

Overview of the responses to the consultation on the report “Managing the footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems” produced by ACRE’s Subgroup on Wider Issues Raised by the Farm-Scale Evaluations of Herbicide Tolerant GM Crops

Background

The report was produced by the ACRE subgroup on Wider Issues Raised by the Farm-Scale Evaluations of Herbicide Tolerant GM Crops. This was a response to the requests by the Secretary of State for the Environment, Food and Rural Affairs and the Agriculture and Environment Biotechnology Commission to assess the wider implications of the Farm-Scale Evaluations (FSE) of genetically modified herbicide tolerant crops.

In March 2006 the report entitled “Managing the footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems” was circulated widely. This overview summarises the responses received¹ and the consequent amendments made to the report. As 30 responses to the consultation were received this document does not give details of every comment received but aims to give a balanced overview of the spectrum of views expressed.

General Comments on the Report

ACRE is grateful to all those who responded to the consultation; the range of views expressed showed the importance of a balanced and proportionate assessment system for all novel agricultural products and techniques to a variety of stakeholders. The responses were also very helpful in improving the report. As a result of this consultation the subgroup has redrafted the report for greater clarity and some sections have been totally revised.

Comparative Sustainability Assessment of GMOs

The proposed use of a comparative sustainability assessment to replace the current risk assessment used for GMOs received a mixed response. Most respondents acknowledged the value of assessing benefits alongside risks, however several respondents expressed the view that the current legislation for GMOs was well founded and should not be changed. ACRE believes that this change in emphasis from the assessment of risk to an overall assessment of impact would lead to goals for sustainability being achieved more quickly than the current system. ACRE stresses that the use of this method would not represent a “softening” of the current regulatory regime, since harmful effects on organisms or ecosystems protected by other national or international agreements or legislation would not be tolerated.

Scope of the Proposed Comparative Sustainability Analysis

Most respondents were in general agreement with ACRE that there was good reason to assess the risks posed to the environment and human health by all novel

¹ For a list of respondents to the consultation refer to Annex 1.

agricultural practices and products. Two responses noted the apparent omission of new animal breeds from the report, this was not a deliberate omission, ACRE recognises that some new animal breeds and the introduction of non-native animals could have a significant impact on the environment. To reflect the adaptability of the CSA method proposed to animals, a case study examining the potential effect of an introduced mammalian species, the mink, to the UK has now been included in the revised report.

Definition of Novelty

Several respondents expressed the view that it was important for the subgroup to define exactly what “novel products and practices” would require assessment in the manner proposed in the report. In Canada where all products with novel traits are regulated (see Section 3.6 and Annex G of the report) definitions of novelty are given according to the product that is regulated. For plants the definition given is "Those plants which possess characteristics or traits sufficiently different from the same or similar species should require an assessment of risk". However such definitions have led to confusion about which products are captured by the legislation, as highlighted by the forum held in March this year². The subject of novelty is also tackled in other legislation, for example the Novel Foods Regulation (258/97)³ foods that do not have a significant history of consumption within the EU before 15 May 1997 are assessed. The current interpretation of pesticide legislation is that a product containing a single “new” reagent (surfactant or active ingredient not previously used in the European Union) would trigger a formal assessment⁴.

The subgroup has given a recommendation of what should be taken into account when identifying products and practices that require assessment in Section 4.16 of the report, however the Committee maintains the view that ultimate decision of definitions should be taken by policy makers.

Scale of Assessment

Several responses indicated that there are already many regulations affecting farming and that increase in this load would jeopardise the livelihood of farmers. The subgroup agrees that this is not desirable and has indicated in several sections of the report that the comparative sustainability analysis should not be done at the farm level. Several sections of the report have been revised to remove ambiguity about this point.

Some respondents commented that the farm was the desirable area for consideration, however, the overall impact of a technology is likely to be related to the scale of uptake of the product. It is therefore appropriate to take the impact of a product or practice on a greater scale into account in the CSA. ACRE acknowledges that in some cases the use of certain products or practices may be damaging in some environments (e.g. a particular soil type or at a particular time of year) and not in others. This point is recognised in national legislation for pesticide use and it is

² <http://www.nationalforumonseed.com/documents/PNTWGI.pdf>

³ <http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1997/R/01997R0258-20040418-en.pdf>

⁴ http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/ACP/ACP_guide03v1.pdf#search=%22ACP%20defining%20novelty%20active%20substance%22

important that recommendations for use could be attached to novel products or practices.

