ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

Advice on the implications of the farm-scale evaluations of genetically modified herbicide-tolerant crops

Date: 13 January 2004

A. Summary

1. The Advisory Committee on Releases to the Environment (ACRE) has considered the results of the farm scale evaluations (FSEs) of genetically modified herbicide-tolerant (GMHT) crops that were published on 16 October 2003. The Committee considered, in addition to the results themselves, written submissions and heard evidence at two specially convened open meetings.

2. The Committee considers that the FSEs provide important and robust evidence concerning the impact of the herbicide regimes associated with the three GM crops studied. ACRE believes that the FSEs also have implications for agriculture in general, and may feed into a wider discussion concerning environmental impacts of agricultural practices.

3. Concerning the individual crops, ACRE concludes as follows:

   Maize: Based on the evidence provided by the FSE results published in October 2003, if GMHT maize were to be grown and managed as in the FSEs this would not result in adverse effects, as defined and assessed by criteria specified in Directive 2001/18/EC, compared with conventionally managed maize.

   Beet: Based on the evidence provided by the FSE results published in October 2003, if GMHT beet were to be grown and managed as in the FSEs this would result in adverse effects on arable weed populations, as defined and assessed by criteria specified in Directive 2001/18/EC, compared with conventionally managed beet. The effects on arable weeds would be likely to result in adverse effects on organisms at higher trophic levels (e.g. farmland birds), compared with conventionally managed beet.

   Spring-sown oilseed rape: Based on the evidence provided by the FSE results published in October 2003, if spring-sown GMHT oilseed rape were to be grown and managed as in the FSEs this would result in adverse effects on arable weed populations, as defined and assessed by criteria specified in Directive 2001/18/EC, compared with conventionally managed spring-sown oilseed rape. The effects on arable weeds would be likely to result in adverse effects on organisms at higher trophic levels (e.g. farmland birds), compared with conventionally managed oilseed rape.

4. In each case, the Committee emphasises that these conclusions only apply to the management regime used in the farm scale evaluations. Alternative management strategies may have different impacts which may be either beneficial or adverse, and any such alternative strategies will be assessed on the basis of appropriate evidence. In some cases further empirical evidence may be required. The

Committee also stresses that the impacts are due to the herbicide management regime, not the genetic modification itself.

B. The Advisory Committee on Releases to the Environment

5. The Advisory Committee on Releases to the Environment (ACRE) is the statutory advisory committee appointed under section 124 of the Environmental Protection Act 1990 (the EPA) to provide advice to Government regarding the release and marketing of genetically modified organisms (GMOs)[1]. The Committee works within the legislative framework set out by Part VI of the EPA and the GMO Deliberate Release Regulations 2002 which together implement Directive 2001/18/EC[2]. Sections of the Directive most relevant to the assessment of the farm-scale evaluation (FSE) trials are discussed in more detail in Annex 1.

6. ACRE advises the UK Government and Devolved Administrations of Scotland, Wales and (when in operation) Northern Ireland. Advice is given, in England, to the Secretary of State for Environment, Food and Rural Affairs (Defra). In Scotland and Wales we advise the Scottish Ministers and the Welsh Assembly Secretaries, while in Northern Ireland ACRE's advice is received by the Department of the Environment. In addition to Ministers, ACRE also advises the Health and Safety Commission/Executive on human health aspects of releasing GMOs in respect of England, Scotland and Wales.

C. The Farm-scale evaluations of genetically modified herbicide tolerant crops

History, objectives and scope

7. The Farm-scale Evaluations (FSEs) of genetically modified herbicide tolerant (GMHT) crops were a four-year[3] programme of research by independent researchers aimed at studying the effect that the weed management practices associated with these crops might have on farmland wildlife, when compared with weed control used with non-GM crops. The FSEs were initiated in response to concerns raised by English Nature and others that the introduction of GMHT crops might further exacerbate declines in farmland wildlife that have been observed since the middle of the 20th century. The FSEs were designed to test the null hypothesis "that, for each crop, the effect on the abundance and diversity of wildlife of the management of the GM crop does not differ from the effect of the management of the conventional equivalent".[4]

8. The FSEs do not replace existing elements of the regulatory system designed to assess the direct impacts of the crops themselves; instead they augment them by extending the consideration to cover the entire production system. The FSEs did not, therefore, investigate possible direct effects of GMHT crops on human health or the environment (such as the consequences of gene flow). They are also not concerned with the exact nature or derivation of the herbicide tolerance. For

[1] The Committee also advises Government on the releases of non-native species under the Wildlife and Countryside Act 1981.
[2] For further details concerning ACRE and its remit see http://www.defra.gov.uk/environment/acre. For further details of the regulation of GMOs see http://www.defra.gov.uk/environment/gm/regulation/index.htm.
[3] The FSEs began in 1999 with a pilot year. The crops were cultivated over a three-year period (2000-2003).
[4] For general information about the FSEs see http://www.defra.gov.uk/environment/gm/fse For further details of the history of the FSEs see http://www.defra.gov.uk/environment/gm/fse/background/history.htm. For background on the scope and rationale for the FSE see http://www.defra.gov.uk/environment/gm/fse/facts/ssc.htm.

example, tolerance to broad spectrum herbicides may also be produced in crops through conventional breeding, allowing similar weed management strategies to be used with non-GM HT crops.

