

Post-market monitoring of genetically modified crops in the Netherlands

COGEM advice CGM/050414-03

Commission on Genetic Modification (COGEM)

COGEM's task is to advise the government about the risks of genetically modified organisms (GMOs) and to inform the government about ethical and societal issues associated with genetic modification (Environmental Management Act, Section 2.3)

Summary

Before a genetically modified crop, or GM crop, can be approved for the European market, a number of conditions must be complied with. One of these is that a monitoring plan be compiled. This plan must be suited to detect the possible effects of the GM crop on the environment or human health, after the product has been admitted to the market (known as post-market monitoring).

Implementation of the post-market monitoring plan must guarantee safety for humans and environment. The plan has a dual-purpose design. Its first purpose is to obtain confirmation of the environmental risk assessment drawn up when the crop was admitted to the market, while the second purpose is to ensure that any adverse effects are detected that were not predicted on assessing the GMO.

Specific monitoring, also referred to as Case-Specific Monitoring, is suitable for the first case. The latter case refers to effects that could not be predicted, so General Surveillance will be required.

The precise implementation of post-market monitoring still has to take shape. In particular the subject of General Surveillance gives rise to many questions. With this advice COGEM aims at making a contribution to the debate on post-market monitoring that is currently going on in Europe. The advice will contain recommendations on how post-market monitoring could be realised in the Netherlands.

Case-Specific Monitoring

Case-Specific Monitoring has been set up to verify the hypotheses made in the risk assessment. Realisation of Case-Specific Monitoring requires an approach that does justice to the specific situation. This is because the effects to be expected depend on different circumstances. For instance, there are differences in crop characteristics and introduced properties. In addition, the location of the cultivation area may have an influence. The geographic location of these cultivation areas and the prevailing climate conditions determine aspects like the flora diversity in a certain area. The location may also influence the chance of survival of a crop.

There are no major climate differences within the Netherlands, so the effects will differ little within the Netherlands when cultivating a GM crop. However, as approval of crops is regulated at European level, COGEM is of the opinion that on the subject of compiling the monitoring plan, allowance must be made for the various geographic areas and climatological conditions within Europe.

It is mandatory for the notifier to report the observations from Case-Specific Monitoring to the member state in which the market application has been filed. COGEM is of the opinion that this should be done annually and that the results of the monitoring plan should be evaluated annually. Observing this period

makes it possible to modify the plan and/or the cultivation, if necessary, before the new cultivation season starts.

General Surveillance

General Surveillance has been introduced to be able to observe unexpected effects of the cultivation of GM crops. It is inherently impossible to predict what effect will occur and what the scope of this effect will be. In addition, the setting or population in which these effects could occur is either not or hardly predictable. For this reason, General Surveillance, unlike Case-Specific Monitoring must be set up independent of crop, insert and setting, which makes it basically the same for all GM crops.

Case-Specific Monitoring is approached from the GM crop. The modified crop may cause effects on the environment that deviate from the effects of a non-modified crop and thus be reason enough to start specific monitoring.

Because it is not clear in the case of General Surveillance where the effects might occur, an approach from the GM crop position is not possible. Effects of which the cause is unknown will first have to be observed, meaning that General Surveillance will be observation-based.

A frame of reference can be developed by systematically observing certain areas or species over an extended period of time. COGEM's view is that all observations that deviate significantly from the frame of reference must be included in General Surveillance. The frame of reference will differ depending on the area or the species. If it has been established that the observation deviates significantly from the frame of reference, one must be assess if the deviation is a consequence of the cultivated GM crop and if it causes adverse effects for humans and the environment.

Existing monitoring systems

COGEM advocates the use of existing monitoring systems for carrying out General Surveillance. Since these systems have been in use for many years now, their data can be used to establish a frame of reference for comparison of any observations. In addition, these systems have been designed to make it possible to draw statistical conclusions on any observations made.

Terrestrial nature is currently being monitored with the aid of the national Ecological Monitoring Network (NEM). This network monitors both flora and fauna. The 'Monitoring van de Waterstaatkundige Toestand des Lands' (MWTL) network monitors large aquatic areas in the Netherlands, including rivers and coastal waters. Regional waters are monitored by local monitoring systems. Water boards, provinces and 'Rijkswaterstaat' (the Dutch Directorate-General for Public Works and Water Management) are involved here. The condition of the soil is monitored with the aid of the national Soil Monitoring

Network (NMB). By extending this monitoring network with locations where GM crops are being cultivated, possible effects of the cultivated GM crops on the soil can be observed.

Not only are observations that deviate significantly from the frame of reference interesting to General Surveillance, but deviations observed at local level that from a national point of view do not deviate significantly from the frame of reference, and of which it is suspected that they have been caused by cultivation of GM crops, must also be included in General Surveillance.

