ACRE Guidance Note 16

Guidance on Best Practice in the Design of Post-market monitoring Plans in Submissions to the Advisory Committee on Releases to the Environment

Guidance for applicants seeking permission to release genetically modified crops into the environment (under Directive 2001/18/EC)

Department for Environment, Food and Rural Affairs: London

CONTENTS

SUMMARY

The objective of this guidance is to consider explicitly the new requirement for post-market monitoring under Directive 2001/18/EEC for all applications for deliberate release for marketing of genetically modified crops. The guidance considers the main elements and general principles that should be adhered to when monitoring genetically modified crops during marketing and which should be contained within the post-market monitoring plan.

SECTION 1

Introduction, Scope and Aims of this Guidance

1.1 The release of live genetically modified organisms[1] (GMOs) in Europe was, until recently, controlled by Directive 90/220/EEC[2]. The Directive was reviewed and has now been replaced by a revised and updated Directive (2001/18/EC) that Member States had to implement by October 2002[3]. The Directive provides a European Community-wide regime so that no live GMO may be released or marketed in the Community without the consent of the regulatory authorities. Applicants for consent to release must supply a dossier of prescribed information[4] about the GMO, and this should include a detailed risk assessment of its possible impact on human health and the environment. As foods containing, or derived from, GM material are not live GMOs, any potential health effects associated with eating them are not regulated by Directive 2001/18/EC; they are controlled by separate legislation controlling the use of novel foods and processes. Although GM vaccines constitute live GMOs, the human health implications associated with their commercial release is covered by health legislation and so is not addressed here.

1.2 Applications for the deliberate release of GM crops can be for one of two purposes, for research and development (so-called Part B applications), and for commercial release (so-called Part C applications). The Directive stipulates that all releases of GMOs should occur in a stepwise fashion with smaller releases under more controlled conditions being performed on material tested in contained use, progressing to larger scale as greater familiarity with the material is gained. At all stages information gained from each release is used to confirm assumptions made in the risk assessment and to inform further risk assessments. Once sufficient knowledge has been gained about a GM crop a notifier may wish to commercialise the product. The consent to release the GM product into the environment under commercial conditions requires making a further application to the Authorities which must include extra information and a new risk assessment covering commercial conditions of use.

1.3 The principle of feedback from releases, in order not only to confirm or refute assumptions made in the risk assessment but also to inform future risk assessment by identification of potential adverse effects, is a fundamental building block of the

[1] The term ”genetically modified organism” used in this guidance refers to the definition used in section 106 of the Environmental Protection Act 1990.
[2] In the UK, Directive 90/220/EEC was implemented by the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (amended 1995 and 1997) and Part VI of the Environmental Protection Act 1990.
[3] Directive 2001/18 entered into force on the 17 April 2001, the date of its publication in the Official Journal of the European Communities. Directive 2001/18/EC is implemented by the Genetically Modified Organisms (Deliberate Release) Regulations 2002 and Part VI of the Environmental Protection Act 1990
[4] Annex III of Directive 2001/18/EEC

Directive. It permits increasing scale of releases and interaction of a GMO with the environment under part B consents. The conditions of releases always remain open to re-assessment in the light of new information. Directive 2001/18/EC now extends this principle of planned feedback to cover Part C consents in the new requirement for a post-market monitoring (PMM) plan. A plan for PMM is to be included in all commercial applications for release of a GM product, whereby notifiers must state their plans for fulfilling this core principle.

1.4 In the UK, the Advisory Committee on Releases to the Environment (ACRE) reviews all applications to release and market live GMOs and advises Ministers[5] on the potential risks to human health and the environment arising from the releases. The Committee has welcomed the new Directive and, in this document, aims to give guidance on the principles underpinning the new requirement for a PMM plan to monitor for environmental harm. This guidance avoids being prescriptive because each PMM plan will be case-specific – depending on the characteristics of the GM crop variety itself, its management and use. For instance, it is likely that a PMM plan will be very different depending on whether a GM crop is intended for cultivation or for import only. However, consequences associated with the transportation of seed or regenerative material may be a common consideration in each case. This guidance attempts to introduce the structured approach applicants need to take when considering PMM and which ACRE expects to see reflected in PMM plans.