9. All crop cultivation required for the FSEs is now complete, although some further data collection and analysis is continuing. The first set of results for the three spring-sown crops, maize, beet and spring-sown oilseed rape, were published in October 2003. Results for autumn-sown oilseed rape are due in 2004.

10. Applications to cultivate GMHT maize, beet and oilseed rape in the European Union either have been considered (two types of maize and two types of oilseed rape), or are being considered (a further three types of maize, three types of beet and three types of oilseed rape). Details of the current status of these applications are provided in Annex 2.

Results and Conclusions

11. The results of the FSEs for spring sown crops were published on 16 October 2003. The results were published as a series of eight peer-reviewed scientific papers in The Philosophical Transactions of the Royal Society (Biological Sciences)[5]. In addition the FSE research team published a technical commentary and a non-specialist summary of the results[6].

12. Conclusions of the ecological studies are contained in the various scientific papers and summarised in the technical commentary and non-specialist summary. The scientific steering committee for the FSEs (SSC) published final advice to government on the day of publication confirming that, for the spring-sown crops, the null hypothesis had been adequately tested and was rejected for each crop[7].

D. ACRE's consideration of the FSE results

Consideration of the FSE results

13. The FSE results, commentary and non-specialist summary and the SSC advice were forwarded to ACRE on the day of publication. Members of ACRE also attended presentations of the results given by the research team on 16 and 28 October at the Royal Institution in London[8].

Key Findings of the FSEs

14. The FSE research team summarised their key findings and their view of the wider implications of the results in the summary of their commentary on the results. This summary is reproduced verbatim in Box 1.

15. ACRE agrees with the summary provided by the FSE researchers, and, in particular, stresses the following points (Paragraphs 16-19).

[5] *Phil. Trans. R. Soc. Lond.* B (2003) **358**, 1777-1913
[6] Copies of the summaries and details of how to obtain the full papers and given on the FSE web-site at http://www.defra.gov.uk/environment/gm/fse.
[7] SSC advice is available at http://www.defra.gov.uk/environment/gm/fse/results/ssc-advice.htm
[8] Transcripts and online video streams of these presentations are available via http://www.defra.gov.uk/environment/gm/fse or http://www.livegroup.co.uk/sscfarmscaleevaluations.

Box 1: The FSE research team summary of the results

1. The findings of the Farm Scale Evaluations of spring sown genetically modified crops are now published in a special issue of the Philosophical Transactions of the Royal Society. Here, we bring together elements of these findings to assess the potential implications of large scale growing of genetically modified herbicide-tolerant (GMHT) crops on farmland biodiversity.

2. Effects of GMHT beet, maize and spring oilseed rape crops on weeds and invertebrates were investigated across Great Britain during 2000-02.

3. In beet and spring oilseed rape before post-emergence herbicides were applied, there were more weeds in GMHT crops than in conventional crops. Following herbicide applications to GMHT beet and spring oilseed rape crops, weed biomass and seed rain were one third or less than corresponding amounts in conventional crops, resulting in smaller seedbanks. In maize, numbers, biomass and seed rain of dicot weeds were higher in GMHT treatments throughout the season; there was little evidence of effects on seedbanks. Bees, butterflies, common seed-eating carabids and detritivorous invertebrates were found in larger numbers in treatments and crops where there were more forage resources.

4. There were few treatment effects on species diversity and consumer / resource ratios.

5. Differences in mean plant and invertebrate abundance between different conventional crop species were as great as that observed between GMHT and conventional varieties of each crop. In general conventional oilseed rape and beet fields were the richest in flora and fauna, with conventional maize crops the poorest.

6. For each crop, treatment effects could all be explained by the different herbicide regimes, and were consistent between sites, farms, years and different initial levels of weeds.

7. If these trends are maintained under widespread GMHT cropping, then the present herbicide regimes associated with GMHT beet and spring oilseed rape might exacerbate long-term declines of dicot weeds, that include species that are important food resources for many invertebrate, small mammal and bird species. By contrast, these same weeds might increase in abundance following a shift from conventional to GMHT maize cropping, due to the greater weed control exerted by conventional herbicide regimes compared to those used with the GMHT crops.

8. Major sources of variation in potential impacts arise from probable changes in herbicide regimes, tillage systems and crop rotations and from possible long-term interactions between weed and invertebrate populations. All of these potential effects depend greatly upon the management of the crops, the rotations, and upon the provision of forage and habitat resources across the entire farmed landscape.

16. The FSEs were well designed, executed and analysed. The studies were sufficiently replicated to ensure that there was adequate statistical power allowing biologically important changes to be determined with the required certainty.