Currently there are no monitoring systems for monitoring changes occurring in agricultural areas. GM crop growers can be called in to observe these changes. In addition, bodies that inspect agricultural areas randomly, such as the Plantenziektkundige Dienst (PD) a national service for plant health, the NAK, the Dutch general inspection services, and the Ministry of Agriculture's General Inspection Service (AID), may contribute to General Surveillance.

'Task Force'

If a deviation is found, this does not necessarily mean that it is a consequence of the cultivation of the GM crop. For this reason, the observations made in the framework of the above monitoring systems must be analysed and assessed. In addition, the observations made by the farmers and the employees of the agricultural bodies must be investigated.

For assessing these observations, COGEM advocates setting up a 'Task Force on General Surveillance of GM crops'. The Task Force should be composed of experts, for instance, in the field of monitoring networks, genetically modified crops, soil quality, water quality and nature conservation. These experts should meet at least once a year to assess the relationship between the deviations found and the cultivated GM crops. First of all, they must determine whether the deviation found is actually the result of the cultivation of GM crops. If this cannot be determined directly, they can start a follow-up study to further investigate this relationship.

If it is established that the deviation found was caused by the cultivated GM crop, it will have to be determined whether the effect has also caused adverse effects on humans and the environment. Again the Task Force must assess whether such is the case and, if necessary, may start a follow-up investigation. Every year the Task Force should report their findings to the Ministry of VROM. On the basis of these reports and any relevant advice issued by COGEM, the Netherlands Ministry of Housing, spatial planning and the environment (VROM) can subsequently decide to take appropriate measures.

For 'feeding' the Task Force with ideas, COGEM recommends setting up a secretariat affiliated to the Task Force. This secretariat can also handle the statistically processed data from the monitoring systems and the observations

made by the ‘agricultural organisations’ and farmers for assessment by the Task Force. COGEM is of the opinion that the secretariat and coordination of the Task Force should preferably be accommodated in a research institute such as the National Institute for Public Health and the Environment (RIVM) or Alterra. This because of the available expertise in these institutions in the field of monitoring systems, ecology and genetic modification.

Incidents occurring in the Netherlands involving the environment must be reported to the VROM Incident Desk. This procedure is separate from the above monitoring. If the Incident Desk is of the opinion that there may be a connection between the observed incident and the cultivation of GM crops, COGEM will recommend calling in the Task Force the procedure described above can be accelerated.

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1 Introduction

A number of conditions must be complied with before genetically modified organisms (GMOs) can be released into the environment. These conditions are described in the European Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (1). The Directive covers both field trials and market approvals of GMOs.

A precondition is that the notifier must draw up an environmental risk assessment in which it is demonstrated on scientific grounds that the release of the GMO does not have any adverse effects on humans and the environment. Any adverse effects of a GMO or its application will always be compared in the risk assessment with that of the unmodified organism (known as baseline) from which to GMO has been derived.

If the GMO is presented for market approval, another precondition that has to be complied with is that the notifier draws up a monitoring plan. Just like the environmental risk assessment, this plan must be submitted to the licensing authority. In turn, this authority will seek advice from various organisations such as RIKILT and COGEM.

The monitoring plan must be suitable for detecting the possible effects of the GMOs on the environment or human health, after the product has been admitted to the market (known as post-market monitoring). This way, confirmation must be obtained on the correctness of the environmental risk assessment preceding the market introduction. In addition, allowance must be made for the possible occurrence of potentially adverse effects that were not anticipated on assessing the GMO. Implementation of post-market monitoring must guarantee safety for humans and the environment.

Request for advice

On 24 September 2003, COGEM issued a recommendation addressing the risk aspects of Bt-maize 1507 (2). In this recommendation COGEM commented on the post-market monitoring plan presented. In the opinion of COGEM the monitoring plan was not sufficiently differentiated for the areas where the GM crops were going to be cultivated. In addition, COGEM observed that the monitoring plan was too non-committal. At the time, the notifier indicated in the monitoring plan that farmers were only encouraged to monitor for unanticipated effects. In COGEM's opinion clear arrangements on implementation of monitoring must be made to ensure that implementation does not depend on the willingness on the part of growers.

Further to this advice, COGEM received the following request for advice from the Ministry of VROM: '*COGEM is requested to further detail the above observation and to come to concrete proposals that in COGEM's opinion will*

improve the quality of the files and, consequently, also of the risk assessments of such market applications. COGEM is also requested to compile a detailed proposal for the Post-Market Monitoring plan (PMM)' (3).

With this advice COGEM aims at making a contribution to the debate on the post-market monitoring plan currently operational in Europe. The precise implementation of post-market monitoring still has to take shape. For this reason, this advice will contain recommendations to realise implementation of the monitoring plan for genetically modified (GM) crops.

