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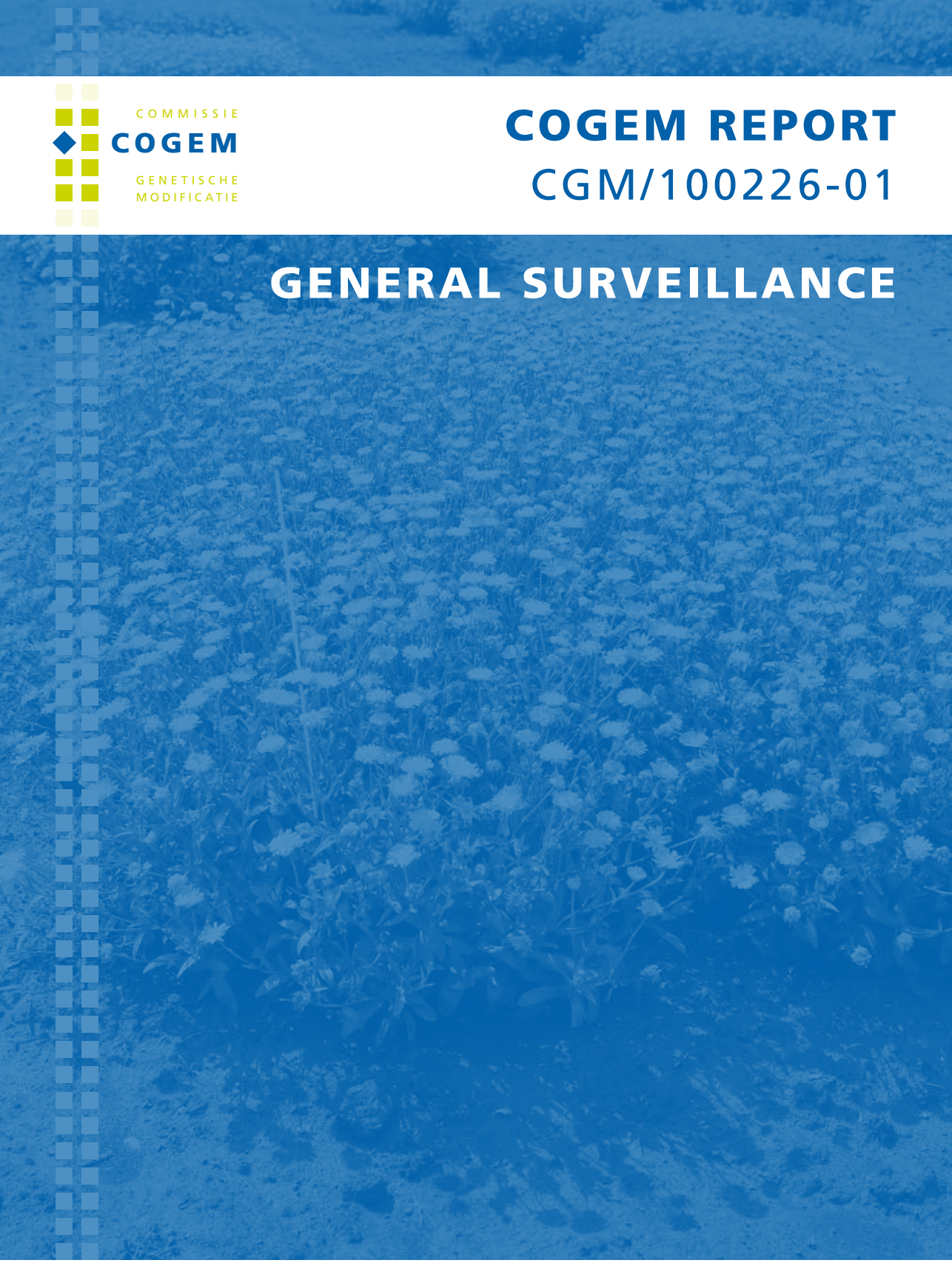
COGEM REPORT
CGM/100226-01

GENERAL SURVEILLANCE



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The Minister of Housing, Spatial Planning and the Environment
Mrs J.C. Huizinga-Heringa
P.O. Box 30945
2500 GX Den Haag

Date: 26 February 2010
Reference: CGM/100226-01
Subject: Submission of the COGEM report on General Surveillance

Dear Mrs Huizinga-Heringa,

Please find enclosed the report on 'General Surveillance'. In this report we examine the requirements for the general surveillance for market authorisation of genetically modified crops.

SUMMARY

In Europe, authorisation holders for GM crops are required to monitor for the occurrence of unanticipated adverse effects from the import and/or cultivation of the GM crop. This is referred to as 'general surveillance'. General surveillance was instituted so that, in case of adverse effects, where appropriate, measures can be taken to protect human health and the environment.
The applicants submit a plan in which they describe how they will carry out this general surveillance requirement. In recent years COGEM has evaluated dozens of these plans. The strategy and methods for general surveillance have now taken on a more definite form and the majority of authorisation holders use the same general surveillance plan.

In this report COGEM describes the aspects of general surveillance which it considers deserve further attention, evaluates how the widely used general surveillance plans for import and for cultivation perform on these points, and identifies which aspects of the plans should be improved. Points for improvement are discussed separately for the general surveillance plans for each type of authorisation (import or cultivation). In addition,

COGEM takes into account whether the crop can be cultivated in the Netherlands and whether the plants can become established in the wild and/or outcross with wild relatives in the Netherlands. The issues raised in this report form the principles that COGEM considers should be followed for general surveillance. COGEM also provides pointers to applicants for improving future general surveillance plans.

The full text of the report is enclosed.