1.5 While the aim of this guidance is to address the PMM for environmental effects of commercial releases of GM crops, it does not discuss specifically the monitoring of human health aspects. The safety of GM crops and products derived from them in food is assessed by the Advisory Committee on Novel Foods and Processes[6] under separate legislation; it is not within ACRE's remit. The Advisory Committee on Pesticides is the statutory, independent body that assesses the safety of pesticides on human health, including those used in association with GM crops. Consequently, ACRE's principle consideration is whether crop debris, dust or pollen from a GM crop could pose an increased risk to human health compared to its conventional counterpart. People involved in the research and development of a new variety over many years, particularly in contained conditions, provide a useful indicator to potential adverse effects of this nature. All notifications for commercial release of GM crops are assessed thoroughly for potential adverse effects on human health before ACRE's advice is given.

[5] UK Government and Devolved Administrations of Scotland, Wales and Northern Ireland
[6] The Food Standards Agency commissioned a feasibility study on the post-market monitoring of novel foods, a report is available at:
http://www.foodstandards.gov.uk/multimedia/webpage/feasibility

SECTION 2

The Principles of Post-market monitoring

2.1 Annex VII of Directive 2001/18/EC[7] describes the requirements for a PMM plan. This section outlines the general principles which should be considered when designing a PMM plan for marketing of GMOs in the European Union.

Objectives

2.2 Directive 2001/18/EC specifies two objectives of PMM, namely to:

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

2.3 It is clear that the monitoring plan should be driven by and closely related to the risk assessment and hence should be clearly related to the assumptions/ predictions included in the environmental risk assessment (ERA). In addition, even if the ERA did not identify risks, its fundamental assumptions still need to be evaluated by case-specific monitoring. It is important to emphasise that each PMM plan will be assessed on a case by case basis. Thus organisms and processes proposed for monitoring, and the techniques to be used, should be appropriate to the trait, the crop, the scale and the type (i.e. import or cultivation) of the proposed release.

2.4 The ERA is expected to identify and assess all potential hazards which might arise from commercial use of a GMO. Thus PMM provides the opportunity to assess the accuracy of any assumptions which may have been made in the ERA. These are anticipated effects. In addition, the second objective of PMM is to extend monitoring beyond this and hence ensure that an unexpected hazard or risk to human health or the environment is identified. These are unanticipated effects. In the first instance, surveillance will be directed at identifying change. If detected, further investigation may be required to determine whether this change is attributable to the GM crop, or

[7] The Directive can be viewed at http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf

its cultivation, and whether the effect will have an adverse, benign or beneficial impact on human health and the environment.

Anticipated and unanticipated effects in the risk assessment.

2.5 Anticipated and unanticipated effects can be broken down into three separate categories as follows:

I. *Anticipated effects*. Potential risks identified in the ERA as worthy of investigation *via* case-specific monitoring as well as those assessed as being extremely unlikely to occur and to cause harm.
II. *Interactive or cumulative effects that are difficult or impossible to predict*. Potential effects that are difficult to predict or assess fully in a single dossier and its risk assessment. e.g. effects that might arise as a result of an increase in the scale of cultivation and potential effects arising as a result of interactions between the GM crop and future varieties (GM and non-GM) that are released.
III. *Unanticipated effects.* Complete unknowns, i.e. potential effects not identified in the ERA, which can only be addressed by general surveillance.

2.6 An important difference between these categories lies in how they may be monitored i.e. either by case-specific monitoring or by general surveillance. Subjects for monitoring in *category I* are case-specific, anticipated effects. They are identified in the ERA and the strategy to monitor them should reflect the degree of uncertainty about their potential to cause harm. However, by the time of its commercial release each GM crop will have been through an iterative process of information gathering involving increasing scales of release. Therefore there will already have been a detailed consideration of anticipated effects and if there was any evidence that suggested an increased risk to human health or the environment consent for commercial release would not have been given.

2.7 *Category II* effects are considered as unanticipated because within the ERA of an individual dossier it may be difficult to predict what effects might arise due to an increase in the scale of cultivation, or the full effects of environmental interactions. For example, the interaction between a GM crop and unknown future releases is difficult to predict. Even though the potential outcome of interactions between releases of GM crops may not be assessed fully within one individual dossier, it remains possible to predict that interactions between GM crops may occur and also what characteristics might reasonably be expected to be affected if they do.