1.2 Post-market monitoring plan

Annex VII to Directive 2001/18/EC indicates the requirements for a post-market monitoring plan. The Annex describes the general principles that must be taken into consideration when drawing up a post-market monitoring plan. The objectives of the monitoring plan are described as follows in the directive:

- *'confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and*
- *identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment.'*

The purpose of the environmental risk assessment is to identify all potential hazards that could result from cultivation of the modified crop. Starting points and method for an environmental risk assessment are laid down in Annex II to Directive 2001/18, which describes that possible direct and indirect adverse effects of the GMO must be addressed in the environmental risk assessment. There are a number of different steps leading up to this risk assessment that will eventually result in a general risk assessment. Only if cultivation of a crop entails negligibly small risks, can a crop be commercially grown in Europe.

The post-market monitoring plan offers one the possibility to check assumptions regarding potential adverse effects made in the risk assessment. Because the effects have been identified in the risk assessment, specific monitoring can be carried out to verify whether the effects really occur. This is why the directive refers to specific monitoring or Case-Specific Monitoring.

In addition to testing the hypotheses that emerge from the environmental risk assessment, the monitoring plan also aims at identifying unanticipated hazards or risks for the environment. Observing these unanticipated effects is referred to in the directive as General Surveillance.

In the recommendations offered in the following report the Case-Specific Monitoring will be elaborated first, followed by a discussion on how General Surveillance is carried out .

2 Case-Specific Monitoring

As stated previously, Case-Specific Monitoring has been set up to verify the hypotheses that were made in the environmental risk assessment. COGEM is of the opinion that for implementation of Case-Specific Monitoring a case-by-case approach should be observed, because the effects that may occur depend on different factors. For instance, there are differences in crop characteristics and introduced properties. In addition, the geographic location of the cultivation areas may have an influence. The location of the cultivation area and the climate conditions prevailing there determine aspects like the flora diversity in that area and also influence the chances of survival of a crop.

There are no major differences in cultivation conditions in the Netherlands, so the effects will differ little when cultivating a GM crop species. However, as approval of crops is regulated at European level, COGEM holds the opinion that in compiling the monitoring plan, allowance must be made for the various geographic areas and climatological conditions within Europe.

Choice for frame of reference

Before effects can be measured, a frame of reference (known as 'baseline') must first be determined against which the effects of the cultivated modified crops can be tested. It will be clear that the frame of reference outside the field will differ from that in the field. Existing agricultural practices can be used for the frame of reference in the field.

For the frame of reference for non agricultural areas, data collected by several monitoring systems, in many cases for a substantial number of years, can be used. These systems will be discussed further in the next chapter.

Determining parameters

After defining the frame of reference, it is important to select the parameters that have to be monitored. Again, a case-by-case approach should be followed here. At least the parameters must be relevant and practically workable.

In the framework of the COGEM research programme for 2004 a literature study was carried out into the methodology for testing the effects of GM crops on non-target organisms. In future, the results of this study may be used by notifiers to verify hypotheses on the effect of the cultivation of GM crops on non-target organisms in Case-Specific Monitoring.

Duration of the monitoring

It is mandatory for the notifier to lay down the planned duration of Case-Specific Monitoring (1). COGEM holds the opinion that one cannot determine in advance how long this period of time will have to be. Again, this must be

based on the results of the environmental risk assessment. If delayed effects are anticipated, monitoring in the field will have to be continued after the cultivation period.

Analysis and reports

Data analysis must be carried out in a scientifically and statistically sound manner. The notifier is responsible for carrying out the monitoring plan and thus for data analysis. However, he/she is not under an obligation to carry out the analysis him/herself (4).

Yet it is mandatory for the notifier to report the observations to the member state in which the market application has been filed. This member state may modify the monitoring plan, if necessary. Still, its implementation will remain the responsibility of the notifier.

COGEM is of the opinion that the results of the monitoring plan should be evaluated annually. Observing this period makes it possible to modify the plan, if necessary, before the new cultivation season starts. If there is reason to do so, for instance, when adverse have been observed, appropriate measures can be taken.

3 General Surveillance

General Surveillance was introduced to be able to observe unanticipated effects of the cultivation of GM crops. This refers to potentially adverse effects that were not anticipated on assessing the GMO. Determining cumulative and/or delayed effects that were not anticipated, also falls within General Surveillance (4). General Surveillance is aimed at identifying these effects at an early stage.

It is inherently impossible for unanticipated and long-term effects to predict what effect will occur and what the scope of this effect will be. In addition, it is hardly or non-predictable in what setting or population these effects might occur. For this reason, unlike Case-Specific Monitoring, General Surveillance must be set up independent of crop, insert and setting. That makes General Surveillance basically the same for all GM crops.

In the case of General Surveillance it is not clear where the effects could occur, therefore approaching the matter from the GM crop is not possible. Effects of which the cause is not known, will first have to be observed. Then it must be determined whether the observations are related to the cultivated GM crop. That means that General Surveillance is observation-based.