Yours sincerely,

Professor Bastiaan C.J. Zoeteman

Chair of COGEM

c.c. Drs. H.P. de Wijs
Dr. I. van der Leij

COGEM REPORT
CGM/100226-01

GENERAL SURVEILLANCE

Colophon
Design: Avant la lettre, Utrecht
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Translation: Derek Middleton

COGEM provides scientific advice to the government on the risks to human health and the environment of the production and use of GMO's and informs the government of ethical and societal issues linked to genetic modification.

SUMMARY

Applications for consent to import and/or cultivate a GM crop in Europe must satisfy a number of conditions. First, the applicant must prepare an environmental risk assessment in which all potential hazards that could arise from the import or cultivation of the GM crop are identified. GM crops are only authorised in the EU when the risk assessment has shown that the risk of potential adverse effects on human health and the environment are negligible. The applicant must also submit a monitoring plan, which must include a description of how the requirement for 'general surveillance' will be met (general monitoring or general supervision).
General surveillance was instituted to determine whether the GM crop or its use leads to the occurrence of any unanticipated adverse effects on human health or the environment so that remedial measures can be taken if an adverse effect is confirmed. The applicant must draw up a general surveillance plan and is legally responsible for implementing this plan.

COGEM PRINCIPLES FOR GENERAL SURVEILLANCE

As the objective of general surveillance is to identify the occurrence of any unanticipated adverse effects, it cannot be based on any scientific hypotheses about the type, magnitude or location of potential effects. General surveillance therefore consists of monitoring for the occurrence of unanticipated effects. It should be noted that any unanticipated effects may occur anywhere and so it cannot be known in advance how an unanticipated effect will become manifest. This means that in practice it will be difficult to observe unanticipated adverse effects. GOGEM therefore considers general surveillance to be an early warning system for identifying significant unanticipated adverse phenomena that may be caused by a GM crop. If an adverse phenomenon is observed, further study will be needed to establish whether the observed effect is caused by a GM crop.

General surveillance was instituted to identify unanticipated adverse effects on human health and the environment. Organisations with expertise on human health and the environment are best placed to detect any unanticipated effects and should therefore be involved in general surveillance.

COGEM has previously advised that as well as monitoring in individual fields, existing networks should be used to provide nationwide monitoring. In response to this advice, the Dutch government decided to take responsibility for surveillance outside the cultivation areas and to appoint the Netwerk Ecologische Monitoring (Ecological Monitoring Network) to carry out this task. The scope of this report is therefore restricted to the general surveillance carried out by the applicant in the crop fields and field margins.

THE CURRENT GENERAL SURVEILLANCE PLANS CAN BE IMPROVED

COGEM notes that recently various different applicants have submitted a similar general surveillance plan. The general surveillance plans accompanying applications for 'import and processing' differ from those for 'cultivation'. COGEM observes that the submitted plans can be improved with respect to the following general points:

- In almost all cases the authorisation holder appoints third parties to carry out the surveillance activities. COGEM is of the opinion that the authorisation holder should guarantee that the observations agreed to in the monitoring plan are actually undertaken.
- The authorisation holder should immediately inform the European Commission and the Member States of any unanticipated adverse effects caused by a GM crop and take direct measures to protect human health and the environment.
- All observations collated by the authorisation holder must be retrievable. If all the recorded observations can be retrieved by the Member States or the competent authority, the correctness of the conclusions drawn by the authorisation holder from these observations can be verified.

Specific points for improvement in the general surveillance plan for consents for import

COGEM is of the opinion that the general surveillance plan currently in circulation is adequate for the import of crops that cannot become established in the wild and/or outcross in the Netherlands. COGEM observes that the general surveillance plan is inadequate for the import of (parts of) a crop that, in the Netherlands, is able to become established in the wild and/or outcross:

- Crops that can become established in the wild should be monitored for the occurrence of environmental impacts. The general surveillance plan should also include provisions for observing the areas where material that is capable of propagation, such as seed, may be unintentionally released into the environment.
- When applications for consents for cultivation are accompanied by an application for authorisation for import and processing, the general surveillance plan should not only contain measures for identifying unanticipated effects during cultivation, but also for identifying unanticipated effects arising from import and processing.

Specific points for improvement in the general surveillance plan for consent for cultivation

The widely used general surveillance plan is satisfactory for crops that cannot be cultivated in the Netherlands, but is inadequate for crops that can be cultivated in the Netherlands. The following points for improvement can be identified:

- The authorisation holder must guarantee that a sufficient number of observations are made and reported.
- The farm questionnaire should be expanded to include questions designed to elicit

observations about changes in the persistence and invasiveness of the GM plants, and growers should also be asked if any unanticipated effects have occurred in the farmyard, because the GM crop could have been present in such areas.

- The questions about the presence of animals must be subdivided so that information can be obtained about the numbers of mammals, birds of prey, other birds and insects encountered in the fields. The questionnaire must also contain questions on whether abnormal numbers of other animals were present and whether any dead animals have been found.
- The annual monitoring report should include details on the number of questionnaires sent out and the number of returned and completed questionnaires. In addition, the report should state the areas in which the GM crop has been cultivated. This information can be used to determine whether or not sufficient observations have been made.

CONTENTS

1

INTRODUCTION

A number of conditions must be met before a GM crop may be imported or cultivated. These conditions are stated in Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.[1]

One of the conditions is that the applicant prepares an environmental risk assessment. The purpose of the environmental risk assessment is to identify all potential hazards that could arise from the import or cultivation of a GM crop. The principles and methodology of the risk assessment are set out in Annex II to Directive 2001/18.[1] This states that the risk assessment should identify and evaluate potential adverse effects of the GM crop, both direct and indirect. The potential adverse effects of a GM crop or its use should always be compared with the effects of the non-modified crop from which it is derived; this is the 'baseline'. GM crops are only authorised in the EU once the environmental risk assessment has shown that their import or cultivation involves a negligible risk.