2.8 *Category III* comprises potential hazards that are completely unanticipated. Again, these are more appropriate to general surveillance.

2.9 It is helpful to consider each of these categories in turn when designing a PMM plan. The plan should state clearly which category each of its elements is intended to address. While case-specific monitoring and general surveillance each have distinct roles to play in PMM, the boundaries between the two may sometimes be blurred. It is acceptable to design some overlap between them but the underlying principles of the choices and distinctions made should be given in the plan.

Case-specific monitoring

2.10 Case-specific monitoring relies upon the individual characteristics of each GM crop variety, its specific modification and its ERA. Case-specific monitoring should be linked directly to the ERA using the characteristics of the GM crop to formulate hypotheses.

2.11 Case-specific monitoring should take into account the potential direct and immediate effects on the environment and human health linked to the introduced trait and the inserted or modified genes which have been considered in the environmental risk assessment.

2.12 In addition, where it is appropriate, potential delayed, cumulative or indirect effects resulting from the introduced trait and the inserted or modified genes identified in the ERA should also be considered[8].

2.13 Whilst an application to market a GM crop should be informed by past research and development releases, it is inevitable that there may not be direct experience of the use of the GM crop at the scale of, and for the length of time associated with, its intended commercial and agronomic use. The potential risks associated with increased scale and length of time of use should always be addressed in the ERA and PMM provides the opportunity to further inform this assessment. Together, the potential effects of scale and time may be considered as the cumulative effects of the release of that particular GM crop. In certain situations it will be appropriate to consider cumulative effects case-specifically, whereas in others, general monitoring might be more suitable. In either case, the applicant should explain why a particular monitoring strategy has been chosen.

2.14 Case-specific monitoring should be continued for a period agreed in the first instance as part of the PMM plan before consent is issued. This period should be of sufficient length to enable detection of effects consequent with the cultivation of the GM crop

[8] Guidance on the approach to environmental risk assessment is provided in Guidance Note 12, which may be obtained from: ACRE Secretariat, Zone 3/G9, Ashdown House, 123 Victoria Street, SW1E 6DE or by request by email to acre.secretariat@defra.gsi.gov.uk.

and it may be different to the proposed period for the consent (which is time-limited to a maximum of 10 years under the new Directive).

General surveillance

2.15 The purpose of general surveillance is to look for differences that are outside of the normal variation experienced in agriculture. Such effects may then be flagged for further investigation, in particular whether they are specific to the GM crop and whether they might adversely affect human health or the environment. General surveillance is pertinent for longer-term observation and detection of unexpected developments. Some of these developments will be in *category II*, i.e. associated with cumulative effects and interactions between crop varieties. In other cases, the hazards addressed by general surveillance may be completely unanticipated (*category III*).

2.16 General surveillance may be null hypothesis driven, i.e. testing the prediction that there is no change compared with conventional agriculture. This differs from case-specific monitoring, where the hypothesis is often that a particular assumption made in the risk assessment is correct.

2.17 In considering effects that might result from the interaction of different GM crop varieties, it should be possible to use the ERA and case-specific elements to predict possible effects and to design a general surveillance strategy that could detect them.

2.18 General surveillance should not only facilitate the systematic observation of the effects of the release, but also the interpretation of results. It could be considered as contributing to monitoring the 'state of the environment' and should make use of existing, established routine surveillance practices. For examples please refer to Annex 1.

Good Monitoring Practice

2.19 Monitoring is not a static process but should be viewed as iterative, using feedback from reporting to inform each round of monitoring and enabling improvements and/ or amendments as appropriate. Outcomes should feed back into the reassessment of PMM plans and especially where an explanation of an unexpected event is warranted.

2.20 The monitoring plan should give information on the mechanisms for identifying and confirming any observed effects that should enable further measures to be taken as appropriate. A proposed frequency for reporting should be included for each aspect of the plan.

2.21 Since consents will now be time-limited the process of renewal of consent makes provision for amending or complementing the conditions of the consent, which may include the conditions for PMM.

2.22 It should be borne in mind that the design of the monitoring programme will also reflect on the quality and usefulness of the data produced to ensure a scientifically rigorous investigation is undertaken.