3.1 Approach to General Surveillance

Because unanticipated effects may occur anywhere, COGEM holds the opinion that no species or areas can be excluded in advance from General Surveillance. This means observations will have to be made at a national level. A distinction can be made here between observations in terrestrial and aquatic nature, in which the soil and the agronomic system have a separate position.

Just as with Case-Specific Monitoring, a frame of reference must be defined to be able to measure effects. The frame of reference will differ, depending on the area or the species. A frame of reference can be developed by systematically observing certain areas or species over an extended period of time.

COGEM is of the opinion that all observations that deviate significantly from the frame of reference must be included in General Surveillance.

If a deviation is measured, this does not necessarily mean that it is a consequence of cultivating a modified crop. The GM crops are part of a dynamic ecosystem. Many factors such as air and water pollution, climate change, succession, urban expansion, land development and changing agronomic practices all have their influence on the ecosystem. The majority of the observed changes will either not or not solely be the consequence of the cultivation of GM crops. COGEM expects that in most instances it will not be directly possible to demonstrate a causal relation between cultivation and effect, and that a further study will be necessary.

If the observed deviation has been demonstrated to be the consequence of the cultivated crops, it must be determined whether or not this effect is adverse. Only in the latter case, action has to be taken.

3.2 Monitoring systems

There are various possibilities for observing effects. An integral General Surveillance monitoring system can be set up covering both terrestrial and aquatic nature. Such a system has the advantage of being very comprehensive. However, since it still has to be developed, there will, in most cases, not yet be a frame of reference for comparison of observations made. In addition no GM crops are being currently cultivated in the Netherlands, and it is not certain that this will happen in future. Setting up a new system will certainly take several years. This entails the risk that if no GM crops are going to be cultivated in the Netherlands, an expensive system will have been developed that is not going to be used.

It is also possible to use existing monitoring systems. As in many cases, these systems have been in use for many years now so their data can be used to establish a frame of reference. Moreover, these monitoring systems are already operational, and if it is possible to link up with them, the costs for General Surveillance will remain limited. Some monitoring systems, however, do not cover all areas and species found in the Netherlands. This is because they have not been designed with General Surveillance in mind, but serve other policy purposes. Yet COGEM holds the opinion that they will provide a suitable starting point for General Surveillance. If there is reason to do so, it can be decided to add several areas or species to the systems in future.

On the basis of the above arguments, COGEM believes that for generating data to recognise any deviations from the baseline, the best choice will be to use existing monitoring systems.

The monitoring systems described below are operational in the Netherlands. In the long term, COGEM considers it useful to strive for integration of the Dutch and European monitoring systems in order to realise a European General Surveillance that will make it possible to monitor outside the national borders as well; in this way changes may be signalled at an earlier stage.

Monitoring terrestrial nature

Since 1995, influences on terrestrial nature have been registered with the aid of the Ecological Monitoring Network (NEM). Several groups of species are monitored in this network (Annex 1). The NEM is run jointly by the Ministry of Agriculture, Nature and Food Quality (Ministry of LNV), the Ministry of Transport, Public Works and Water Management (Ministry of V&W) (in

particular, the National Institute for Coastal and Marine Management [RIKZ]) and the Institute for Inland Water Management and Waste Water Treatment (RIZA), the Ministry of Housing, Spatial Planning and the Environment (Ministry of VROM), the National Institute for Public Health and the Environment (RIVM) and Statistics Netherlands (CBS) (5). The government can evaluate their policy and, if necessary, modify it with the aid of the data produced by the NEM.

The data for the NEM are supplied by private data management organisations (PGOs) such as SOVON (Dutch Centre for Field Ornithology), the ‘Vlinderstichting’ (Dutch Butterfly Conservation) the VZZ, the Dutch Society for the Study and Conservation of mammals (see Frame 1). In addition, site managers for Staatsbosbeheer (commissioned by the Dutch government to manage a considerable share of all the nature reserves in the Netherlands), Natuurmonumenten (an independent association for the management and protection of the Dutch landscape, nature areas and cultural heritage) and the Dutch Ministry of Defence, have taken species counts in the framework of the PGO monitoring

Frame 1: PGO monitoring networks

In the Netherlands many private organisations are engaged in collecting and managing ecological data. These so-called PGOs collect the data in a structured manner. Inventories are usually made by volunteers once or several times a year, which makes it possible to distinguish between natural fluctuations and trends in nature. The PGOs monitor specifically for certain species groups. Usually their monitoring networks are independent of each other. These networks are made up of several hundreds or more monitoring locations representative of the entire country. The locations are often relatively small, e.g. several hectares. The numbers of individuals of key species and other species of the species group in question are counted at these locations.

Source: National nature monitoring networks of the NEM in 2002 (14)

networks. Then there are two countrywide networks within NEM that are mainly the responsibility of the provinces (see Annex 1).

The observations generated by the various monitoring networks end up eventually at the CBS. Every year the CBS calculates index figures and trends using a specially developed statistical method (6). The resulting trends and index figures are then used by the end users of the NEM (CBS, RIVM, PGOs and Rijkswaterstaat (Annex 2).