Besides the information required for the risk assessment, the applicant must also submit a monitoring plan. The objective of the monitoring plan is to identify the occurrence of any adverse effects of GM crops or their use on human health and the environment after the GM crop has been placed on the market ('post-market environmental monitoring'). If it is confirmed that a GM crop causes an adverse effect, measures will be taken to protect human health and the environment.

Post-market environmental monitoring consists of two parts: 'case specific monitoring' and 'general surveillance'. Case-specific monitoring is designed to confirm that any hypotheses regarding the occurrence and impact of potential adverse effects of the GM crop or its use in the environmental risk assessment are correct. Case-specific monitoring is therefore only necessary when the environmental risk assessment gives reason for it. General surveillance was instituted to determine whether the GM crop or its use leads to the occurrence of any unanticipated adverse effects on human health or the environment so that remedial measures can be taken when an adverse effect is confirmed. The preparation and implementation of a general surveillance plan is compulsory in all cases.

The strategy and actions set out in the general surveillance plan apply to the whole of Europe. It is therefore not possible to make reference in the general surveillance plan to specific Member States. In Europe there are various organisations and institutes that can be enlisted to carry out general surveillance tasks. However, these organisations are usually not active in all the EU Member States. This means that different organisations may be involved in general surveillance activities in different Member States and that the actions undertaken to implement the general surveillance plan may vary between Member States.

In recent years COGEM has issued advice on dozens of applications for authorisations to place GM crops on the market. For these advices studies and evaluations of the submitted plans for post-market environmental monitoring where done. In most cases the environmental risk assessment gave no cause for case-specific monitoring and the monitoring plan only contained measures for general surveillance. Recently, various applicants have submitted the same general surveillance plan. The approach set out in this general surveillance plan is consistent with that described by Lecoq et al. (2007).[6] This suggests that most applicants have chosen to take this approach. However, COGEM believes that several aspects of this general surveillance plan could be improved. This applies both to the general surveillance plan submitted with applications for import consents and to the general surveillance plan submitted with applications for cultivation consents. In this report COGEM first describes the aspects of general surveillance that deserve consideration. This is followed by an evaluation of the approach followed in the general surveillance plans and a discussion of the points in these plans that can be improved upon. The report therefore provides pointers to applicants for improving future general surveillance plans.

2

ISSUES RAISED BY COGEM ON GENERAL SURVEILLANCE

General surveillance was instituted to determine whether the GM crop or its use leads to the occurrence of any unanticipated adverse effects on human health or the environment so that remedial action can be taken. The general surveillance plan is designed to enable the detection of unanticipated adverse effects of a GM crop after it has been placed on the market. These may be direct or indirect effects caused by the GM crop that occur immediately or after some time.

GENERAL SURVEILLANCE IS AN EARLY WARNING SYSTEM FOR SIGNIFICANT UNANTICIPATED ADVERSE EFFECTS

General surveillance was instituted to remain alert to potential effects of this relatively new technique so that any unanticipated effects that may occur after the GM crop has been placed on the market can be observed. General surveillance is not based on hypotheses about the type, magnitude or location where a potential effect may could occur,[2] because these would by definition exclude certain potential effects. A difficulty with general surveillance is that this makes it impossible to carry out specific research to verify or falsify a hypothesis. General surveillance therefore consists of monitoring geographical areas where a GM crop is processed or cultivated, but in practice it is difficult to observe and identify unanticipated adverse effects because any unforeseen effects may occur within a wide area and it is not possible to know in advance how an unanticipated effect will become manifest.[3] Monitoring for the occurrence of these effects is therefore rather like looking for a needle in a haystack. COGEM considers general surveillance to be an early warning system for observing significant unanticipated adverse effects, pointing out that when an effect is observed, detailed research is needed to determine whether or not the observed effect is caused by the GM crop. It will be difficult to determine whether an effect is caused by the GM crop or by other factors.[3] If an observed adverse effect is associated with the GM crop or its use, further research will be needed to ascertain the cause and consequences of the adverse effect.[3]

NATIONAL MONITORING SYSTEM IMPORTANT FOR GENERAL SURVEILLANCE

As described above, unforeseen effects may arise anywhere, which means that no species or geographical areas can be excluded in advance from general surveillance. For this reason COGEM has previously stated that nationwide monitoring is needed in order to detect the occurrence of unanticipated effects. COGEM advised the Dutch government to make use of existing monitoring networks to carry out this task.[4] The Dutch government subsequently decided to take responsibility for general surveillance outside the cultivation areas. This means that the government undertakes general surveillance outside the fields where GM crops are cultivated.

The government is currently setting up a monitoring system which makes use of existing monitoring networks. In accordance with previous advice by COGEM, this will ensure nationwide monitoring for unanticipated effects. At the moment the government is still consulting with existing monitoring networks, such as the Netwerk Ecologische Monitoring (Ecological Monitoring Network). No firm agreements about the details of the monitoring system have yet been made. COGEM stresses the importance of setting up a comprehensive and good quality nationwide monitoring system that has sufficient sampling points and considers all relevant organisms. As soon as the details of the monitoring system have been defined, COGEM will assess whether it meets its expectations. COGEM notes that the nationwide monitoring system can also play a role in identifying any unanticipated effects of imported GM crops. In the exceptional case of potential unanticipated effects occurring outside the chain of importing and processing industries, these effects could be identified by the nationwide monitoring system.

SOME CONCERNS ABOUT GENERAL SURVEILLANCE

The authorisation holder is legally responsible for implementing general surveillance.[1] However, as described above, the Dutch government has taken responsibility for general surveillance outside the cultivation areas. In practice, therefore, when authorisation is given for cultivation, the authorisation holder is primarily responsible for general surveillance in the cultivation areas (fields and field margins). The approach adopted by authorisation holders to meet their general surveillance obligations depends on the type of authorisation (import or cultivation). When authorisation is given for import and processing, the general surveillance plan focuses on observing unanticipated effects arising from the importation, handling and processing of parts of the GM crop.[6] When authorisation is given for cultivation, the general surveillance plan pays particular attention to the observation of unanticipated effects arising from the cultivation of the GM crop. Although the approach taken to general surveillance differs for each type of authorisation, COGEM wants to draw special attention to some aspects relevant to both types of consent. These points are explained below.