Reporting

2.23 Accurate, well written and timely reporting is central to the principles of PMM. This is particularly important in view of the need to ensure that any further investigation that is needed can be planned, agreed and implemented in a timely fashion. In addition, the acquisition of a body of data on releases and cross-correlation between datasets will contribute to underpinning of general surveillance in the long term.

2.24 The plan should contain a proposal for reporting that should state all elements clearly including timing and frequency and also triggers for the submission of additional reports if necessary.

2.25 The plan should also include a proposed mechanism for alerting the Regulatory Authorities to any unanticipated effects that may have arisen.

2.26 A report should also be submitted to the Regulatory Authorities if, during monitoring, the management and agronomic practices anticipated in the dossier are altered. This might include a change to the whole rotation in which the GM crop is one component or a change to one aspect of a rotation. The PMM plan may need to be revised accordingly to take account of these changes.

2.27 The report should set out the results of the monitoring in agreement with the layout and design of the PMM plan to assess the interpretation of results and also to confirm that monitoring has proceeded as agreed.

2.28 The report should contain a scientifically rigorous analysis of the results of monitoring. Results should be given in a way that is clearly explained including the power and appropriateness of the data to answer the hypotheses. Any conclusions, in particular those with regard to the need for further monitoring, should be highlighted. Interpretation of data and all conclusions should be considered in the light of existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the GMO, or its use, or of other factors.

2.29 If further investigation is warranted, the report should give a recommendation as to what this should entail, which if necessary, may incorporate elements of both case–specific monitoring and general surveillance as appropriate.

2.30 It is important to bear in mind when writing the report that it will be made public and any commercial in confidence information should be clearly labelled as such. Such a designation for individual pieces of data may be questioned by the Regulatory Authorities and applicants must be prepared to justify claims for commercial in confidence designations.

SECTION 3

Case-specific Monitoring

The design of a case-specific monitoring plan

3.1 The guiding principal of case-specific monitoring is the evaluation of the assumptions made as part of the ERA. Having identified the relevant assumptions, the monitoring plan should give the design and intended method of execution of experiments to test the hypotheses arising from the ERA assumptions. For example, the ERA for an insect-resistant crop might conclude that the effect on non-target insects is no different from that of conventional agriculture and the monitoring plan should then be designed to test this assertion. Whilst ACRE acknowledges that many of the issues that apply to GM crops apply equally to non-GM crops, there is a separate regulatory regime controlling the release of GM crop varieties that does not apply to non GM crops.

3.2 Each plan should establish the extent of PMM to be carried out, justifying this with reference to the ERA. The following parameters might be considered:

- the location(s) to be monitored, including whether these are agricultural or peri-agricultural;
- the extent of the distance from areas of cultivation of the GM crop;
- the frequency and timing of monitoring, both during and after cultivation.

3.3 The physical and temporal extent of monitoring should be stated in the plan (giving regard to any potential long term or cumulative effects) and will depend on the specific nature of the risks identified in the ERA.

3.4 The plan should identify clearly who is responsible for each aspect of the monitoring and who is responsible for monitoring that the plan is carried out appropriately[9].

3.5 For all parameters selected for measurement (see below), clear protocols should be included. Data collection methods should be consistent with good scientific practice and primary data should be archived for a specified period.

[9] Specifying the position of individuals within organisations that are responsible for aspects of PMM including the plan, is acceptable; giving their names is not necessary.

Identifying parameters for measurement

3.6 The characteristics that should be measured will depend on the assumptions made in the ERA, thus they will vary according to the characteristics of individual GM crop plants and the associated modification in a case-specific fashion.

3.7 The key factors determining whether a parameter needs to be monitored are the same as those in risk assessment: is there a potential adverse effect on this parameter, how likely is it that the effect will occur; what are the consequences if it does occur?

3.8 The parameters chosen for measurement in the PMM plan should be drawn from the ERA. Thus for case-specific anticipated effects (*category I*), they will include trait-specific characteristics of the GM crop and also characteristics which might be predicted to change as a result of that transformation event. The plan should give special attention to those aspects of the release which may apply particularly to commercial use of a GM crop, as compared to a releases for research and development, such as the area and length of time of the release and handling and transport of the release. Interactive or cumulative effects arising as a result of this increase in scale of cultivation (*category II* effects) should also be addressed in the plan, in cases where these are sufficiently predictable to allow case-specific monitoring. In other cases, these effects should be addressed under the general surveillance section of the plan.