COGEM has noted here that the funding and thus the continuity of the NEM has grown uncertain. In January 2004, the CBS withdrew as sponsor and the Ministry of LNV took over this task. At the moment it is not yet clear in what way the funding of the NEM will be realised in future. A properly functioning NEM will be essential if proper General Surveillance is to be guaranteed. For

this reason, COGEM considers it vital that the funding of the NEM be safeguarded for the future.

Monitoring the soil

Strictly speaking, soil falls in the category of terrestrial nature, However, observing effects in the soil requires a different monitoring strategy than the one described above. For this reason this type of monitoring is discussed separately below.

A large number of processes take place in soil that are important to humankind because of the contribution they make to the provision of food and clean drinking water. Soil organisms such as microorganisms, nematodes, potworms, earthworms, mites and springtails, have an important role in these processes. Microorganisms, in particular, are present in the soil in large numbers. The number of bacteria species in every gram of soil is estimated at 10,000 to 15,000. However, the majority of these species are not known (7). It will be clear that not all changes going on in the soil can be observed. This means a selection will have to be made to be able to measure the soil quality.

Currently running is the monitoring programme using BoBI, the Biological Indicator for Soil Quality for making inventories of soil ecosystems in the Netherlands. This project has linked up with the older Dutch Soil Quality Monitoring Network (LMB) that focuses on the abiotic state of the Dutch soil due to the pH, heavy metal content and the presence of pesticides in the soil. The BoBI, which focuses on biological soil quality (8), is run as a partnership by RIVM, Alterra, Wageningen University and BLGG, a Dutch Laboratory for soil and crop testing.

The LMB (and thus BoBI) has drawn samples from a total of 200 locations over a five-year period. Out of these 200 locations, 39 are situated at arable farms (9,10). Sampling also takes place on dairy farms, at horticultural establishments, bulb growing farms and in forests.

LMB sampling takes place at farm level. Because soil organisms generally spread slowly and have a small radius of action, it is necessary to sample at the location where the GM crop is being cultivated. No GM crops are cultivated on the farms where monitoring is currently taking place. To carry out studies into unanticipated adverse effects of GM crops on the soil, soil samples have to be taken in the field. In this way the data currently produced by the LMB can be used as a frame of reference.

Measuring effects of GM plants can be considered as an extension of the current LMB tasks package. Therefore COGEM advocates of assigning additional locations where measurements can be taken from soil where GM crops are being cultivated. Extending the LMB in this matter will make the way for the implementation of General Surveillance pertaining to soil.

Monitoring aquatic nature

There is currently an extensive network in the Netherlands for measuring any possible changes in water quality. A major part of this network consists of what is known as 'Monitoring van de Waterstaatkundige Toestand des Lands' (MWTL), a collective name for a series of national water monitoring programmes being carried out on commission of RIKZ and RIZA. MWTL is actively applied to the 'large waters' of the Netherlands, including rivers, lakes (e.g. IJsselmeer, Markermeer), transition waters (e.g. Haringvliet, Volkerak) and coastal waters (11).

MWTL comprises three networks; physical, chemical and biological. The physical network aims mainly at water levels, water temperatures and the position and level of coast and seabed. The chemical network measures the presence of substances that are not natural to water systems, such as certain nutrients, heavy metals, and radioactivity. Finally, the biological network measures the essential links in the food chain that are part of the aquatic ecosystem, from single-celled plants such as algae up to birds and seals (12).

In addition to the 'large waters', considerable monitoring of aquatic areas takes place at regional level. For instance, provinces measure the water tables and the Water Boards and the Ministry of Transport, Public Works and Water Management monitor the quality of regional waters. These data might also supply important information for General Surveillance.

Non-significant observations

The above monitoring networks use statistical methods for the interpretation of their data. This is why, in the opinion of COGEM, using existing monitoring networks to detect changes that mean a statistically significant deviation from the baseline, is the best way to implement General Surveillance in the Netherlands.

However, observations that do not mean a significant deviation may also supply interesting information for General Surveillance. In many cases the above monitoring systems have been developed to draw conclusions at a national level. Differences occurring at a local level could be considered negligible for trends calculated at a national level. If the people operating the monitoring networks and agricultural organisations suspect a causal relation between a locally observed non-significant change and locally cultivated modified crops, these observations should also be investigated further.

Monitoring agricultural nature

No specific systems are operational for monitoring agricultural nature in the Netherlands. Yet different parties or individuals may contribute to General Surveillance.

Under Directive 2001/18 it is mandatory for the notifier to immediately report new information on the risks of the modified crops for humans and the environment to the competent bodies. Through contacts with farmers who use his products, the notifier gets a good insight into the effects that occur in Dutch agricultural areas as well as in agricultural areas elsewhere in Europe. In COGEM's opinion this method of collecting information must become part of General Surveillance.