17. A particularly striking feature of the FSE results was their consistency between sites, farms, years and initial weed abundances. This indicates that robust and reproducible effects of the herbicide management regime occur, and increases the level of certainty which can be ascribed to the reported effects.

18. Differences reported in weed biomass, seed returns and seedbank densities were key to ACRE's considerations. Under the conditions of the FSEs, weed seed returns were significantly reduced in GMHT beet and spring-sown oilseed rape crops compared with their non-GM counterparts. This in turn was shown to reduce the respective seedbank densities. Conversely, the weed seed rain in GMHT maize was higher than its non-GM comparator, although the difference was not detected in the seedbank. The Committee also notes that further data concerning effects on seedbank densities in years following the cultivation of the GMHT crop will be available in the future, which may further increase the certainty concerning effects on this parameter.

19. Changes in invertebrate numbers were generally more complex and less affected by GMHT cropping than was weed abundance. Effects tended to be associated with certain species groups and in particular, with the time of year. Fewer butterflies in spring oilseed rape and beet, and lower numbers of bees and Heteroptera in beet were detected but whether these changes are representative of wider effects on these species is uncertain. Carabids that feed on weed seeds were more abundant in halves of fields under conventional management. Conversely, soil-dwelling collembola that feed on decomposing plant material were more abundant in GMHT crops.

Submissions of written evidence

20. Prior to the release of the FSE results it was announced that ACRE would give any interested parties the opportunity to consider the FSE results and their implications and to submit evidence as part of the deliberation process. Evidence was accepted in the form of up to two-sides of A4 for a period of one month following publication of the results. The submission deadline was 16 November 2003. Sixty eight submissions were received and copies of all submissions were forwarded to ACRE for consideration[9].

Open meetings

21. ACRE held two public open meetings, on 25 November 2003 in London and 4 December 2003 in Edinburgh. Prior to the meetings ACRE members selected from the written submissions a number of contributions to be heard in person. The selection of 14 submissions was made to provide a range of opinions concerning the implications of the FSE results, with a focus on submissions that the Committee felt addressed issues that were important for their deliberations. In addition the FSE researchers were invited to make a presentation at each of the open meetings. Each invited contributor was given the opportunity to present their argument and then ACRE members asked questions of the contributor. Each meeting was concluded with a period for questions from the floor[10].

Summary of written and oral evidence

22. Many of those making submissions wanted to emphasise that the FSE trials explored the consequences of weed control using broad spectrum herbicides (in this case, used in association with GMHT crop varieties), on farmland biodiversity. Most agreed that the FSEs were scientifically rigorous and provided valuable information on farmland ecology although there were some criticisms of the design and scope of these trials. ACRE has considered these and, where

[9] All submissions are available at http://www.livegroup.co.uk/acrefarmscaleevaluations
[10] Details of the invited contributions and full transcripts of the meetings are available at http://www.livegroup.co.uk/acrefarmscaleevaluations.

appropriate, taken them into account when drawing its conclusions. The main points raised in submissions on the design of the FSEs were:

- *Crop yields* were not reported in the FSE results and a number of submissions highlighted this as a key omission. The concern expressed was that if GM crop yields were not at least as high as their non-GM counterparts the impact of their associated management practices would be underestimated. The Committee was presented with evidence from the public, FSE farmers and industry based on observations and measurements ranging in scale from a few fields to entire crops. Submissions provided evidence both for and against differences in yield between the conventional and GMHT crops. Regular recording by the FSE research team showed that the levels of weed control achieved in the GMHT treatments in rape, beet and maize did not affect the ability of the crops to grow and develop at the same rate as in the conventional comparators (Figure 2, Champion et al. 2003[11]).

- *Herbicide usage*. In the FSEs, farmers were advised on the treatment of their crops with glyphosate and glufosinate herbicides by SCIMAC. There were different viewpoints on this. It was suggested that if GMHT crops were to be commercialised farmers may alter weed management regimes associated with them in order to achieve better weed control, and that, therefore, the FSEs represent minimised impacts on biodiversity. This point was often raised alongside a scepticism that the HT crops were not grown so as to achieve yields at least as high as those in the conventional comparisons. An alternative point of view raised in submissions was that had the FSE farmers gained more experience in growing GMHT crops they may well have gained more confidence in the ability of the broad spectrum herbicides to control weeds and used them more reactively, and possibly later in cultivation. Some submissions questioned whether the scrutiny of management practices by the FSE scientists resulted in farmers reducing chemical usage on the non-GM half of fields thereby providing a false comparator for management practices associated with GMHT crops. It should be noted that an audit of herbicide inputs conducted as part of the FSEs found no evidence that usage had been biased in the trials (Champion et al., 2003[11]).

- *Use of atrazine*. Farmers involved in the maize FSEs used glufosinate in the absence of other herbicides on the GMHT halves of fields. A number of submissions argued that this would be an unlikely scenario if maize with tolerance to this herbicide were grown commercially in the UK. Evidence was presented which showed that in the USA, in particular, glufosinate is used with a residual herbicide such as atrazine. Those submitting this evidence suggested that this would be inevitable in the UK, thereby negating the trials in the FSEs using glufosinate. Contrary to this evidence, others considered that the farming situations (in particular crop rotations and climate) in the USA and elsewhere, are significantly different from those in the UK.