3.9 As in the ERA, it is important to consider both potential immediate and delayed effects in the PMM plan. Immediate effects occur during cultivation, and may be either *directly* linked to the introduced trait or modification of the GM plant, or *indirect* effects arising as a result of a causal chain of events, such as through transfer of genetic material. *Delayed* effects are those more likely to become manifest as a result of widespread or long-term commercial use of a product or they may be effects which may remain after the commercial use of the product has ended. An example of the aspects of monitoring which could be included in this approach is given below for an insect resistant GM crop:

- *Direct effects*: e.g. monitoring for any immediate effects on non-target organisms, in order to evaluate the basic assumptions made about the GM crop in the ERA.
- *Indirect effects*: e.g. monitoring of insect resistance in any neighbouring wild relatives, which may be appropriate if gene flow is a strong possibility.
- *Delayed effects*: e.g. monitoring for the potential build up of resistance in pest organisms resulting from widespread and long-term use of the GM crop.

Analysis and reporting

3.10 It is important that the hypotheses derived from the ERA and to be tested in the PMM plan, should be specific and clearly stated. The plan should specify the type and number of sites to be monitored and their distribution. Sufficient information should be supplied so that the statistical power of the monitoring can be evaluated.

3.11 The results of case-specific monitoring should be compiled into a report and the plan should state the proposed time and frequency of reporting. If the results are to be published this should be within a reasonable timeframe and the plan should specify both the route and timing of publication. Both raw data and the results of analysis should be made available to the official authorities. A summary of the results of PMM will be placed on the Public Register.

SECTION 4

General Surveillance

Approaches to Surveillance

4.1 This section outlines the principles underlying general surveillance, as opposed to case-specific monitoring. It is important that existing surveillance measures (see Annex 1 for examples) are utilised. There are two categories of potential effects which might fall under general surveillance: *category II* effects i.e. those about which the nature of a possible change is to some extent predictable, for example cumulative effects of increasing the scale of cultivation in space and time and effects resulting from the interaction between different GM crop varieties, and *category III* effects i.e. those that have not been identified in the risk assessment and are completely unanticipated.

4.2 The approach taken for case–specific monitoring is not appropriate for either of these categories. Rather, effects in both these categories are best considered by observation, feedback and reporting. However, the feedback collected will differ between these two categories; *category II* observations can be directed using knowledge of the traits whereas, in contrast, *category III* effects are by definition completely unanticipated and will require more generalised observation.

4.3 Consent holders should consider engaging those who work in, and are familiar with, the agricultural environment, for example farmers, agronomists and grain handlers, with the task of noting unanticipated effects that could be associated with the cultivation of a GM crop. This may require a questionnaire approach in which questions could reasonably be expected to cover the crop and its immediate environment together with farm wide changes. It might be helpful to provide these in the form of a table with tick boxes. Some examples of types of questions are given below - these are intended as guidance only.

- Have you noticed any increases or decreases in weed numbers in the crop or field margins?
- Have you noticed any increases or decreases in the amount of wildlife (e.g. the numbers of birds or butterflies or mammals) in the crop or field margins?
- Have you had more or fewer pest problems (e.g. fungal diseases, outbreaks of insect pests) ? If there were more pests how did you deal with this?
- Have you noticed any increases or decreases in the number of volunteers? Has your management of the crop changed in any way? If yes, give details.

4.4 Consent holders need to demonstrate that they are being proactive in acquiring feedback from farmers and other relevant sources. The monitoring plan should outline their procedures for such consultation, including the frequency at which they will make contact, the questions they will ask and what they will do with the information they receive. The plan should also outline how existing monitoring programmes will be utilised.

4.5 There are several large-scale monitoring schemes that offer 'general surveillance' of the UK landscape and ecology (for examples, see Annex 1). One of the several national monitoring schemes is Countryside Survey, an audit of countryside which encompasses both detailed field observations and satellite imagery and which has proved effective in detecting habitat changes in the agricultural environment. This is described in more detail in Annex II.