The involvement of growers in the cultivation of the GM crops makes them an obvious choice for involvement in the implementation of General Surveillance. Growers are very well aware of the local situation and they know their own agricultural practice best. That makes them the obvious choice for recognising changes in the field at an early stage.

Some people in Europe suggest that it should be made mandatory for growers to systematically report effects they observe in their fields with the aid of questionnaires. This way one could ensure that all fields are assessed in the same manner.

In Germany studies have been carried out since 2000 into the workability of such questionnaires. Growers of insect-resistant and herbicides-tolerant maize have cooperated in the studies. The studies showed that growers were not opposed to filling in the forms. Since 2000/2001, 101 questionnaires have been analysed, and no adverse effects of GM crops have been reported (13).

COGEM is of the opinion that having the farmers concerned fill in questionnaires could, basically speaking, be a good instrument for commenting on any adverse effects. However, COGEM emphasises that reporting adverse effects could also entail adverse aspects for the grower. Consequently, the grower may be less inclined to report unexpected effects, which would reduce the value of the results from the questionnaire.

Calling in independent bodies such as the Plant Health Department (PD) of the Ministry of LNV, the Dutch General Inspection Service (NAK) of the Ministry of LNV (AID), the VROM Inspectorate and the Rural Areas Department (DLG) may also be an instrument to detect unexpected effects. These bodies randomly inspect farms in the arable and horticultural sectors at random, observing unexpected changes in and around the field. In order to include their observations in General Surveillance, COGEM advocates setting up an Incident Desk where these and other observations can be reported.

3.3 Analysis and assessment

The observations must be analysed in order to determine whether they statistically deviate from the selected frame of reference. After that it will have to be assessed whether the deviations found are: 1) actually due to the effect of the cultivated GM crops and 2) are they harmful?

Currently, data from the monitoring networks are first statistically analysed before they reach the end users. Annual trends are calculated from the data. The statistically processed data from the monitoring networks must be interpreted in a sensible manner to determine what has caused the changes. Non-significant deviations and the observations from agricultural nature must also be explained.

Task Force

COGEM is a proponent of setting up a 'Task Force on General Surveillance of GM crops' for interpreting the observations made. The Task Force should be composed of experts, for instance, in the field of monitoring networks, genetically modified crops, soil quality, water quality and nature conservation. COGEM considers it important that the current end-users of the monitoring networks become members of the Task Force. This is because they have a broad experience with interpreting the data from the monitoring networks. Moreover, this way differences in interpretation of the data can be discussed and reporting of contradictory effects are prevented.

These experts should meet at least once a year to assess the relation between the deviations found and the cultivated GM crops. First of all, they must determine whether the deviation found is actually the result of the cultivation of GM crops. If this cannot be determined directly, they can start a follow-up study to further investigate this relation. Every year the Task Force should report their findings to the Ministry of VROM. On the basis of these reports and any relevant advice issued by COGEM, the Ministry of VROM may subsequently decide to take appropriate measures.

For feeding new ideas into the Task Force, COGEM recommends setting up a secretariat linked to the Task Force (see Figure 3.1). This secretariat can handle the statistically processed data from the monitoring systems and also the observations made by the 'agricultural organisations' and farmers for assessment by the Task Force.

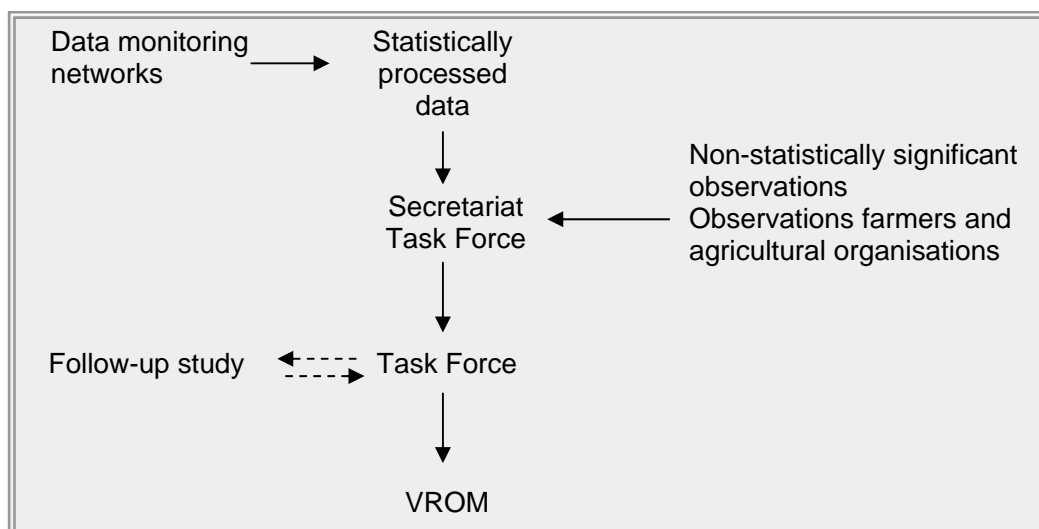


Figure 3.1: Design analysis and assessment data with the aid of Task Force.