- *The wider picture – environmental and human health effects were not studied in the FSEs*. The Committee received a number of submissions identifying parameters that were not taken into account in the FSEs but

[11] *Phil. Trans. R. Soc. Lond.* B (2003) **358**, 1801-1818

which are thought to be relevant to ACRE's considerations. These include differences in toxicity, persistence and dosage of the active ingredients in the herbicides on farmland biodiversity. A number of submissions suggested that glyphosate and glufosinate used in association with their respective GMHT crops might well provide environmental benefits. A number of submissions, including those from FSE farmers, highlighted that the trials did not take into consideration the reduction in machinery usage on the GM halves of fields, or the possibility of direct drilling or under sowing – all of which may be facilitated by the use of herbicide regimes associated with the cultivation of GMHT crops and which have potential environmental benefits. One submission discussed the use of Life Cycle Assessments (LCA) to compare the environmental and human health consequences associated with entire systems. This submission reported on LCA of non-GM sugar beet and GM sugar beet production managed under conditions similar to those used in the FSEs. A draft LCA was subsequently provided to the Committee, showing potential benefits of the GMHT system in terms of wider environmental impacts.

- *Organic farming methods*. A criticism raised in a number of submissions was that comparisons with organic farming methods were not included in the FSEs.

- *Organisms that were not studied*. The fact that birds and a number of 'relevant species' such as earthworms were not directly studied in the FSEs was raised in some submissions. For certain organisms, the practical difficulties in taking measurements were recognised, although some felt that bird species could have been studied. Leading on from this, it was proposed that where there is uncertainty about the impacts of GMHT management on wider biodiversity a precautionary approach should be taken on the release of GM crops.

- *Split fields*. In general, it was accepted that the use of split fields rather than paired fields was the preferred design. However, some submissions cautioned ACRE to consider whether this might have biased the results for mobile invertebrates. It was reasoned that a lower weed abundance in one part of the field might result in the migration of mobile invertebrates to a part of the field with higher weed abundance thereby emphasising the difference.

23. Where comments in submissions are specific to particular FSE crops these are raised in the following section where maize, spring-sown oilseed rape and beet are considered individually.

24. In addition to these submissions, the GM Science Review Panel chaired by Sir David King has provided its opinion on the FSE results to ACRE[12]. The Panel considered the FSE publications in detail and commented on the design and quality of the trials, and on the results and implications for farmland biodiversity in the future. The GM Science Review Panel concluded:

"If all else remains constant and the three crops are introduced and managed in the way they were in the trials, then for GMHT beet and spring oilseed rape a significant reduction would be expected in weed biomass and weed seed return

[12] Available at http://www.gmsciencedebate.org.uk/pdf/gmsci-fse-acre.pdf

resulting in fewer nectar resources for pollinators and fewer weed seed resources for granivorous birds. For GMHT maize the opposite is expected. These effects arise from the crop management regimes associated with these GMHT crops (i.e. the herbicide application) and are not a direct consequence of the way the crops have been bred."

Writing the advice

25. Following the open meetings ACRE met in closed session on 15 December 2003 to deliberate the implications of the FSE results and evidence submitted from stakeholders. This advice was then drafted.

E. ACRE's advice

26. ACRE has been asked by Government to advise on the implications that the FSE results have for the cultivation of GMHT crops in the UK. Consequently, this document and the advice it contains is based solely on the assessment of the management effects reported in the FSE results. The Committee has considered, for each crop, whether the data reported in the FSEs provide evidence that the management regimes associated with GMHT crops result in direct or indirect adverse effects on the environment compared with the relevant conventionally managed non-GM crop.

27. The Committee acknowledges the significant contribution that the FSEs have had to the understanding of farmland ecology and consider it important that the results are viewed from a perspective wider than GMHT crop management. A key aspect of the findings of the FSEs is the observation that the impacts of the management regime associated with GMHT crops are no greater than the differences between different conventionally managed crops. The results also suggest that all major changes in agricultural practice (including, for example, the use of herbicide tolerant crops produced by conventional breeding), not just those associated with GM crops, may need to be scrutinised in terms of their environmental impact.

28. In this regard, a key question concerns the balance between the use of land for food production and approaches that promote wider biodiversity. The Committee hopes that the FSE results will trigger a debate on these issues that goes beyond a narrow, GM-focussed discussion. This will require a consideration of the magnitude of environmental impact of agriculture that is seen to be acceptable.

29. Consideration of the broader issues outlined above is beyond the scope of this advice. However, the Committee considers these issues to be important and will, as a result of issues raised during deliberation on the FSE results, establish a subgroup to examine the wider implications of the FSEs. The work of this subgroup will begin during 2004.