THE LOCATIONS WHERE GM CROPS ARE PROCESSED OR WHERE MATERIAL CAPABLE OF PROPAGATION MAY BE UNINTENTIONALLY RELEASED INTO THE ENVIRONMENT DESERVE PARTICULAR ATTENTION

General surveillance was instituted to detect unanticipated adverse effects on human health and the environment. Making observations is crucial to achieving this. In some places there is an increased chance of the occurrence of potential unanticipated effects. These are places where the GM crop is cultivated or processed. In places where material capable of propagation, such as seeds, may be unintentionally released into the environment there is also an increased chance of unanticipated effects occurring. COGEM therefore considers that particular attention should be given to these locations when monitoring for the occurrence of unanticipated adverse effects.

THE AUTHORISATION HOLDER MUST GUARANTEE THAT OBSERVATIONS ARE MADE

Moreover, COGEM is of the opinion that guarantees should be given that observations will actually be made. If the authorisation holder appoints third parties to carry out the observations, guarantees must be given that those parties will indeed carry out the observations.

IMPORTANCE OF INVOLVING ORGANISATIONS WITH EXPERTISE IN THE FIELD OF HUMAN HEALTH AND THE ENVIRONMENT

As mentioned above, general surveillance was instituted to detect unanticipated adverse effects on human health and the environment. Organisations with expertise on human health and the environment will therefore be best placed to observe any unanticipated effects. For this reason, COGEM places great importance on these organisations being involved in general surveillance.

ALL ADVERSE EFFECTS SHOULD BE REPORTED ANNUALLY

In addition, COGEM argues that annual reports on all observed adverse effects are essential to obtain a clear picture of the potential occurrence of unanticipated adverse effects resulting from the cultivation or use of the GM crop.

THE EUROPEAN COMMISSION AND THE MEMBER STATES SHOULD BE IMMEDIATELY INFORMED WHEN AN ADVERSE EFFECT OF A GM CROP THAT REQUIRES REMEDIAL ACTION IS DETECTED

When a GM crop causes an adverse effect for which direct measures have to be taken to protect human health and the environment, the necessary action should be taken as quickly as possible. For this reason COGEM believes that in such cases the authorisation holder should directly inform both the European Commission and the Member States.

ALL OBSERVATIONS MUST BE RETRIEVABLE

COGEM further believes that all observations reported to the authorisation holder must be retrievable. At the moment the authorisation holder is the party that must investigate whether an observed effect is adverse or not and whether it is caused by the GM crop. However, this is difficult to determine because an effect may also be caused by other factors.[3] If all the observations reported to the authorisation holder can be retrieved, it will be possible to assess whether the conclusions drawn by the authorisation holder are valid and whether or not they are based on sufficient observations.

THE WEIGHT GIVEN TO THESE POINTS DEPENDS ON THE CROP AND THE TYPE OF AUTHORISATION

Although the points described above are important for all types of authorisation, the weight given by COGEM to each of these points depends on the type of authorisation (import or cultivation). When authorisation is granted for cultivation, the GM crop is grown in the field for a certain length of time. The chance of unanticipated effects occurring is therefore greater than if the crop, or part of the plant, is only imported. The traits or characteristics of the GM crop in question are also considered by COGEM when evaluating a general surveillance plan. For a GM crop that can become established in the wild in the Netherlands, the chance of an unanticipated affect occurring is larger than for a GM crop that cannot become established in the wild in the Netherlands. The chance of unanticipated effects caused by GM crops whose transgenic trait can outcross with species present in the Netherlands is also greater than for GM crops that cannot cross with other plant species present in the Netherlands.
As described earlier, recently various authorisation holders have submitted the same general surveillance plan. This is true for both the general surveillance plan submitted with applications for import consents and for the general surveillance plan submitted with applications for cultivation consents. The following chapters contain descriptions of the general surveillance strategy and monitoring actions included in the widely used general surveillance plans for each type of authorisation (import and cultivation).

These are followed by descriptions of the points which in COGEM's view need to be improved upon. These considerations also take account of the traits and characteristics of the genetically modified crop.

3

GENERAL SURVEILLANCE FOR IMPORT

3.1 THE APPROACH TO GENERAL SURVEILLANCE FOR IMPORT

Recently various applicants have submitted the same general surveillance plan when applying for authorisation to import GM crops. In particular, this general surveillance plan is submitted by all applicants who are members of the European Association of Bioindustries (EuropaBio). A few applicants have submitted other general surveillance plans. However, the majority of the submitted general surveillance plans have taken the following approach.

THIRD PARTY MONITORING FOR UNANTICIPATED EFFECTS

Most of the authorisation holders are not directly involved in the trade in or processing of the GM crop. The authorisation holders therefore appoint third parties to carry out the monitoring for unanticipated adverse effects. These are the so-called 'operators', who are involved in the import, handling and processing of parts of the GM crop. They work with the GM crop and therefore, according to the applicants, are best placed to observe and report any unanticipated adverse effects. The operators identify effects within the framework of their routine surveillance of the commodities they handle or use. This routine surveillance is based on the 'hazard analysis of critical control point' (HACCP) system, which consists of identifying any hazards to food safety so that measures can be taken to reduce or eliminate these hazards.[5] The HACCP system is therefore, in principle, not geared to identifying potential environmental impacts. The authorisation holder provides the importers/traders and the processing industry with guidance to facilitate the monitoring and reporting of any unanticipated adverse effects.