It is difficult to predict the extent of uptake or how and where a product or practice will be used until farmers have had some experience with the technology. In order to overcome this difficulty, trialling, together with appropriate monitoring is useful as a means by which appropriate data can be collected.

The report has been revised in paragraphs 4.17 and 4.18 to take these considerations into account.

Impacts on Innovation

Several of the responses commented that extending risk assessment to agricultural products and practices which fall outside existing legislation might constrain future innovation. In particular respondents were concerned that it would be time consuming and expensive to collect the data required for the matrix.

By taking into account the overall benefits associated with a new product or practice in comparison with currently available systems, ACRE's proposals are designed to encourage innovations that can assist government commitments for sustainable agriculture. However, in cases where harm could be caused to the environment, it is important to assess the potential for any damage to organisms or ecosystems that are protected by national and international agreements or legislation, alongside appropriate mitigation strategies, prior to large scale use of products or practices. ACRE recommends the use of trialling and monitoring to ensure that relevant evidence can be gathered for decision making.

Policy makers will ultimately be responsible for any future implementation of the methods proposed by ACRE and current thinking in government is to try to reduce the regulatory burden as much as possible. ACRE supports this approach but recommends that emphasis should be placed on ensuring regulatory consistency with policy goals in any future revisions of legislation affecting farming and the environment.

Transparency and Objectivity

Many of the responses highlighted the importance of ensuring that the process was both transparent and objective. A wide range of possible ways in which these objectives might be achieved were proposed by respondents.

Two main methods of public/ stakeholder consultation were proposed;

- 1) A full public consultation during the assessment process.
- 2) The participation of a range of stakeholders in setting the risk assessment criteria was proposed by several respondents.

ACRE has considered both of these options and notes that the first method is currently used in Directive 2001/18. The public are invited to make representations during the assessment process and any new information effecting the evidence-based risk

assessment is investigated by an appropriate committee before a final decision is made. ACRE fully supports this approach.

The second approach is used before regulations are put in place, a wide range of stakeholders are engaged before the full public consultation process begins on any statutory measures that are subsequently imposed. ACRE recommends that criteria used in comparative sustainability assessments should be linked to sustainable farming policy goals and that research effort should focus on finding relevant indicators in order to make the process as objective as possible.

The criteria used in the revised matrices in section 5 of the report are given as examples only and would require further development, especially by economists and social scientists before the CSA was used.

Despite widespread agreement that public and other stakeholder views should contribute in some way to the process, a number of responses indicated that some parties with vested interests had an undue influence in assessments under existing GMO legislation. ACRE accepts that in some European Member States political considerations sometimes over-ride evidence-based assessments in voting decisions and safeguard actions taken on GMOs.

Several respondents highlighted the importance of objectivity of the assessors and the Committee agrees that it is important. The Committee also agrees with respondents who have highlighted the need for the panel of independent assessors to have an appropriate range of expertise to complete evaluations of sustainability assessments provided by applicants.

The matrix pro-forma presented in Section 5 of the report has been revised and segregates criteria more explicitly than the pro-forma matrix presented in the draft report. This modification is designed to increase transparency since the previous version allowed bulking of environmental effects and the trade-offs made would not have been clear.

In revising the matrices the Committee considered various approaches proposed by respondents such as weighting of criteria and the use of quantitative data or scoring to assess the magnitude of effects. However, the Committee has maintained the original methods in the case studies. Policy aims with respect to sustainable farming are likely to be subject to change through time and therefore the importance of different criteria to policy makers will change through time. Decisions regarding the relative importance of different effect could be made by policy makers by explicitly weighting criteria in the matrix or could simply be done through implicit weighting in judgements made by expert panels.

The use of quantitative information in the matrix is very useful in assessing relative effects of products, however it is not possible to be prescriptive about thresholds to define acceptability (this argument also applies to the idea of red-lining and is discussed in more detail below). Whilst a group of experts is likely to be in general agreement with broad categorisations of high, medium and low, the use of scoring on a number scale, though equally subjective, will generally lead to more disagreement

and may lead those reading the matrix to believe that the scores can simply be added to determine the outcome of the assessment.

