

Advice on the implications of the Farm Scale Evaluations for biodiversity in the UK

British statutory nature conservation agencies; Countryside Council for Wales, English Nature, JNCC and Scottish Natural Heritage

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1. Introduction

1.1 This advice represents the combined views of the three British statutory nature conservation agencies (English Nature, Countryside Council for Wales and Scottish Natural Heritage) and the Joint Nature Conservation Committee. The agencies are statutory consultees in the process by which applications for release of genetically modified organisms (GMOs) into the environment are considered, and also have a general duty to advise government on conservation policies. We are solely concerned with potential impacts of GMO releases on the living environment and on sustainable use of our natural resources, including protected sites and the wider countryside. We have no locus on matters of public health and safety. The GMO Lead Agency, based in English Nature, undertakes JNCC's work on GMOs on behalf of the other statutory country agencies.

2. **We are satisfied that the FSE research protocol was of sufficient scope and statistical power to enable the UK regulatory authorities to discharge their responsibilities under the GMO Deliberate Release Directive to consider the indirect impacts on biodiversity of the crops in question.**

2.1 Annex II of Directive 2001/18 makes it clear to regulatory authorities that they must;

- i Consider the indirect effects of the GMO on the environment, including changes in agricultural management associated with the GMO
- ii Perform this assessment by comparing the GMO and its associated management systems with equivalent non-transgenic organisms

2.2 Our view is that the design of the FSE experiments conforms very well to these criteria. The experiments were set up to investigate the impacts on farmland biodiversity of changing herbicide systems from conventional weed control used on non-modified crops with the broad spectrum weed control used on the three GMHT crops. Importantly, the methods used in our opinion reflect very well the most likely outcome of general release of these crops if they were to be used as set out in the application dossiers. The use of herbicides on the conventional halves of the fields was shown to be typical of the methods that were normally used on the farms in question, and the broad spectrum herbicides used over the growing GM crops were applied according to the recommendations of the companies that submitted the dossiers. We are therefore firmly of the view that the outcomes from the FSEs fairly represent the most likely impacts on biodiversity from releasing these crops commercially.

3. **In our view the evidence from the FSEs constitutes sufficient information to make robust regulatory decisions on possible commercialisation of GMHT spring oilseed rape, sugar beet, fodder beet and maize.**

3.1 The FSE experiments were statistically over-powered in the sense of being able to detect smaller changes in treatment effects than were first envisaged. This was somewhat surprising but partly due to remarkable consistency of effects within crop type, from year to year over a wide geographic range and over a variety of different farms. The data sets collected were very large, covering a range of organisms sampled from different trophic (feeding) levels. This enabled robust analysis to be made of the impacts of the different herbicide regimes on trophic levels within food chains, and of factors such as seed return that are vital to the maintenance of biodiversity within cropped landscapes.

- 3.2 The results were, as the Steering Committee and research team reported, clear and conclusive. The use of broad-spectrum herbicides over GMHT beet and spring oilseed rape gave large reductions in biomass and density of the primary trophic level, non-crop plants. This in turn had, as ecological theory predicts, an adverse effect on invertebrate abundance, especially those insects that rely on non-crop plants as a nectar source. Seed rain and seed banks in the following year were substantially reduced in the GMHT crops. The results for GMHT maize show that using this herbicide system results in more biodiversity in and around fields compared with the conventional residual herbicide system in general use on forage maize.
- 3.3 We know that as break crops, oilseed rape, sugar beet and fodder beet fields are relatively weedy, replenishing seed banks between years of growing cereal crops. This means that despite their comparatively small area in the UK they are disproportionately important for farmland biodiversity, especially birds. For example, research on diets of farmland seed-eating birds in East Anglia shows that the most common weeds of sugar beet – fat-hen *Chenopodium album*, knotgrass *Polygonum aviculare*, and black-bindweed *Fallopia convolvulus* – are those whose seeds are most commonly found in the guts of skylark, dunnocks, linnets and reed buntings, all of which are listed as priority species in the UK Biodiversity Action Plan (Clarke *et al.* 2003). Recent BTO/Defra research found that oilseed rape stubbles had higher densities of weed and crop seeds on the soil surface than any other crop studied and some fields supported high densities of birds, especially early in winter. In Scotland, overwintering oilseed rape stubbles had higher densities of seed eating passerines than any other crop. (Hancock and Wilson 2003). Oilseed rape fields are known to be important spring feeding grounds for several species of farmland birds (Burton *et al.* 1999). The Watkinson *et al.* (2000) model of skylarks feeding on seeds of fat-hen in sugar beet crops illustrates how populations of this bird could be adversely affected by reductions in weeds resulting from the use of broad-spectrum herbicides over the GMHT beet crop.
- 3.4 We agree with the research team view that the implications for general farmland biodiversity can be clearly seen from the results. If GMHT beet and spring oilseed rape were released for general commercial use, there would be a further reduction in farmland biodiversity. If GMHT maize were released, and atrazine continues to be used to control weeds in conventional cropping (but see below), the opposite would be the case.
- 4 We are convinced by the evidence from the FSEs that commercial use of GMHT spring oilseed rape and beet would have adverse impacts on biodiversity in farmland landscapes. This would hinder government policy to enhance biodiversity. We are equally convinced that the evidence from the experiments on GMHT maize shows that there would be no more harm to biodiversity than current conventional weed control methods in this crop.**
- 4.1 We cannot and will not try to predict the magnitude of adverse or beneficial effects on biodiversity of herbicide regimes associated with the crops tested. Models developed by Sutherland *et al.* and Watkinson *et al.* may eventually give some insight into the immediate effects, but, as the FSE research team pointed out, such estimates rely on assumptions about uptake by farmers, distribution and areas of GMHT crops cultivated and policy influences such as the impact of CAP reforms on cropped areas. In addition any forward look would have to take into account the impacts of UK and European measures to encourage non-food uses of these crops. We argue that these factors are almost impossible to predict with any degree of certainty.
- 4.2 It is also difficult to predict how farmers would use GMHT crops if they were released commercially. Experience from North America suggests that farmers would target their weediest fields where soil conditions and weed seed banks are such that conventional methods often fail. As a 1999 survey (Lainsbury *et al.* 1999) of sugar beet fields commissioned by English Nature demonstrates, such fields are important habitats for farmland wildlife. It is also possible that farmers might adopt minimal till systems on light soils. These have some environmental advantages, but may have adverse effects on biodiversity. There is little experimental or observational evidence available to be able to predict impacts on biodiversity from these possible developments. The protocols used for the FSE experiments could easily be adapted to investigate biodiversity and other impacts of minimal till systems.