THE AUTHORISATION HOLDER WORKS WITH OTHER COMPANIES AND TRADE ASSOCIATIONS

All but a few applicants are members of EuropaBio. These authorisation holders carry out general surveillance in cooperation with other companies in EuropaBio. The general surveillance plan also states that the authorisation holder of the GM crop col-

laborates with the associations representing the traders and the processing industry in Europe.[6] The associations currently involved in general surveillance are COCERAL, UNISTOCK and FEDIOL. They represent the national associations of traders and companies that handle and process living material. Although the authorisation holder can work with third parties to carry out general surveillance, the authorisation holder remains responsible for the implementation and for correctly carrying out the general surveillance plan.

REPORTING OF UNANTICIPATED ADVERSE EFFECTS BY TRADERS VIA THE ASSOCIATIONS AND EUROPABIO

The general surveillance plan states that EuropaBio informs the traders and processing industry of any newly approved crops for which general surveillance is required. EuropaBio takes on this task on behalf of the authorisation holder.[6] Each year EuropaBio also contacts the associations mentioned above, providing them with an updated inventory of the crops subject to general surveillance. The associations are also reminded of their agreement to report annually on any unanticipated adverse effects or the absence of any such effects. On behalf of the GM crop authorisation holders, EuropaBio maintains a website that contains detailed information on the crops subject to general surveillance. The website also contains a contact point where further information can be obtained and exchanged.[6,7]

The general surveillance plan states that the associations mentioned above will remind their members annually about the requirement to monitor for the occurrence of potential unanticipated adverse effects and to report back each observed adverse effect. They are also reminded that they have a duty to inform and remind their own members of the need to monitor for unanticipated adverse effects.[6] According to the general surveillance plan, the associations make these reports at least annually, not depending on whether adverse effects have been reported to them or not. If adverse effects are observed, the associations must report these immediately.[6] The reports are either sent directly to the authorisation holders or to EuropaBio, which in turn sends the reports on to the relevant authorisation holders.

COLLECTION OF RELEVANT SCIENTIFIC ARTICLES IS PART OF THE MONITORING EXERCISE

The authorisation holder is also required to actively screen the scientific literature for publications relevant to the GM crop.

THE EUROPEAN COMMISSION IS IMMEDIATELY INFORMED WHEN THE GM CROP CAUSES AN ADVERSE EFFECT

The authorisation holder receives the reports from the trade associations and keeps abreast of the relevant scientific publications. The authorisation holder then ascertains whether the reports and publications contain information that is relevant for general surveillance. According to the general surveillance plan, when any of the information thus obtained indicates the occurrence of a potential unanticipated adverse effect, the authorisation holder immediately investigates whether there is a significant correlation between the effect and the GM crop. If this study confirms that the GM crop was present when the adverse effect was observed and that the GM crop was the cause of the adverse effect, the authorisation holder will immediately inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human health and the environment as necessary. The general surveillance plan states that it is important that the remedial action is proportionate to the significance of the observed effect.

A MONITORING REPORT MUST BE SUBMITTED AT LEAST ONCE A YEAR

The authorisation holder must submit a monitoring report, including the results of the general surveillance, to the European Commission at least once a year. This report contains information on all unanticipated adverse effects that have arisen from the use of the GM crop. The report will include a scientific evaluation of the confirmed adverse effect and a conclusion about the safety of the GM crop. Where relevant, the report will also describe the measures that were taken to protect human and environmental safety.

3.2 CONCLUSION BY COGEM ON THE GENERAL SURVEILLANCE PLAN FOR IMPORT

CROPS THAT CANNOT BECOME ESTABLISHED IN THE WILD OR OUTCROSS

For crops that cannot become established in the wild or outcross in the Netherlands, such as soya, cotton and maize, COGEM considers the general surveillance plan described above to be satisfactory. A point for consideration is the making of observations. At the moment, the parties (traders and the processing industry) implementing the

monitoring are under no firm obligation to make observations. COGEM therefore recommends that the authorisation holder requires these parties to do so. Another possibility is that the authorisation holders themselves make the necessary observations if the trader and processing industry have not done so themselves. This would provide a guarantee that the necessary data are collected. COGEM also recommends collecting observations through the use of standard forms.
The general surveillance plan described above states that the authorisation holder will report all unanticipated adverse effects that have occurred as a result of the use of the GM crop. The authorisation holder is the party that investigates whether or not the unanticipated adverse effect is caused by the GM crop. COGEM points out that it will be difficult to determine whether an effect is caused by the GM crop.[3] COGEM is of the opinion that it should be possible to retrieve all notifications received by the authorisation holder in order to verify whether the conclusion drawn by the authorisation holder on the cause of an observed effect is correct.
The general surveillance plan described above also states that the authorisation holder will immediately inform the European Commission when the information confirms that the GM crop is the cause of an observed adverse effect. COGEM is of the opinion that adverse effects caused by a GM crop that require immediate measures to protect human health and the environment should also be reported directly to the Member States. This would allow measures to protect human health and the environment to be taken as early as possible.

CROPS THAT ARE ABLE TO BECOME ESTABLISHED IN THE WILD AND/OR OUTCROSS

In the current approach to general surveillance, operators monitor for the occurrence of unanticipated adverse effects. This monitoring is conducted within the framework of their routine surveillance. It is designed to identify possible hazards to food safety and is not specifically geared to identifying potential environmental impacts. COGEM is of the opinion that this is not adequate for crops that can become established in the wild and/or outcross in the Netherlands, such as sugar beet and oilseed rape. Although in the Netherlands the Netwerk Ecologische Monitoring (NEM) also monitors for the occurrence of unanticipated environmental effects, COGEM considers that the authorisation holder should monitor crops that are capable of become established in the wild and/or outcross for the occurrence of environmental impacts. COGEM is of the opinion that this monitoring should pay close attention to the areas where material capable of propagation, such as seeds, may be unintentionally released from containment. In practice, this will mean that the authorisation holder should ensure that surveillance also covers handling areas and distribution routes to observe any occurrence of unanticipated adverse effects, such as an increase in the potential for plants to become established in the wild.
The points for improvement discussed above also apply to these crops. They would im-

prove the general surveillance plan because the authorisation holder would guarantee that observations are made, that the observations would be reported via a standard form, and that all notifications received by the authorisation holder would be retrievable. Furthermore, adverse effects caused by the GM crop for which direct measures to protect human health and the environment must be taken would be immediately reported not only to the European Commission but also to the Member States.