Dealing with Uncertainty

Three responses made specific comments about the assessment of uncertainty in the CSA. The subgroup acknowledges that this is a difficult area and that there are many different interpretations of how these concerns should be dealt with. During the process of report revision a presentation from Andy Hart from the Central Science Laboratory highlighted techniques for dealing with uncertainty in a systematic way. The Genewatch response suggests that subjective judgements of uncertainty can be scored to transparently indicate how this has been taken into account by assessors in coming to a decision. ACRE has considered these suggestions and has concluded that some quantitative techniques (including scoring) are simplistic and would give a false impression of certainty. However the Committee recognises that modelling techniques can be important in highlighting areas where gaps in knowledge may be important to decision making (reference can be put in to Andy Hart's final report when this has been published).

ACRE proposes that gaps in knowledge should be recognised and the importance of those gaps to policy aims assessed. Knowledge gaps in areas of key importance should be filled by appropriate trials and that monitoring of larger trials or general release should be used in cases where expert opinion judges gaps in knowledge to be less important. ACRE notes that EFSA currently has a working group to examine this issue and looks forward to receiving reports from this group.

Choice of Comparator

Many responses highlighted the importance of choosing an appropriate comparator since this would be critical to the decision of whether to accept or reject an application. Sections 4.15 and 5.8 of the report suggests that a range of possibilities can be assessed using the CSA, in all cases however one option would be to assess the new product or technology against what the crop of technology it is likely to replace, although the scale of use and the subsequent value of the produce (either in economic, environmental or social terms) also needs to be taken into account when choosing a comparator.

Trade-off between risks and benefits

There were a number of different views on how risks and benefits should be assessed and in particular about whether it was appropriate to trade-off benefits to one criteria with risks in another (e.g. risk to biodiversity against benefit to climate change). This question of how to assess incommensurables and how to trade off benefits against damage has been highlighted in Sections 3.3 and 3.7 of the report and is a common problem faced when assessing agricultural systems. Although the assessment framework proposed in the report doesn't explicitly address this question, the CSA allows different weights to be attributed to different categories according to policy objectives or can be implicitly taken into consideration by experts. This has been discussed in this document under the heading "Transparency and Objectivity".

Evidence required

Several responses noted the importance of basing decisions on scientific evidence. Some responses also highlighted the importance of including other evidence and in particular that economic and social considerations had not been given high enough priority in the report.

The subgroup acknowledges the importance of scientific and other objective social and economic evidence to inform the comparative sustainability assessment. However, due to the specialist expertise of members of the subgroup, considerations of social and economic factors are not as detailed as those for environmental factors. Section 5 of the report has been revised to include a very brief consideration of the criteria that could be added in the socio-economic matrices and the pro-forma and illustrative case-studies have been amended accordingly.

One respondent expressed the view that the market would determine which products or practices are economically viable. ACRE acknowledges that this will occur but also acknowledges the views expressed in other consultation responses that the costs to society (externalised costs, for example costs to treat water contaminated by diffuse pollution) should be taken into account when new products or practices are assessed.

Some respondents commented that a full assessment would be difficult in advance of release. The subgroup accepts this point and has suggested trialling and monitoring as a possible solution (see “Dealing with Uncertainty”).

Alternative approaches to assessing risk

JNCC two-step approach

Several respondents made comments and suggestions on this point; some agreed with the two-step assessment process presented to the subgroup by the Joint Nature Conservation Council. The JNCC propose that the first stage of the process should be statutory and consider only the risks. The second stage of the assessment would then be done on an advisory basis and only for products that had passed the risk assessment stage. The subgroup has explained in Section 4.6 of the report why this method was rejected and retains its original view because this approach fails to take into account the potential for mitigation strategies to reduce or eliminate any harmful effects of a release or use occurring and has the potential to block technologies that would improve sustainability.

One response highlighted the Norwegian Gene Technology Act as an example of a system that employs a cost-benefit analysis. This system has elements of both pure “risk assessment” and a cost-benefit analysis. Exactly how the system should operate is not clearly defined in the legislation and much depends on the interpretation used, however the approach can be similar to the system proposed by the JNCC or slightly more flexible depending on the balance of environmental benefits and level of environmental damage anticipated from the use of the product. (should this be included in an Annex to the report?)