4.6 Use of such existing monitoring programmes to provide good baselines for comparison purposes will be important. Consent holders will be unable to match the scale and quality of these data – we do not intend that they undertake this sort of work for themselves. Rather, their monitoring plan should discuss to what extent such information could improve the detection of any large-scale and long-term changes in the farm environment. For example, if the Countryside Survey recorded a large and persistent change in breeding bird populations in its surveyed fields, it might be possible to assess the likelihood of this being due to changes in farming practice as long as it was known what proportion of the surveyed fields were sown with GM crops. Clearly this would not provide a mechanistic explanation for the change in bird populations, nor could cause and effect be inferred, but it would flag up a potential issue, which is the primary role of general surveillance.

Reporting requirements

4.7 The general principles of reporting as laid out in Section 2 apply particularly to general surveillance. The key to good surveillance will be accurate, timely and responsive reporting.

4.8 Not only should the proposed period for reporting of general surveillance be included in the plan, together with the subject of the reporting and the frequency of submission of reports, but also emergency procedures and triggers for non-timetabled reporting such as an unanticipated adverse effect.

4.9 The core of the proposals for general surveillance reporting is to make appropriate use of existing monitoring that will detect significant changes at the field, farm and landscape level that might be connected to specific releases. Surveillance of this kind generates added value when integrated and made accessible through open and

compatible databases. We strongly support the principle that the general surveillance programmes for specific releases should aim to deliver information in a form that is compatible with the wider UK and EU monitoring programmes. This will maximise the long-term value of this information. The Committee also recommends that data collation and interpretation should be carried out by an independent body which would consider the information gathered from PMM and national monitoring schemes. This possibility will be considered by Government.

ANNEX 1

Examples of existing monitoring initiatives

The BTO/JNCC/RSPB Breeding Bird Survey (BBS)[7] is a national project aimed at keeping track of changes in the breeding populations of widespread bird species in the UK. The BBS involves over 1700 participants who survey more than 2000 sites across the UK, monitoring the population changes of over 100 bird species.

The Rothamsted Insect Survey[8] (Plant and Invertebrate Ecology Division) operates two national networks for monitoring insect populations in the UK. One is run with the help of the Scottish Agricultural Science Agency and monitors aphids, and the other monitors moths. Daily samples are taken for most of the year, and these date back to 1964 and 1933 respectively. The spatial and temporal scales of monitoring have led to standardised, long-term datasets which are internationally recognised as the most comprehensive for any terrestrial invertebrate groups anywhere in the world. The aphid data now form part of an even larger EC-funded network.

The United Kingdom Butterfly Monitoring Scheme (BMS) [9] was set up in 1976 to provide information on changes in the abundance of butterflies at selected monitored sites throughout the United Kingdom. The BMS consists of a network of sites throughout the UK where butterflies are recorded weekly along fixed transect routes for six months of the year (April to September). Data are collated annually to monitor changes in the abundance of butterflies.

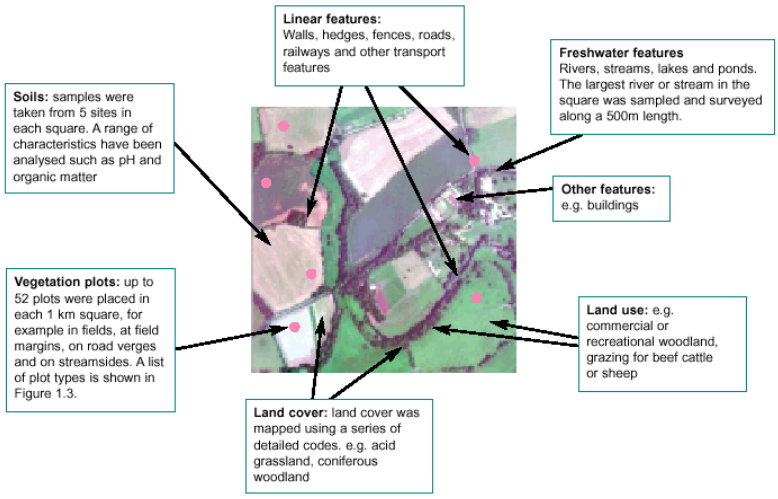
The Biological Records Centre (BRC) [10], established in 1964, is the national focus in the UK for species recording, other than birds. It works with the voluntary recording community throughout the Britain and Ireland. The BRC database contains nearly 12 million records of more than 12000 species. BRC is working with many other organisations to develop the National Biodiversity Network (NBN)[11]. NBN is being developed to co-ordinate the efforts of over 60000 volunteer and professional naturalists who collect data on the occurrence of species of plant and animal species in Britain and Ireland. These developments will involve some 80 national biological societies and species recording schemes and over 70 local records centres.