4

GENERAL SURVEILLANCE FOR CULTIVATION

4.1 THE APPROACH TO GENERAL SURVEILLANCE FOR CULTIVATION

In recent years several companies have applied for authorisation to cultivate a GM crop. The most recent general surveillance plans for cultivation consents have been the same. The approach set out in the most recent general surveillance plans is consistent with that described by Lecoq et al. (2007). This leads us to believe that the different applicants have chosen to follow this approach and COGEM expects that in the future the majority of applicants will use this general surveillance plan. This general surveillance plan takes the following approach.

THIRD PARTY MONITORING FOR UNANTICIPATED EFFECTS

The general surveillance plan states that the authorisation holder will not monitor for unanticipated effects, but will make use of various sources for detecting unanticipated adverse effects. The growers of the GM crop are considered by the applicant to be the primary source of information because they are the closest observers of the GM crop.[6] Each year several farmers/growers are sent a questionnaire in which they are asked whether the cultivation of the GM crop leads to any deviations from the usual situation. Other sources of information are also used (as appropriate), such as existing observation networks, stewardship programmes, the scientific literature and official websites. These information sources are described briefly below.

Farm questionnaire contains questions about the conventional and the GM crop

The purpose of the farm questionnaire (sent to growers and farmers) is to obtain information about the GM crop and also baseline information, such as cultivation practices. It includes questions about the crop grown area to identify the location and size of the cultivation area, the soil characteristics and general pest pressure. Information is also obtained about the cultivation practices in conventional fields. Several questions are about the GM crop itself. These are questions about the cultivation practices used for the GM crop and on the disease, pest and weed pressure, and whether the occurrence of mammals, birds and insects (wildlife) is the same or different from the usual situati-

on. The authorisation holder expects that growers/farmers, based on their experience with the cultivation of the conventional crop, will be able to assess whether conditions surrounding the cultivation of the GM crop are the same or different from the cultivation of the conventional crop.

Company stewardship network is in contact with the growers of GM crops
Another source of information described in the general surveillance plan is the 'company stewardship network'. The authorisation holder remains in contact with the grower through a network of suppliers and distributors. Companies involved in farm sales, in particular, are regular visitors to the farmers and their fields. The authorisation holder states that the 'company stewardship network' ensures continuous and efficient communication with the farmer and that any complaints about a product are referred back to the authorisation holder. For this reason, the authorisation holder maintains that this makes it a particularly suitable surveillance network for possible adverse effects.

Annual reports of existing monitoring networks sources of information
Existing surveillance and monitoring networks can also provide information about unanticipated effects. The authorisation holder considers the use of these monitoring networks to be a means to ensure that sufficient observers are available to identify and report possible unanticipated adverse effects, as well as ensuring methodological consistency. In the general surveillance plan the authorisation holder states that not all existing observation networks will be used. The authorisation holder will review the information collected by an observation or monitoring network to determine whether it can make a contribution to general surveillance. When selecting observation networks, the authorisation holder considers it important that the monitoring networks work in the fields of agriculture, the non-agricultural environment, occupational health and livestock welfare. The authorisation holder will consult the annual reports of the selected networks to keep abreast of the results of these monitoring programmes. Findings that indicate that the cultivation of the GM crop leads to an adverse effect will be reported in the authorisation holder's annual monitoring report.
In addition, the authorisation holder states that existing monitoring networks can also provide background information, for example on plant diseases, pests, weeds and climatic conditions. This information is useful for assessing whether any possible unobserved effect is caused by the GM crop or another factor. The authorisation holder states that information from existing networks could be used on an ad hoc basis to determine whether the effect is associated with the GM crop or with another influencing factor.

Other information sources are actively monitored
The authorisation holder also states that existing information sources, such as official websites, scientific publications and expert reports will be actively monitored in order to identify any potential adverse effects.

THE AUTHORISATION HOLDER WILL USE STATISTICAL ANALYSIS TO INVESTIGATE WHETHER THE CULTIVATION OF THE GM CROP LEADS TO SIGNIFICANT DEVIATIONS FROM THE USUAL SITUATION

The authorisation holder states that statistical analysis will be used to ascertain whether the cultivation of the GM crop leads to significant deviations from the usual situation. The widely used general surveillance plan states that 2500 farm questionnaires will be distributed during the ten-year monitoring period. This number has been determined on the basis of calculations and recommendations by Schmidt et al. (2006).[8] The general surveillance plan further states that the authorisation holder will report annually on the occurrence of unanticipated adverse effects and that the statistical analysis will therefore also be carried out annually.

THE AUTHORISATION HOLDER USES STATISTICAL ANALYSIS TO INVESTIGATE WHETHER DEVIATIONS ARE CAUSED BY OTHER FACTORS

The general surveillance plan states that if the statistical analysis confirms that deviations from the normal situation are correlated with the cultivation of the GM crop, the authorisation holder will conduct investigations to identify the cause of these deviations. The authorisation holder will do this first by investigating whether there are any significant differences between the cultivation and environmental factors of the GM crop and the cultivation and environmental factors of a conventional crop, and try to ascertain, for example, whether the observed deviations associated with the cultivation of the GM crop are caused by other factors, such as agricultural practices, pest pressure, the weather, soil type or the crop grown in the field the previous year.

