expert, the BSO (Biological safety officer).

- Biological Safety Officer (BSO)

The BSO should be more or less independent of the activities he/she controls and should be granted with sufficient means and power to perform their tasks. The tasks of the BSO are: the preparation of the written instructions and procedures for protection of the workers and the environment, performing internal audits, preparing reports and evaluations. The BSO has other tasks too, like the supervision of the quality of the workers, education of the workers and other people concerned with GMMs, etc.

- Responsible worker (RW)

In most cases the research institutes has just one BSO who has the total supervisions of all the GMMs activities within the company. In big institutes the BSO is not always present on the 'work floor'. So the Responsible Worker is in charge of the daily management and daily research instructions. He has to keep a record of the used constructs (hosts, vectors, inserts). In the Netherlands the BSO and the RW cannot be the same person.

## 5. Enforcement strategy and methods

To trace any violations of the regulations the Inspectorate for the environment may choose from several options in approach:

- Integrate control. In this method the whole company is examined and all GMMs activities are checked in the light of the GMMs legal obligations.
- Partial. In this method only parts of the GMMs legislation is checked and only part of all activities, for example the storage and dispatchment of GMMs waste, the way internal audits are performed by the BSO, or contents of the written instruction, etc.

- Direct. In the Netherlands it is customary that the supervisions are carried out in co-operation with the licence holder or the BSO. In case of direct supervision, this is independent of the licence holder or the BSO. The consequence of direct supervision is that the BSO is feeling less involved and it is more difficult to get the relevant information.
- Indirect. In this situation the relevant activities of the BSO are supervised by the Inspectorate, with the aim to see if the BSO does his work well enough, like for instance internal audits.

As described above, it is relatively easy to control legal activities (with a licence). It is more difficult to trace illegal activities (without a licence), see also the initiative of our Norwegian colleagues in the European project 'Contained Used', 1999. The question is how to trace these illegal activities. There are several methods available, such as:

- Publications. Result of research projects are discussed in the scientific press, in the popular press, on internet, etc. Comparison with scope of the license gives clearness about the status of the GMMs activities, legal or illegal. It should be noted however that it is often quite difficult to prove that illegal work has been done in the Netherlands and not research partners abroad.
- BSO. In the Netherlands the BSO plays a crucial role in case of internal control within the company that has been licenced. In research institutes like Universities the researchers are working quite autonomously. In these situations it is the duty of the BSO to point out to the researchers that they need to notify any new activity or changes in actions, and to point out the consequence if they work without a notification or a licence. Furthermore the BSO carries out internal audits to trace illegal activities and keeps himself informed on the overall research projects.
- Supervision of GMMs supplies. Commercial companies deliver GMMs and restriction enzymes used among others in GMMs-work. By tracing the customers of these supplies it is possible to trace illegal activities.

Supervision of the GMMs regulations can be carried out by the competent authorities. In the Netherlands we have experience with independent consultancy firms too, which can do a lot of the administrative work in the field of the GMMs supervision.

## 6. Questionnaire results

To get a further insight in the culture of the GMMs enforcement within the EU in 1999 a questionnaire has been send to the several GMMs inspectors in the EU. The countries that responded, have been indicated with the numbers 1 to 6. The results can be found in table 1, the amount of time spent in hours is shown in diagram 2.

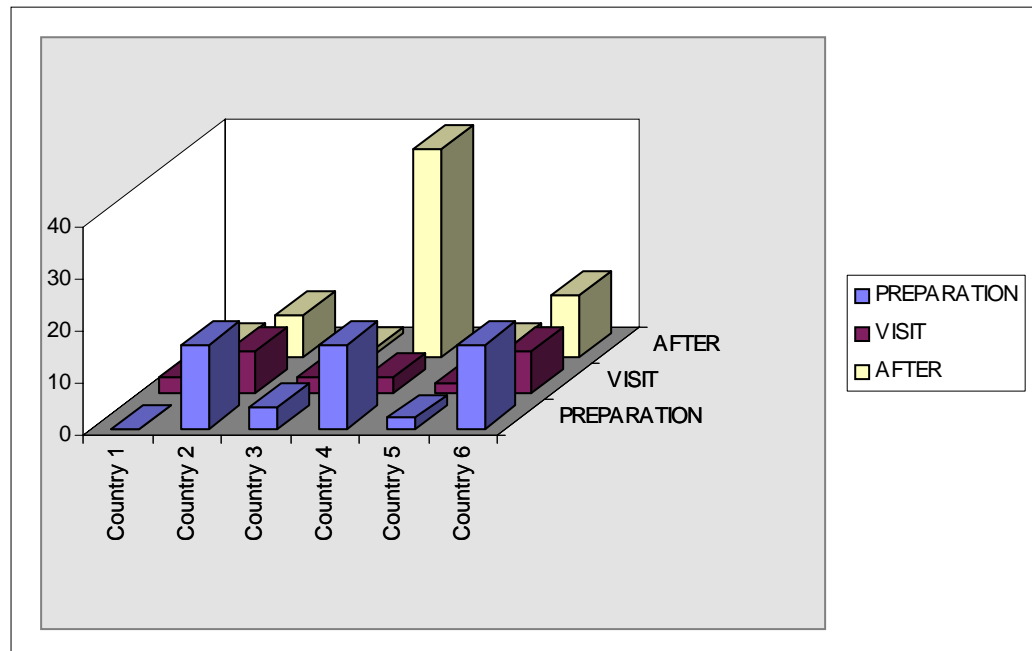
Tabel 1:

**Results of the questionnaire replied by GMMs inspectors of 6 EU countries:**

	(%)	1.	2.	3.	4.	5.	6.
Does a inspection visit comprise:	(%)						
a the entire company		10	0	20	0	10	50
b only individual units/laboratories		90	100	80	100	90	50
c other .....		0	0	0	0	0	0
Do you check:	(%)						
a the administration		0	0	0	20	0	100
b the actual activities		50	100	100	60	100	100
c the ""hardware"" provisions"		0	100	100	10	100	100
d the risk assessment		50	100	100	100	100	0
e other ....		0			0	0	
+ Organisation			100				100
+ qualifications of the employees				100			100
Do you interview	(%)						
a the people who work directly with ggm's			45	0	100	10	0
b the chief of the people who work directly with ggm's		30	100	100	60	100	100
c the biological safety officer		25	100	0	10	100	100
d the head of the company		0	0	0	20	0	30
e other ....		0		0		0	0
+ General Safety Officer and Medical Service			100				
+ Safety Delegate					100		
Is your visit	(%)						
a ad hoc (i.e. based on reported incidents)		30	0	2	0	10	5
b systematically planned in advance		40	100	98	100	90	95
c other		30	0	0	0	0	0
Is your visit announced?	yes	-	0	100	100	100	100
Do you use a checklist?	yes	-	100	100	100	100	100
What action do you take when you notice shortcomings	(%)						
a oral warning		5	100	100	80	100	100
b written warning		90	100	30	0	100	100
c sanctions		5	-	0	0	100	5
d publicity		0	0	0	0	0	2
e other ....		0	0	0		0	0
+ Injunctions					80		
What is the average time required per inspection visit for (hr)							
a preparation		0	16	4	16	2	16
b travelling		2	-	3	8	2	2
c the actual visit		3	8	3	3	2	8
d administrative work afterwards		2	8	1	40	2	12
e other ...		6	0	0	0	0	0
What is the the primary reason for an inspection visit	(%)						
a potential health risk (worker)		50	100	40	90	100	50
b potential environmental risk		20	100	50	10	100	100
c political significance		10	0	0	0	0	5
d reconrol after warning/recidivism		20	0	10	0	100	20
e other .....		0	100	0	0	0	0

Diagram 2:

Average time needed for the preparation of the inspection, the inspection itself, and the after care (in hours):



Out of the results of the questionnaire the following can be concluded:

- Preparation of a visit takes longer than the actual visit. The subsequent inspectors report also takes longer than the actual inspection.
- In most of the situations an inspection is announced previously.
- An inspection takes place at individual laboratory of a company.
- Inspectors in general do use an 'inspection checklist' , that is drafted beforehand.
- During the visit the inspector talks with the head of the research division where 'GMMs' contained use take place. Furthermore the inspector talks with the person who is responsible for biological safety.
- In case of violations of the GMMs regulations the Inspectorate most of the time only uses an oral or a written warning. Most countries have little or no experience to bring the cases to court, or with administrative fines
- The time needed for a visit is between 8 and 67 hours. It is evident however, that this figures are difficult to compare. In the case of 8 hours the legal matters are clearly defined and the visit concerns just one licence without long travelling time. In the case of 67 hours the GMMs regulations in the country are rather new, the inspections are integral. If many illegal activities are observed it will also take more time to give advise about notifications or application for a licence.