Countryside Survey 2000 [12]. For a detailed description of this monitoring program see Annex II.

[7] http://www.bto.org/bbs/take_part/introduction.htm
[8] http://www.rothamsted.bbsrc.ac.uk/res/corporate/ltexperiments/ltexp2.htm#Rothamsted%20insect%20survey
[9] http://bms.ceh.ac.uk/
[10] http://www.brc.ac.uk/
[11] www.nbn.org.uk
[12] http://www.cs2000.org.uk/survey.htm

ANNEX II

Countryside Survey 2000 (CS2000) is a major audit of the British countryside. It has involved both detailed field observations and satellite imagery which has provided a complete land cover census for Great Britain and Northern Ireland. One of its aims is to provide national and regional estimates of the extent of the different broad habitats found in the countryside and the character of the different vegetation types associated with them.



The field survey covers both terrestrial and freshwater habitats. It also aims to report on the extent and condition of important landscape features such as hedges and walls. Detailed field observations have been made in a random sample of 1 km grid squares across Great Britain. Altogether, 569 sample squares were visited; 366 were in England and Wales, and 203 were in Scotland. Selection of squares was based on land classes, cartographic data, land form and environmental characteristics. Many of the sample sites were first visited in 1978 and subsequently in 1984 and 1990 providing a time series of changes in the countryside. In each 1-kilometre square, surveyors mapped land cover and landscape features and recorded vegetation species and cover values in:

200m^2 random plots (x 5);
2m x 2m plots in semi-natural vegetation (x 5); and
1m x 10m linear plots along -

- boundaries (x 5);
- hedgerows (x 2);
- streamsides (x 5);
- roadsides (x 5).

Collection of data such as habitat types, hedgerows, plant species and freshwater invertebrates complements powerful satellite imagery enables a deeper level of ecological understanding.

Another important output from CS2000 is information from the survey of breeding birds recorded in the field survey squares. The project involved two visits to the survey squares in spring and summer. The results will be particularly valuable in helping us understand how the mosaics and condition of broad habitats affects the composition of bird communities. The work provides more detailed information about land cover than is available to interpret data from the Breeding Bird Survey. It extends the measures of habitat quality available from CS2000 to another important species group. Such work will assist in understanding and forecasting the wider ecological effects of habitat change.

ANNEX III

Discussion of terms

Harm is an adverse effect. What constitutes harm to the environment and human health is not clearly defined in existing legislation, however, ACRE has laid out its criteria for gauging harm in a report entitled: '*The criteria used by ACRE to gauge harm when giving advice on the risks of releasing genetically modified organisms to the environment'*[13]. In addition, the existing framework of questions for those making applications to release GMOs does give an indication of areas of concern. This is supplemented by additional guidance from ACRE, particularly that concerning the effects on wider biodiversity[14].
It is important to draw a distinction between harm and change. If a release brings about changes to the *status quo* it does not automatically follow that these changes are harmful. Consequently, general monitoring may identify changes and further investigations may be needed to determine those that are potentially harmful. In line with the relevant legislation this assessment is strictly one of 'harm' rather than a cost/benefit type analysis.

Hazard is a condition or situation that may cause harm. In identifying a hazard the likelihood of an adverse effect arising from it is not taken into account. For example, a GM crop maybe extremely hazardous to certain insects but the risks to these organisms may be negligible because in reality they would never be exposed to the hazard.

Risk is the potential of a hazard to cause harm i.e. it takes exposure to the hazard into account as well as its potential consequences. For example, the risk to human health and the environment will be negligible even if gene flow from a particular GM crop to a neighbouring non-GM crop is inevitable, because the consequences of gene flow do not adversely affect human health and the environment.

[13] http://www.defra.gov.uk/environment/acre/harm/pdf/acre_harm_report.pdf
[14] http://www.defra.gov.uk/environment/acre/biodiversity/guidance/pdf/assess-guide.pdf