BASELINE INFORMATION IS USED WHEN ASSESSING THE CONSEQUENCES OF AN ADVERSE EFFECT CAUSED BY A GM CROP

The authorisation holder states that the potential consequences of the effect will be evaluated if there is scientifically valid evidence that an adverse effect is caused by the GM crop. The authorisation holder will compare the adverse effect and its consequences with the effects caused by conventional agricultural practices (the baseline). If necessary, the authorisation holder will take remedial action to protect human health and the environment.

THE EUROPEAN COMMISSION IS IMMEDIATELY INFORMED IF THE GM CROP CAUSES AN ADVERSE EFFECT

The general surveillance plan states that the authorisation holder will discuss any adverse effects associated with the cultivation of the GM crop in the monitoring report, which is submitted annually to the European Commission. However, if an adverse effect that needs immediate action to protect human health and the environment is observed, this adverse effect will be reported immediately to the European Commission.

4.2 CONCLUSION BY COGEM ON THE GENERAL SURVEILLANCE PLAN FOR CULTIVATION

CROPS THAT CAN BE CULTIVATED IN OTHER EUROPEAN COUNTRIES, BUT NOT IN THE NETHERLANDS

The general surveillance plan described above sets out the surveillance strategy for the occurrence of unanticipated adverse effects from the cultivation of a GM crop. Applications for consents for cultivation are often accompanied by an application for a consent for import and processing. However, some of the submitted general surveillance plans do not address monitoring for unanticipated adverse effects from import and processing. It is theoretically possible that the import and processing of parts of a GM crop will lead to the occurrence of different effects than the cultivation of the same GM crop. When an application for consent for cultivation is accompanied by an application for a consent for import and processing, COGEM considers it important that monitoring should be carried out for unanticipated adverse effects of the import and processing of the GM crop. In these cases, therefore, COGEM expects that this should also be covered in the general surveillance plan. Recently the European Commission has published a standard reporting procedure for monitoring to be followed by authorisation holders. The explanatory notes to this reporting standard indicate that the European Commission also considers that authorisation holders should monitor for the occurrence of unanticipated adverse effects of import and processing.[9] The most recently submitted general surveillance plans have therefore also included provisions on monitoring for unanticipated adverse effects of import and processing.

CROPS THAT CAN BE CULTIVATED IN THE NETHERLANDS

COGEM is of the opinion that the general surveillance plan described above is inadequate for crops which can be cultivated in the Netherlands. The points for improvement are discussed below.

COGEM wants a guarantee that sufficient observations will be made

The growers of the GM crop are considered by the authorisation holder to be the most important source of information for identifying unanticipated adverse effects. In the general surveillance plan the authorisation holder states that a number of farmers/growers will be asked to fill in a questionnaire. In these questionnaires the growers are asked whether the cultivation of the GM crop leads to any deviations from the usual situation. At the moment the growers of the GM crop are not obliged to fill in the questionnaire.

As a sufficient number observations must be made to be able to detect unanticipated adverse effects, COGEM wants the authorisation holder to guarantee that a sufficient number of observations will be made and reported. One way of doing this is to make it compulsory for the farmers/growers to complete and return the questionnaire. COGEM also wants authorisation holders to state, in their annual monitoring reports, the number of questionnaires that were sent out and the number of completed questionnaires returned, and also the areas in which the GM crop was cultivated. This information can be used to determine whether or not sufficient observations have indeed been made. The explanatory statement accompanying the recent decision by the European Commission on monitoring reports indicates that the European Commission expects that the authorisation holder should report the number of completed questionnaires and the cultivation areas.[9]

Furthermore, COGEM makes the following comments about the number of farm questionnaires that should be completed. The EFSA states that the number of questionnaires should be large enough to obtain sufficient statistical power.[2] The required number of questionnaires stated in the general surveillance plan is based on the recommendation by Schmidt et al., in which the amount of questionnaires needed is calculated according to the parameters $\alpha=0.01$ and $\beta=0.01$.[10] This calculation method is followed in the widely used general surveillance plan, in which it is stated that the intention is to issue a total of 2500 farm questionnaires in the EU over a period of ten years. However, to determine the number of questionnaires that is required, it is necessary, besides the parameters α and β, to determine the size of the effect that must be observed. The calculation of the required number of questionnaires ignores this aspect. COGEM therefore has doubts about the calculation used to determine the number of questionnaires.

COGEM wants more questions in the farm questionnaire

COGEM is of the opinion that the farm questionnaire should be complemented with additional points in more detail. It should contain questions designed to identify any changes in the persistence and invasiveness of the GM plants. Suitable questions would address changes in susceptibility to abiotic stress and in the number of adventitious plants. Furthermore, COGEM considers that the questions on the presence of animals should be subdivided to obtain information on the presence of mammals (including deer and mice), birds of prey (including falcons, goshawks), other birds (including pigeons, sparrows) and insects (including butterflies, bees, beetles, ladybirds). In addi-

tion, COGEM considers that the growers should be asked whether abnormal numbers of other animals were present and whether any dead animals have been found.
COGEM is also of the opinion that the growers must be asked whether they have noticed anything unexpected in the farmyard, because the GM crop may also be present in the areas in and around the farm buildings, which could lead to unanticipated effects occurring in these areas as well.

Importance of using existing government run monitoring networks in the Netherlands

COGEM assumes that growers will be able to observe certain unanticipated effects. In particular they will observe changes in the agronomic aspects of the crop and factors that influence the crop. However, farmers and growers are not trained to observe other effects. It is therefore not realistic to expect that growers will notice unanticipated effects in the wild flora and fauna, for example.[11] COGEM is therefore of the opinion that it is crucially important to make use of existing monitoring networks in order to detect all possible unanticipated effects in good time. In an earlier report, COGEM advised the Dutch government to enlist the aid of existing monitoring networks in general surveillance.[4] In accordance with this advice, the Dutch government is currently making arrangements for using existing monitoring networks for general surveillance outside the cultivation areas.