## 7. Enforcement of the contained use regulation in the Netherlands

The method of enforcement in the Netherlands in 1999 in the field of contained use of GMMs is determined by the revision of the regulations in the end of 1998. The revised regulation is already anticipating the EU Directive 98/81/EC amending Directive 90/219/EEC. This is accomplished by demanding written safety regulations and procedures. Furthermore it has become obligatory to keep a register of constructs and employees, the result of internal audits etc. In this way it is possible to verify their used hosts, vectors and inserts, and to make conclusions about the quality and the quantity of their internal audits. Also the tasks and the responsibilities of the BSO and the Responsible Worker are legally rooted. The BSO is the primary contact person towards the inspector and is seen by the inspector as the spokesman of the company.

If a BSO does neglect his duty or when he has not enough power, the inspector gives a report to the licence holder about this issue, with the purpose to make the position of the BSO stronger by giving the BSO better facilities or better instructions. In few cases the inspector may require a more competent person in the position of BSO.

In the Netherlands the inspectors use a checklist. This checklist is mostly used as a guideline and a support. With a checklist it is easier to report and to evaluate the results for a typical group of GMMs companies. Furthermore it is an instrument to provide harmonisation in approach between different inspectors and in course of time.

When a serious shortcoming or bigger offence is observed there are several possibilities. The measures taken depend on the seriousness of the offence, and may be influenced by factors like publicity or credibility of the Inspectorate. The principle is that the same shortcoming or offence with different companies leads to the same reaction of the Inspectorate. These principles have laid down in 'Enforcement Strategy for GMMs'.

The sanctions used in the Netherlands to promote compliance are:

- Written warnings;

After a visit there always follows a letter of the Inspectorate with the results of the Inspection. In most cases the offences are less serious. In the letter the date is called when the shortcoming has to come to an end. The after care may consist of a subsequent inspection, or a control of documents that have been send in.

- Penal sum;

The penal sum is only applied in bigger offences which are less easy to stop. In such a case, in a letter of the Inspectorate a term is given in which the offence has to come to an end.

- Withdrawal of the licence;

This measure only is taken in case of a serious offence, and is seen by the licence holder as a very severe measure. It has not been used the last few years.

- Withdrawal of the legal admission of the BSO by the government;

This measure is applied if the BSO neglects his tasks.

- To inform the district attorney;

In case of bigger offences in the Netherlands there will always be written an official report to inform the district attorney. Because of the complexity of the matter, the district attorney mostly also will be contacted personally to provide oral information on the case.

- Publicity;

In order to provide a more general warning the press may be informed. This year a company has planted GMMs without a valid licence, so in consultation with the district attorney press release has been issued.

In a few cases we treat the companies with the idea to inform the press if they are breaking the rules. This treat is enough for the companies to comply.

## 8. Conclusion

From discussions with the EU GMMs inspectors we can conclude that in some countries the GMMs regulations are quite new and that these countries are still in the process of developing a strategy for GMMs enforcement and recognising the problems in enforcement. Other countries already gained much experience in the field of the enforcement of GMMs. Countries that have less experience with enforcement of the GMMs regulation often also have little experience with enforcement in general or at least little contact between these Inspectorates. Countries with experience in enforcement of GMMs regulations do execute their enforcement actions on headlines in similar ways.

So the enforcement in various countries is in different phases of the enforcement live cycle. Apart from that there may be important cultural differences between the countries that may explain differences in enforcement.

From experience of the enforcement of GMMs regulations in the Netherlands, following can be concluded:

Giving the BSO more legal responsibility than is required in the EU regulations will make inspections more efficient. This also holds true for demanding a proper administration with written internal procedures and safety regulations. An important issue in this respect is also the obligation for the BSO to perform internal audits and to report and evaluate these internal controls. This method is seen in the Netherlands as highly effective and highly efficient, it makes the companies more responsible for their own GMMs activities. An proper administration enables verification. This administration makes it possible for the Dutch inspectors to supervise on headlines and only in detail as a check-up on the task of the BSO.

From experience we have learned that it is important to know and further develop the possibilities for sanctions in case you need them. Users should know the possible sanctions, but you should only use these sanctions if it is necessary to hold your credibility.

Furthermore it can be concluded that it is more efficient to inspect a company on specific topics in a rather short time, than to control the company integral. Short and therefore more frequent inspections are more efficient.

Apart from this it is important that the inspector has enough knowledge about GMMs by reading technical literature as reviews etc, so that the inspector will be seen as a GMMs specialist particularly in the field of legislation and enforcement.

*(This article is written under the 'enforcement project directive 90/219, action 11' as agreed in Manchester 1999 and Vienna 2000.)*