30. In addition, the Committee believes that the papers published in October 2003 represent the first stage in the continuing analysis of the data collected in the FSEs. There is likely to be considerable further exploitation of this body of data, which will include modelling impacts of the cultivation of GMHT crops at the landscape level. ACRE will continue to monitor the development of this work, and may review the advice presented here if new and significant findings emerge.

Maize

Summary of written and oral evidence

31. Evidence was submitted that ranged from the opinion that the FSE maize results indicated that no adverse environmental effects would result from the introduction of GM glufosinate tolerant maize (and that in fact benefits would be realised), to the view that environmental impacts were underestimated or not fully understood.

32. Evidence in written and oral submissions that can be applied to the FSEs in more general terms is presented in paragraph 22. Here, concerns that are specific to the maize results are discussed, and, in particular, the implications of the use of atrazine in the conventionally managed halves of the FSE fields. This herbicide was used on the non-GM field halves at 75% of maize FSE sites (see page 8 of the FSE commentary[6]), but it is due to be phased out in Europe in April 2005. Some consider that this makes the comparisons between conventional weed management and glufosinate treatments in maize redundant, or at least only useful as long as atrazine is still in use. Others suggest that comparisons should be made using data solely from non-GM maize plots in the FSEs on which atrazine had not been applied. Conversely, a number of submissions agreed with the FSE research team who suggested that, when atrazine and other herbicides used in the FSEs are no longer available, they are likely to be replaced by herbicides that provide a similar degree of weed control and the maize results from the FSEs are still relevant.

ACRE's advice on GM HT maize (including transformation events T25, Bt176, Bt11, and 1507)

33. In formulating its advice concerning GMHT maize ACRE considered the current regulatory context (Annex 2). There are current consents, issued under Directive 90/220/EEC in 1997 and 1998 which permit the cultivation of maize containing transformation events T25 and Bt176 in the European Union. ACRE first gave advice to Government on T25 maize in June 1996; in December 2002 the Committee presented further advice[13] in response to comments raised during the hearing convened to consider the addition of maize variety Chardon LL[14] to the National Seed List. ACRE gave advice to Government on Bt176 maize in July 1998. All consents issued under Directive 90/220 expire in October 2006.

34. The FSE data represent 'new information' concerning transformation events T25 and Bt176 in the sense of Article 20 of Directive 2001/18/EC, and the Committee considered whether this new information provides grounds for amending or revoking the consents.

35. There are also applications to place on the market maize containing transformation events Bt11 and 1507 for cultivation. ACRE's consideration of the FSE results will form part of the Committee's assessment of these applications. There is also an application to place on the market maize containing transformation event NK603 for cultivation. This maize is glyphosate-tolerant, unlike the maize used in the FSEs which is tolerant to glufosinate. Therefore, the potential impacts of glyphosate-tolerant maize on wider biodiversity are not directly addressed by the FSEs.

[13] Available at http://www.defra.gov.uk/acre/advice/advice20.htm
[14] Chardon LL is a maize variety which contains transformation event T25.

36. ACRE concludes that:

> Based on the evidence provided by the FSE results published in October 2003, if GMHT maize were to be grown and managed as in the FSEs this would not result in adverse effects, as defined and assessed by criteria specified in Directive 2001/18/EC, compared with conventionally managed maize.

37. ACRE has arrived at this conclusion because the results demonstrate that there is a 2-fold greater weed biomass and 2-fold greater seed rain in the GMHT maize fields compared with conventionally managed maize (Tables 2, 4 and 5 of Heard et al. 2003[15]), and this is likely to have either a neutral or positive impact on organisms at higher trophic levels (e.g. farmland birds). The quantitative nature of any impacts at higher trophic levels remains uncertain, but the data do not suggest that these impacts would be negative.

38. This conclusion however, can only be confidently ascribed to future GMHT maize crops if they are managed in the same way as they were in the FSEs. In addition, this conclusion may change if the conventional herbicide management regimes for maize are altered. Accordingly ACRE recommends that any future commercial cultivation of GM glufosinate-tolerant maize be limited to the conditions under which it was grown in the FSEs, or conditions that have been shown not to result in adverse effects.

39. As it is already known that the principal management practice for conventional maize is to be phased out in April 2005, ACRE recommends that studies are initiated immediately that consider the validity of the conclusions of the FSE results in the light of this phasing out of atrazine and the introduction of new weed management regimes for non-GM maize. Such studies might include further analysis of the FSE dataset. A comparison of the impacts of new management regimes with that based on atrazine might also be appropriate, focussing on critical indicators such as weed seed biomass and seed rain.

40. In line with this, the Committee recommends that applicants implement a post-market monitoring scheme to monitor changes in conventional management practice, with particular reference to atrazine, before the expiry of the T25 and Bt176 maize consents in October 2006. The Committee also recommends that herbicide usage on both conventionally managed non-GM and GMHT maize is monitored during this period.

Beet

Summary of written and oral evidence

41. Evidence was submitted that ranged from the opinion that the FSE GM beet results indicated no adverse environmental impact, to the view that the effects would be damaging to the environment. The impact on the weed seedbank was frequently cited as the most biologically important result with food chain implications for farmland birds. Submissions suggesting that the results do not represent adverse effects argued this within the wider context of recent change in agricultural systems.