COGEM holds the opinion that the secretariat and coordination of the Task Force should preferably be accommodated in a research institute such as the National Institute for Public Health and the Environment (RIVM) or Alterra. These institutes have experience with interpreting the data produced by the current monitoring networks. In addition, they possess the required ecological knowledge to be able to identify the relations between the effects found and their possible causes. Both institutes also have expertise in the field of genetic modification.

What is damage?

If it has been established that the deviations found have been caused by GM crops, it must be determined whether the effect is adverse or causing damage. Measures only have to be taken if the effect found has adverse effects for humans and environment (1).

However, it is not easy to define the concept of ‘damage’, a value-related concept that can be interpreted in various ways. A frequently mentioned definition of environmental damage is that described in European Directive 2004/35/EC on environmental liability with regard to preventing and remedying environmental damage. This directive, the result of 10 years of discussion, is directed to the European protected flora and fauna, aquatic areas and the soil.

COGEM holds the opinion that this definition of environmental damage is too limited in the case of General Surveillance and, consequently, does not suffice. The directive was designed at European level, so that damage to or loss of many (protected) organisms of Dutch flora and fauna are not considered damage. The directive also describes environmental damage only to exist when

there is a adverse effect on human health. Adverse effects on the soil function or soil ecology that do not affect human health are not considered damage.

In order to come to a consensus on the concept of ‘damage’ observed in the framework of General Surveillance, COGEM views this is a problem to be studied by the Task Force referred to earlier.

Incidents

In the unlikely event of extreme deviations, such as a suddenly rapidly declining population size of a certain species, the Incident Desk at VROM should come into play. This procedure is separate from General Surveillance. The Incident Desk comes under the VROM Inspection, staff department Crisis Management. When a report is received by the Incident Desk, the inspectors responsible for GMO inspection (VROM Inspection in the northwest region of the Netherlands) are called in. They in turn can take further action. Currently, the VROM inspection is working on compiling an incident procedure to enable adequate action in the event of an incident.

COGEM recommends that the Task Force be convened if there are indications that the incident is connected with the cultivation of GM crops. Then the procedure described above can be accelerated.

3.4 Conclusions on General Surveillance

COGEM advocates using the existing monitoring networks to implement General Surveillance. This is the best way to detect deviations from the frame of reference. The committee is aware that the systems do not cover all areas and species found in the Netherlands; however, they consider the systems highly suitable as a starting point for General Surveillance. In future it can be decided to add several areas or species to the monitoring networks.

Not only statistically significant observations yield interesting information for General Surveillance, but deviations observed at local level must also be included in General Surveillance. These are deviations that from a national point of view are not significant, but of which it is suspected that they have been caused by local cultivation of GM crops.

Of the monitoring systems active in the Netherlands, NEM is responsible for observation of terrestrial nature in the Netherlands. Aquatic areas are monitored by the MWTL and by regional monitoring programmes. For monitoring the effects on the soil as a result of cultivation of modified crops, new locations will have to be added to the LMB. These locations will have to be situated in the fields where GM crops are being cultivated.

There is no monitoring network available for the agricultural areas in the Netherlands. Growers of modified crops and employees of institutes involved in arable farming and horticulture may find unexpected deviations here.

COGEM is of the opinion that all deviations reported by experts will subsequently have to be interpreted by a Task Force, who will have to determine whether the effect found has been caused by a GM crop and, if so, whether this effect has adverse consequences for humans and the environment.

COGEM recommends setting up a secretariat to provide information to the Task Force. This Task Force can make a first selection of the data generated by the monitoring systems and people involved in agriculture. Both Task Force and secretariat can be accommodated by an institute such as RIVM or Alterra.

If incidents should occur, these must be reported to the Incident Desk at VROM. If the Incident Desk is of the opinion that there is a relation between the observed deviation and the cultivated GM crop, COGEM is in favour of calling in the Task Force.

4 Recommendations

Below are several recommendations by COGEM to realise a further implementation of the post-market monitoring plan.

For Case-Specific Monitoring COGEM recommends:

- observing a strict case-by-case approach for Case-Specific Monitoring since for every new introduction other factors will play a role.
- allowing for the various climatological and geographical settings within Europe when drawing up a monitoring plan.
- having the monitoring plan evaluated every year, which will make it possible to modify the plan, if necessary, before the new cultivation season starts.