Red Lining

ACRE acknowledges that it is important to protect the environment from certain types of environmental damage (such as those that affect organisms or ecosystems that are protected by national or international agreements or legislation), especially where the damage is not recoverable. ACRE also accepts that in some cases it will not be possible to mitigate or compensate certain impacts.

The Committee considered a proposal made in the Genewatch response, to use “red-lining” within the Comparative Sustainability matrix. Red lining allows assessors to reject a novel product or practice on the basis of unacceptable adverse effects but must be based on current subjective assessment of what is and what is not acceptable. Policy goals change through time and it is therefore not possible to be prescriptive about particular thresholds of acceptability.

Separation of Environmental and Socio-economic considerations

Other responses suggested that two separate matrices should exist for environmental and economic benefits. Section 4.13 of the draft report acknowledges that such a method would be possible. However the Committee believes that a more balanced assessment taking into account all factors would be produced by a Committee with a full range of expertise and therefore that a single matrix should be assessed.

Degree of Assessment

One response proposed a sliding scale or tiers of assessment according to the risk posed by the product. A similar approach has been presented to ACRE by the project team for Defra project AR0317, Environmental Impact of Crop Production Practice beyond the Farm-scale Evaluations⁵, which is due to report next year.

The Committee agrees that this is a possible approach and has indicated in section 4.16 of the report that the scale, trait and species released should be taken into consideration and at section 5.2 of the report that only relevant technical and scientific details would be required in the CSA. ACRE stress that it is important to assess the potential risks and benefits of products and practices that may be regarded as high risk or are to be released on a large scale. However where anticipated uptake is on a smaller scale it may be reasonable to reduce the detail required in the risk assessment. An example of where this is done in current practice is under the current GM legislation (2001/18/EC). Different levels of detail are required from applicants wishing to release GM products that are not intended for marketing (Part B) and those that are intended for marketing in Europe (Part C).

Implementation

Many of the respondents did not appreciate exactly what purpose the subgroup were proposing for the CSA. Several of the responses indicated that the undesirability of

⁵ Further details about the aims of the project can be found at; http://www2.defra.gov.uk/research/project_data/More.asp?I=AR0317&M=KWS&V=AR0317&SCOPE=0

new regulation covering products and practices that are not currently regulated and noted that any legislation introduced should not disadvantage UK farming. Other respondents expressed the view that ACRE's proposals did not go far enough and that all farming practices should be regulated using methods such as those proposed by ACRE.

ACRE produced this report primarily to stimulate discussion within regulatory bodies in the UK and around Europe and therefore specific recommendations for implementations were not made in the first draft of the report. However in the light of comments made on the consultation draft, the report has been revised to make specific suggestions about how comparative sustainability assessments could be used. In the revised version of the report ACRE has made recommendations for short and long-term goals for the implementation of the ideas put forward (see section 7 of the revised report).

ACRE recommends that any future legislation on GMOs incorporating comparative sustainability assessments should be implemented at European level. However, ACRE sees potential uses for the CSA to be used at a national level in a non-regulatory context or in the assessing regulations relating to the environment and various suggestions have now been included in the report.

ACRE

www.defra.gov.uk/environment/acre

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Annex 1
List of Respondents to the Consultation

1. ADAS
2. Advisory Committee on Pesticides
3. Agricultural Biotechnology Council
4. Agricultural Industries Confederation
5. Bayer Biosciences
6. Biotechnology and Biological Sciences Research Council
7. British Grassland Society
8. British Society of Plant Breeders
9. British Trust for Ornithology
10. Brooms Barn
11. Joanne Clarke
12. David Coggon
13. Crop Protection Association
14. Friends of the Earth
15. Genewatch
16. GM Freeze
17. Les Firbank
18. Italian Agency for Environmental Protection and Technical Services
19. Brian John
20. Munlochy GM Vigil
21. National Farmers Union
22. Nature Conservation Agencies
23. Netherlands – Ministries of the Environment and Agriculture and RIVM
24. Royal Society for the Protection of Birds
25. Scottish Agricultural College
26. SCIMAC
27. SCRI
28. Soil Association
29. Swiss Expert Biosafety Committee
30. Syngenta