42. Evidence in written and oral submissions that can be applied to the FSEs in more general terms is presented in paragraph 22. Many submissions supported the

[15] *Phil. Trans. R. Soc. Lond.* B (2003) **358**, 1819-1832

view that the management practices associated with the cultivation of GMHT beet would adversely affect the environment. Others wanted to emphasise that the FSEs only studied the effects of one management approach whereas GM crop-herbicide combinations provide a flexibility to design weed control strategies to meet biodiversity targets and to minimise the likelihood of resistance to the herbicide occurring. There was disagreement in submissions as to whether farmers would adhere to restrictions in using these herbicides and whether this could be monitored satisfactorily.

43. The biological importance of any statistically significant differences observed in the FSEs was questioned in submissions. One argument presented was that change should be looked at in the context of other variables in agriculture such as crop type, seasons, location in the field etc. In line with this, many submissions wanted to emphasise that the FSEs showed that differences observed between crops were significantly greater than those occurring as a result of the management practices associated with GM and non-GM crops. Taking this further, some felt there was an argument for supporting biodiversity in field margins and other dedicated areas rather than attempting to manage biodiversity in the cropped fields themselves. Some felt that HT crops might allow farmers to maximise the efficiency with which their land is farmed, leaving more land to be managed for biodiversity.

44. A few submissions argued that because these GMHT crops are used as break crops in rotations, the impact of increased weed control in them was more significant than it would be in other points in the cycle of rotations which support less wildlife. Others argued that this is a simplistic view in that the use of glyphosate in broad leaved break crops could lead to reduced herbicide usage in previous and subsequent cereal crops.

ACRE's advice on GM HT beet (including transformation events T9100152, H7-1 and A5/15)

45. In formulating its advice concerning GMHT beet ACRE considered the current regulatory context (Annex 2). There are no current consents in the European Union which permit the cultivation of GM beet. However, there are three current applications to market beet containing transformation events T9100152, H7-1 and A5/15 for cultivation – two of these are for sugar beet, and one is for fodder beet. Reports on these dossiers have yet to be prepared by the lead Member States concerned and thus the dossiers have not been considered by ACRE. The advice presented here considers only the implications of the FSE results – if and when these applications enter the European phase of the regulatory process ACRE will consider all aspects of the risk assessment of these types of GM beet.

46. ACRE concludes that:

> Based on the evidence provided by the FSE results published in October 2003, if GMHT beet were to be grown and managed as in the FSEs this would result in adverse effects on arable weed populations, as defined and assessed by criteria specified in Directive 2001/18/EC, compared with conventionally managed beet. The effects on arable weeds would be likely to result in adverse effects on organisms at higher trophic levels (e.g. farmland birds), compared with conventionally managed beet.

47. ACRE has arrived at this conclusion because the results demonstrate that there is a 5-fold lower weed biomass and 3-fold lower seed rain in the GMHT beet

fields compared with conventionally managed beet, and this results in a 1.2-fold lower return of seeds to the weed seedbank (Tables 2, 4 and 5 of Heard et al. 2003[15]). Although there is not a statistically significant reduction in the weed seedbank density in the second year following cultivation of the GMHT crop the effect size remains large (1.25-fold reduction), and, considering the results as a whole, a persistent effect on weed seedbank densities would be expected.

48. Given the changes in arable weed populations, it is likely that this would have an impact on organisms at higher trophic levels including invertebrate, small mammal and bird species. The quantitative nature of any impacts at higher trophic levels remains uncertain, but the data suggest that these impacts are likely to be negative.

49. This conclusion however, can only be confidently ascribed to future GMHT beet crops if they are managed in the same way as they were in the FSEs. The Committee considers that it may be possible to manage weeds using GMHT beet such that the impact on biodiversity is less or comparable to that of conventionally managed beet – a number of suggestions concerning how this may be achieved were presented in submissions to the Committee.

50. It is for those applying for consent to market GMHT beet to propose alternative management strategies (mitigation measures), and such proposals should be supported by appropriate evidence. It may also be necessary to determine the effectiveness of management strategies as part of post-market monitoring plans. In this context it is clear from the FSE results that weed biomass, seed rain and seedbank densities are important indicators of biodiversity impacts.

Spring-sown oilseed rape

Summary of written and oral evidence

51. The evidence submitted concerning spring-sown GMHT oilseed rape made similar arguments to those concerning GHMT beet, which are summarised in paragraphs 41 to 44.

ACRE's advice on spring-sown GM HT oilseed rape (including transformation events Ms1xRf1, Ms2xRf2, Ms8xRf3, GS40/90 and pHoe6/Ac)

52. In formulating its advice concerning GMHT oilseed rape ACRE considered the current regulatory context (Annex 2). Two applications under Directive 90/220/EEC for the cultivation of oilseed rape containing transformation events Ms1xRf1 and Ms1xRf2 received approval in the European Union in 1997, although consents concerning these applications have yet to be issued by the French authorities. ACRE gave advice to Government on Ms1xRf1 and Ms1xRf2 oilseed rape in September 1995. All consents issued under Directive 90/220 expire in October 2006.