For General Surveillance COGEM recommends:

- using the existing monitoring systems to collect data that can be used to determine significant changes compared to the baseline.
- using the Ecological Monitoring Network (NEM) for observing effects on terrestrial nature.
- using the MWTL and regional monitoring programmes for monitoring aquatic areas.
- adding new locations to the LMB to be able to measure the soil quality in relation to genetically modified crops.
- using the organisations involved in arable farming and horticulture for detecting unexpected effects in agricultural areas. Growers of the GM crops may also have a task here.
- setting up a Task Force manned by experts in the field of monitoring networks, GM crops, soil quality, water quality and nature conservation. These experts assess whether the deviations found are the consequence of cultivated GM crops or whether further study is required to determine this relation. They also have to assess whether an effect is harmful.
- setting up a secretariat affiliated to the Task Force. This secretariat receives the processed data from the monitoring networks. In addition, observations can be reported to the secretariat that are not statistically significant at regional level, but of which there is a suspicion that they are related to the cultivation of GM crops. Observations made in agricultural areas can also be analysed here. The secretariat carries out an initial screening and sends on data to

the Task Force if there is a suspicion of a causal relation between the deviation and GM crop.

- accommodating the secretariat and coordination of the Task Force at a research institute such as RIVM or Alterra. This is because of the available expertise in the fields of monitoring networks, ecology and genetic modification at these institutions.
- calling in the Task Force as soon as an incident is reported to the VROM Incident Desk that can be connected to the cultivation of GM crops.

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Annex 1

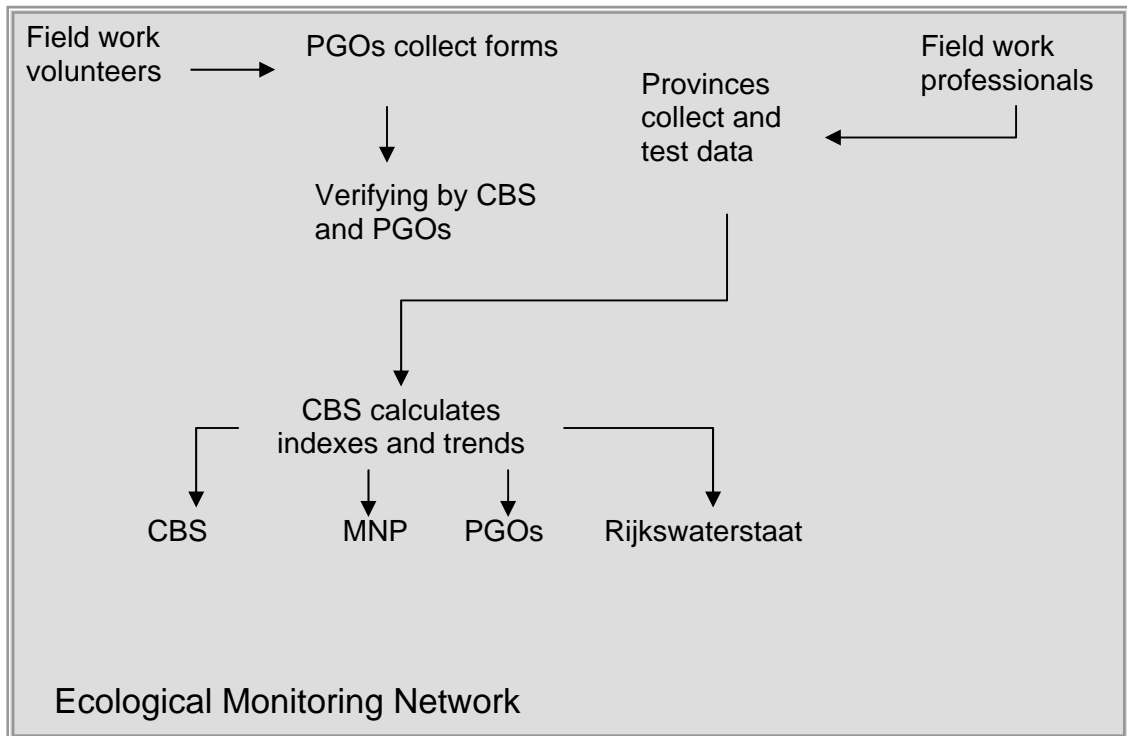
The NEM monitoring networks with their coordinating institutes

<i>Monitoring network</i>	<i>Coordination</i>
Reptiles	RAVON
Amphibians	RAVON
Bats winter count	VZZ
Hares/Day-active mammals	VZZ, SOVON, CBS
Breeding birds	SOVON
Meadow birds	Provinces, SOVON
Rare breeding birds	SOVON, RIKZ
Nesting maps	SOVON
Water birds	SOVON, RIKZ
Diurnal butterflies	Dutch Butterfly Conservation
Dragonflies	Dutch Butterfly Conservation
Flora: Environment & Nature Quality	CBS, Provinces
Lichen	BLWG
Fungi in forests	Netherlands Mycological Society (NMV)

Source: National nature monitoring networks of the NEM in 2002 (14)

Annex 2

Design of the Ecological Monitoring Network



PGO: Private data management organisations
CBS: Statistics Netherlands
MNP: Netherlands Environmental Assessment Agency