4.3 What we can be sure about is that if these crops were to be commercialised in the near future by the unconditional general release that we believe is implicit in the application dossiers, there would be ecologically significant reductions in farmland biodiversity within and around GMHT beet and spring oilseed rape. This would in our view be likely to take farmland biodiversity, especially populations of some farmland birds, in the opposite direction to that envisaged by the overall thrust of UK government policies, which are intended to maintain and enhance biodiversity on cropped land. This policy thrust is illustrated well by the government's Quality of Life target for recovery of farmland birds, several of which are dependent on arable land for crucial parts of their life cycles. Equally, we are firmly of the view that using GMHT maize could have several environmental advantages over current systems of cultivation, including higher in-crop biodiversity, more biodiversity in the crop margins and verges, and the possibility of having weeds or under-sown crops in maize stubbles over winter.

5 We believe that scientifically defensible decisions on commercial release of these crops can be made on the basis of the FSE results. GMHT spring oilseed rape and beet should not be commercialised. GMHT maize may be commercialised, subject to further consideration of future conventional herbicide systems that could be used to replace atrazine.

5.1 Our advice to government is that the decision on whether to release these crops should be based on the above considerations of trends shown by the FSE results, and not on whether mitigation measures could be used to alleviate the effects on biodiversity of the broad spectrum herbicides associated with GMHT beet and oilseed rape. So far as we are aware applicants have not put forward management strategies aimed at countering adverse effects, and the FSE results show that delayed spraying, as advocated by some researchers, would have no real advantage to in-crop biodiversity. Although the general *trends* in effects on biodiversity are clearly shown by the FSE results, attempts to estimate the *magnitude* of adverse or beneficial impacts over whole rotations and landscapes are premature and likely to be misleading; regulatory decisions should be based on the most likely current impacts on biodiversity identified by the FSE results. We believe that this approach fits well with the precautionary principle outlined in the Directive.

5.2 Our farmland wildlife is already at a very low ebb and we cannot therefore risk any further reductions caused by commercialisation of GMHT oilseed rape and beet crops known to have adverse effects on biodiversity. By the same criterion the use of GMHT maize cropping systems that have been shown to give biodiversity benefits may be permitted, providing that these cropping systems are demonstrably safe for the environment more generally, and the crops themselves are safe for human and animal health. **Since the main conventional method of weed control in forage maize, atrazine, is to be phased out in the next 18 months, it will be necessary to identify which herbicides will replace atrazine in maize, and how the impacts of these on biodiversity compare with the GMHT system.**

6 The FSE results show that changes in cropping patterns in farmed landscapes have a substantial impact on biodiversity.

The results show that management systems associated with different crops have very different impacts on biodiversity. This comes as no surprise to the statutory agencies, who have argued for many years that the introduction of novel crops and changes in cropping patterns should have been assessed before they were introduced. Changes such as from grassland to forage maize, from spring to winter crops and from hay to silage have had profound impacts on the general biodiversity associated with arable landscapes, and have been major factors adversely affecting specific groups such as farmland birds and rare arable plants. **We strongly recommend to Defra that protocols such as those used in the FSEs should be used to better understand and quantify impacts on biodiversity of major changes in farmed landscapes, not only those proposed for the future, but to review the impacts those which are now established in our countryside.**

References

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Directive 2001/18/EC - ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

This Annex describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environmental risk assessment (e.r.a.) referred to in Articles 4 and 13. It will be supplemented by guidance notes to be developed in accordance with the procedure laid down in Article 30(2). These guidance notes shall be completed by *.