53. The FSE data represent 'new information' concerning transformation events Ms1xRf1 and Ms1xRf2 in the sense of Article 20 of Directive 2001/18/EC, and the Committee considered whether this new information provides grounds for amending or revoking the consents.

54. There are also applications to place on the market oilseed rape containing transformation events Ms8xRf3, GS40/90 and pHoe6/Ac for cultivation. Reports on these dossiers have yet to be prepared by the lead Member States concerned and thus the dossiers have not been considered by ACRE. The advice presented here considers only the implications of the FSE results – if and when these

applications enter the European phase of the regulatory process ACRE will consider all aspects of the risk assessment of these types of GM oilseed rape.

55. ACRE concludes that:

> Based on the evidence provided by the FSE results published in October 2003, if spring-sown GMHT oilseed rape were to be grown and managed as in the FSEs this would result in adverse effects on arable weed populations, as defined and assessed by criteria specified in Directive 2001/18/EC, compared with conventionally managed spring-sown oilseed rape. The effects on arable weeds would be likely to result in adverse effects on organisms at higher trophic levels (e.g. farmland birds), compared with conventionally managed oilseed rape.

56. ACRE has arrived at this conclusion because the results demonstrate that there is a 3-fold lower weed biomass and 5-fold lower seed rain in the GMHT oilseed rape fields compared with conventionally managed spring-sown oilseed rape, and this results in a 1.3-fold lower return of seeds to the weed seedbank (Tables 2, 4 and 5 of Heard et al. 2003[15]). Although there is not a statistically significant reduction in the weed seedbank density in the second year following cultivation of the GMHT crop the effect size remains large (1.25-fold reduction), and, considering the results as a whole, a persistent effect on weed seedbank densities would be expected.

57. Given the changes in arable weed populations, it is likely that this would have an impact on organisms at higher trophic levels including invertebrate, small mammal and bird species. The quantitative nature of any impacts at higher trophic levels remains uncertain, but the data suggest that these impacts are likely to be negative.

58. This conclusion however, can only be confidently ascribed to future spring-sown GMHT oilseed rape crops if they are managed in the same way as they were in the FSEs. The Committee considers that it may be possible to manage weeds using GMHT oilseed rape such that the impact on biodiversity is less or comparable to that of conventionally managed oilseed rape – a number of suggestions concerning how this may be achieved were presented in submissions to the Committee.

59. It is for those applying for consent to market GMHT oilseed rape to propose alternative management strategies (mitigation measures), and such proposals should be supported by appropriate evidence. It may also be necessary to determine the effectiveness of management strategies as part of post-market monitoring plans. In this context it is clear from the FSE results that weed biomass, seed rain and seedbank densities are important indicators of biodiversity impacts.

60. The conclusions concerning spring-sown GMHT oilseed rape do not necessarily apply to autumn-sown GMHT oilseed rape. The potential impacts on the management regime associated with autumn-sown GMHT oilseed rape will be examined when the FSE results concerning this crop are published in 2004.

F. Annex 1 – The risk assessment of genetically modified organisms

The entire regulatory process is underpinned by a detailed environmental risk assessment, prepared by the applicant, which examines and evaluates any possible adverse effects associated with the release of a particular GMO. This risk assessment is reviewed by ACRE.

In assessing applications every possible precaution is taken to ensure that human health and the environment are protected. Only if the risks are considered to be very low will the release be allowed to proceed. In the context of GM plants, a very low risk generally means that the GM variety is not thought to pose any greater risk than the release of its non-GM equivalent[16]. In addition to an assessment of direct effects of a GMO the risk assessment must also consider indirect immediate and delayed effects arising from management practices specific to that GMO.

Some sections of Directive 2001/18/EC are especially relevant to the assessment of the FSE results. These include Article 4(1):

"Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs."

Annex II of the directive goes on to give further detail of the scope of the risk assessment, stating that:

"Adverse effects may occur directly or indirectly through mechanisms which may include changes in management, including, where applicable, in agricultural practices"

The potential environmental impact must therefore take into account:

"Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GM plant when these are different from those used for non-GM plants"

ACRE has produced guidance of how such management affects should be assessed[17].

[16] For full details of the risk assessment conducted see http://www.defra.gov.uk/environment/gm/background/risk/index.htm.
[17] further details are available from http://www.defra.gov.uk/environment/acre/biodiversity/index.htm

G. Annex 2 – Current status of the regulatory process

Currently no GM crops have all the required approvals to allow them to be grown commercially in the UK. The current status of the crops grown in the farm-scale evaluations (FSEs) is set out below[18].

Maize

The herbicide tolerant maize variety under test in the FSEs has full marketing approval for cultivation in the EU – the maize contains transformation event T25. A final decision has not yet been made in relation to seed listing in the UK for a variety of this maize known as ChardonLL. The outcome of an application for pesticide approval will be decided in the light of the FSE results.