COGEM considers that monitoring should sometimes be continued after the period of consent

In the general surveillance plan described above, the duration of the general surveillance period is limited to the period of consent. Some crops, such as sugar beet, produce seed that can remain viable for several years. COGEM is therefore of the opinion that monitoring for unanticipated adverse effects should continue for a longer period in cases where this is warranted by the biology of the crop. This may mean that monitoring should continue for several years after the consent has expired.

Monitoring for unanticipated effects of import and processing must not be neglected when authorisation is given for cultivation, import and processing

Applications for consents for cultivation are often accompanied by an application for a consent to import and process GM crops. In these cases, COGEM considers it important that the general surveillance plan also includes provisions for monitoring for unanticipated adverse effects from import and processing. If this is not the case, COGEM considers that the general surveillance plan should be amended to include such provisions.

COGEM considers that all observations collated by the authorisation holder should be retrievable

In the general surveillance plan described above the authorisation holder states that any unanticipated adverse effects associated with the cultivation of the GM crop will be discussed in the annual monitoring report. This implies that not all observations

received by the authorisation holder will be described in the monitoring report. This makes it impossible to verify that all relevant observations have been reported by the authorisation holder. COGEM is of the opinion that it should be possible to retrieve all the observations received by the authorisation holder in order to verify that all relevant observations have been reported.

The Member States should also be immediately informed when an adverse effect of a GM crop that requires measures to be taken is detected

The general surveillance plan described above states that the authorisation holder will immediately inform the European Commission when the information confirms that an adverse effect is associated with the cultivation of the GM crop and that measures should be taken immediately to protect human health and the environment. COGEM believes that in these cases the Member States should also be immediately informed. This would allow measures to protect human health and the environment to be taken as early as possible.

Statistical analysis of the collated information is not justified

The opinion of the EFSA on post-market monitoring shows that it attaches considerable value to a statistical analysis of the collated information.[2] The authorisation holder therefore states that the information collected from the farm questionnaires will be subject to a statistical analysis to investigate whether the cultivation of the GM crop is associated with deviations from the usual situation. COGEM points out that the information obtained from the questionnaire survey does not warrant statistical analysis. In the questionnaire the growers are asked whether there have been any deviations from the usual situation, in other words, from the situation in which a conventional crop is cultivated. Three different cases may be taken to represent the usual situation: (1) a reference area where no GM variant of the crop concerned is cultivated; (2) a fixed reference value or a fixed range within which the observations cannot be considered to be deviations; (3) a value or series of observations from earlier observations in the same field when no GM crop had been cultivated there. These three types of references correspond with three different statistical procedures. However, no questionnaires are filled in by growers of conventional crops, which prevents any comparison being made with a usual situation.[12] Neither are the growers asked to provide quantitative data, such as numbers of certain organisms. Given the above, COGEM is of the opinion that the information gathered permits only a very limited statistical analysis.

As described earlier, general surveillance cannot be used to verify or disprove a particular hypothesis, because formulating a hypothesis involves making assumptions about the effects that could occur and so certain effects would by definition be excluded. Moreover, COGEM notes that a thorough statistical analysis of the information collected by general surveillance is not possible. In light of the above comments, COGEM considers general surveillance to be an early warning system for observing significant unanticipated adverse effects. When an unanticipated effect is observed and further

investigation is needed to identify the cause of this effect, COGEM considers it important that this study makes use of data that warrant statistical analysis and that these data are analysed by means of a thorough statistical procedure. For this reason, control data need to be collected during the investigation into the cause of an unanticipated adverse effect, including quantitative data, such as the number of organisms present.

5

CONCLUSION

During the past years COGEM has issued advice on dozens of applications for consent to place GM crops on the market. During the process of issuing these advices evaluations of the submitted general surveillance plans were made. Various aspects of these plans could be improved.

In the current situation, COGEM draws the following conclusions about the widely used general surveillance plan for **import and processing**:

- The plan is satisfactory for crops that cannot become established in the wild or outcross.
- The plan is inadequate for crops that are able to become established in the wild and/or outcross. COGEM considers that for these types of crops, surveillance is required to observe the occurrence of environmental impacts. This monitoring should pay close attention to the areas where material capable of propagation, such as seeds, may be unintentionally released from containment.
- The plan would be improved if the authorisation holder provided a guarantee that observations will be made.
- The plan would be improved by the use of a standard questionnaire for recording observations.
- The plan would be improved by making it possible to retrieve all observations received by the authorisation holder.
- The plan would be improved if the Member States were directly informed in cases where adverse effects caused by a GM crop require immediate measures to protect human health and the environment.

In the current situation, COGEM draws the following conclusions about the widely used general surveillance plan for **cultivation**:

- The plan should also contain provisions for monitoring for unanticipated adverse effects from import and processing.
- The plan is inadequate for crops that can be cultivated in the Netherlands. In these cases COGEM considers that:
  - the authorisation holder must guarantee that a sufficient number of observations are collated;
  - the number of distributed and completed questionnaires should be reported;
  - the cultivation areas of the GM crop should be stated;
  - the farm questionnaire should be expanded to include questions on changes in the persistence and invasiveness of the GM plants and on unanticipated effects in the farmyard;

- the questions on the presence of animals should be subdivided;
- for crops whose seeds remain viable for several years, monitoring should continue for a longer period, which implies that in some cases monitoring should continue for some years after the consent has expired;
- the general surveillance plan would be improved by making it possible to retrieve all observations received by the authorisation holder;
- the general surveillance plan would be improved if the Member States were also directly informed of cases whereby adverse effects linked with the cultivation of a GM crop require immediate measures to protect human health and the environment.

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