With a view to contributing to a common understanding of the terms "direct, indirect, immediate and delayed" when implementing this Annex, without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, these terms are described as follows:

- "direct effects" refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;
- "indirect effects" refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management.
Observations of indirect effects are likely to be delayed;
- "immediate effects" refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;
- "delayed effects" refers to effects on human health or the environment which may not be observed during the period of the release of the GMO but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environmental risk assessment is also that an analysis of the 'cumulative long-term effects' relevant to the release and the placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment, including inter-alia flora and fauna, soil fertility, soil degradation of organic material, the feed/ food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

A. Objective

The objective of an e.r.a. is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The e.r.a. should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

B. General Principles

In accordance with the precautionary principle, the following general principles should be followed when performing the e.r.a.:

- identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

* Date referred to in Article 34.

- the e.r.a. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;
- the e.r.a. should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, i.a., GMOs already in the environment;
- if new information on the GMO and its effects on human health or the environment becomes available, the e.r.a. may need to be re-addressed in order to:
 - = determine whether the risk has changed;
 - = determine whether there is a need for amending the risk management accordingly.

C. Methodology

C.1. Characteristics of GMOs and releases

Depending on the case the e.r.a. has to take into account the relevant technical and scientific details regarding characteristics of:

- the recipient or parental organism(s);
- the genetic modification(s), be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;
- the GMO;
- the intended release or use including its scale;
- the potential receiving environment; and
- the interaction between these.

Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments can assist the e.r.a..

C.2. Steps in the e.r.a.

In drawing conclusions for the e.r.a. referred to in Articles 4, 6, 7 and 13 the following points should be addressed:

1. Identification of characteristics which may cause adverse effects:

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use, will assist in identifying the particular potential adverse effects arising from the genetic modification. It is important not to discount any potential adverse effect on the basis that it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include:

- disease to humans including allergenic or toxic effects (see e.g. items IIA(11) and IIC(2)(i) in Annex IIIA, and B(7) in Annex IIIB);
- disease to animals and plants including toxic, and where appropriate, allergenic effects (see e.g. items IIA(11) and IIC(2)(i) in Annex IIIA, and B(7) and D(8) in Annex IIIB);
- effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see e.g. items IVB(8), (9) and (12) in Annex IIIA);
- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, e.g. by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see e.g. items IIA(11) e) and IIC((2)(i)(iv) in Annex IIIA);
- effects on biogeochemistry(biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see e.g. items IIA(11) f) and IVB(15) in Annex IIIA, and D(11) in Annex IIIB).

Adverse effects may occur directly or indirectly through mechanisms which may include:

- the spread of the GMO(s) in the environment
- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not
- phenotypic and genetic instability
- interactions with other organisms
- changes in management, including, where applicable, in agricultural practices.

2. Evaluation of the potential consequences of each adverse effect, if it occurs

The magnitude of the consequences of each potential adverse effect should be evaluated. This evaluation should assume that such an adverse effect will occur. The magnitude of the consequences is likely to be influenced by the environment into which the GMO(s) is (are) intended to be released and the manner of the release.

3. Evaluation of the likelihood of the occurrence of each identified potential adverse effect

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the GMO(s) is intended to be released, and the manner of the release.

4. Estimation of the risk posed by each identified characteristic of the GMO(s)

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

5. Application of management strategies for risks from the deliberate release or marketing of GMO(s)

The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined.

6. Determination of the overall risk of the GMO(s)

An evaluation of the overall risk of the GMO(s) should be made taking into account any risk management strategies which are proposed.

D. Conclusions on the potential environmental impact from the release or the placing on the market of GMOs

On the basis of an e.r.a. carried out in accordance with the principles and methodology outlined in sections B and C, information on the points listed in sections D1 or D2 should be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental impact from the release or the placing on the market of GMOs:

D2. In the case of genetically modified higher plants (GMHP)

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.
 2. Any selective advantage or disadvantage conferred to the GMHP.
 3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species
 4. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).
 5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.
 6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).
 7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it if it is intended to be used as animal feed.
 8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).
 9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.
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