A further herbicide tolerant maize variety known as Bt-176 also has full marketing approval for cultivation in the EU. Bt-176 is modified for tolerance to glufosinate ammonium and insect resistance and has been developed by Syngenta. This variety has seed listing approval in Spain.

Three further varieties of GM maize currently have applications for cultivation under consideration in the EU. They are known as Bt11, line 1507 and line NK603 developed by Syngenta, Pioneer and Monsanto respectively. Bt11 and line 1507 are modified for resistance to some insects and glufosinate ammonium, and NK603 is tolerant to glyphosate. These applications are being considered by France and Spain as lead Member States. None of these varieties have a seed listing or approval for the associated herbicide. It is noted that the results of the FSEs are not directly applicable to NK603 as this variety is resistant to a difference herbicide to T25.

The current status concerning maize is summarised in the following table:

Transformation event	Company	Herbicide tolerance	Used in FSEs	Part C approval	Seed listing	Pesticide approval
T25	Bayer	Glufosinate ammonium	Yes	Yes	No	No
Bt-176	Syngenta	Glufosinate ammonium	No	Yes	Yes in Spain	No
Bt11	Syngenta	Glufosinate ammonium	No	No	No	No
1507	Pioneer	Glufosinate ammonium	No	No	No	No
NK603	Monsanto	Glyphosate	No	No	No	No

Beet (sugar and fodder varieties)

The herbicide (glyphosate) tolerant beet used in the FSEs was grown under research consents (Part B) issued by the UK authorities. The application for commercial cultivation of sugar beet (event T9100152) was first made in 1999 and is being handled by the Belgian authorities. The application for fodder beet (Line A5/15) was first made in 1997 and is being dealt with by Denmark. Both dossiers were updated and re-submitted by Monsanto after the new Directive 2001/18 came into force. The Belgian and Danish authorities will be considering the new evidence from the FSEs

[18] For further details see http://www.defra.gov.uk/news/2003/031013c.htm and http://www.defra.gov.uk/environment/gm

before taking a view on whether the applications comply with the terms of the Directive.

A third application for commercial cultivation of glyphosate tolerant sugar beet (event H7-1) from Monsanto has been made to the German authorities. None of the current or pending beet varieties have a seed listing in the EU or UK Neither is there any pesticide approval for the relevant herbicide, glyphosate, on any of the GM crops. Any such approval must be granted by Ministers, after scrutiny by the independent statutory body, the Advisory Committee on Pesticides.

The current status concerning beet is summarised in the following table:

Transformation event	Company	Herbicide tolerance	Used in FSEs	Part C approval	Seed listing	Pesticide approval
T9100152 (sugar)	Monsanto	Glyphosate	Yes	No	No	No
A5/15 (fodder)	Monsanto	Glyphosate	Yes	No	No	No
H7-1 (sugar)	Monsanto	Glyphosate	No	No	No	No

Oil seed rape

The herbicide tolerant oil seed rape used in the FSEs (Ms8xRf3) was grown under a research consent (Part B) issued by the UK authorities. The application for commercial cultivation was first made in 1996 and is being handled by the Belgian authorities. The dossier was updated and re-submitted by Bayer after the new Directive 2001/18 came into force in October 2002. The Belgian Authorities have yet to take a view on whether the application complies with the terms of the Directive. If the Belgian authorities decide the evidence presented in the dossier on the safety of the GM crop does not comply with the criteria in the Directive they can reject the application and the GM crop will not be allowed to be grown anywhere in the EU. If however they decide the application complies fully with all the safety requirements in the Directive, they will forward it to other Member States, including the UK, for consideration. Member states will then make a collective decision on whether to accept or reject the application.

In addition to Ms8xRf3, four other types of herbicide tolerant rape, also developed by Bayer, are currently under consideration for cultivation in the EU (Ms1xRf1, Ms1xRf2, GS40/90, pHoe6/Ac). All have been genetically modified to make them tolerant to the herbicide glufosinate ammonium (trade name Liberty). Two of the applications were given approval in 1998 but are still awaiting the go ahead from France, which is the lead member state in that instance. The other applications are currently being assessed by the German authorities.

None of the current or pending oil seed rape varieties have a seed listing. Neither is there any pesticide approval for the relevant herbicide, glufosinate, on any of the GM crops. Any such approval must be granted by Ministers, after scrutiny by the independent statutory body, the Advisory Committee on Pesticides.

The current status concerning oilseed rape is summarised in the following table:

Transformation event	Company	Herbicide tolerance	Used in FSEs	Part C approval	Seed listing	Pesticide approval
Ms8xRf3	Bayer	Glufosinate ammonium	Yes	No	No	No
Ms1xRf1	Bayer	Glufosinate ammonium	No	Yes	No	No
Ms1xRf2	Bayer	Glufosinate ammonium	No	Yes	No	No
GS40/90	Bayer	Glufosinate ammonium	No	No	No	No
pHoe6/Ac	Bayer	Glufosinate ammonium	No	No	No	No