



SCOTTISH EXECUTIVE

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PROPOSED CHANGES TO THE NATIONAL LIST WRITTEN REPRESENTATIONS AND HEARINGS PROCEDURES

Introduction

1. This paper sets out proposals for changing the Written Representations and Hearings provisions in the Seeds (National Lists of Varieties) Regulations 2001 in the light of the recent experience with CHARDON LL - the first genetically modified (GM) plant variety to be proposed for addition to the UK National List.

2. The review was presaged in a reply to a Westminster Parliamentary question in November 2000 when the UK Government said that it would consider in the light of the CHARDON LL Hearing "...whether the current arrangements are satisfactory for all parties. If changes are proposed, all interested parties in due course will be fully consulted."

3. In summary, we believe that the National List system is not the appropriate place to challenge GM safety assessments. Instead we plan to put in place improved, effective and transparent mechanisms that will enable public concerns on GM safety to be heard and taken into account **before** approvals are granted (i.e. under the Directive 2001/18/EC regime on the release of GMOs which is currently the subject of a public consultation on draft implementing legislation in Scotland www.scotland.gov.uk/library5/environment/rdrdg-00.asp.)

4. We have therefore reviewed all the regulatory processes, which apply to the progression of a GMO from development through to marketing. In particular we have taken account of the quite separate EU legislation that scrutinises GM crop safety. Our aim has been to design a system which:

- is transparent and open;
- enables the public to raise concerns and identify GM safety issues at early stages (ie when the original decisions on the safety aspects of proposed GM releases are being considered);

- preserves existing arrangements for making representations about core national list issues; and
- is efficient and pays due regard to the appropriate use of taxpayers' money.

Background

5. The National List system implements EC Directives and is concerned with the agricultural qualities of candidate varieties. It is effectively a quality control mechanism to ensure that the varieties available to UK agriculture meet certain minimum criteria. As far as GM varieties are concerned, they must already have GM approvals for release into the environment or marketing before they enter the National List system. Before they are proposed for addition to the National List they must have a marketing approval under the GM release directive and authorisation under the Novel Foods regulation where appropriate.

6. The current procedures for making Written Representations and requesting a Hearing about seeds issues were introduced following the UK's accession to the EC and were aimed at National List applicants and the seeds industry as those primarily affected by proposed decisions. They predated GM plant varieties and were never intended to deal with GM safety issues. In 1990, (when GMOs including GM crops had become an issue) the EU introduced separate legislation, Directive 90/220/EEC, under which decisions on the safety of GM releases had to be taken before releases into the environment could be permitted. These decisions are taken on the basis of independent, expert advice eg in the UK from the Advisory Committee on Releases into the Environment (ACRE) and the Advisory Committee on Novel Foods and Processes (ACNFP).

Lessons from the CHARDON LL Hearing

7. Key issues which have been highlighted in the review of the Chardon Hearing can be summarised as follows:

Concerns raised:

Almost all of the evidence submitted by the parties dealt with GM safety issues, effectively questioning the marketing consent granted under Directive 90/220/EEC, and/or the authorisation granted under the Novel Foods Regulation. There was comparatively little focus on the core National List criteria of Value for Cultivation and Use (VCU) and Distinctness, Uniformity and Stability (DUS). This is unsatisfactory both for the person/organisation raising concerns and for the decision-making process. The logical time and place for public concerns on GM crop safety issues to be heard is **before** the GM safety decision is made, not afterwards.

Costs:

Concerns about costs have been raised in many quarters. On the one hand, those making Written Representations or applying for a Hearing had to pay statutory fees. This was perceived by many as an unfair constraint on public debate, but the fees are specified in the National List legislation, which was originally conceived as an opportunity for industry to make technical representations rather than as a facility for public debate. Indeed, as part of a service to industry, Treasury principles should require the Government to achieve full cost recovery on this process. On the basis of the Chardon Hearing, this would have involved fees of around £7,500 to participate in the Hearing, which is plainly unacceptable.

On the other hand, the Chardon Hearing will have cost the tax-payer around £0.5million. While there is general agreement that appropriate and timely public consultation is vital, this is a large sum and we need to be sure that any such process is managed as efficiently as possible.

Options for change

8. The Government's¹ over-riding priority on GMOs is to safeguard human health and the environment. GM crops could not be commercialised in the UK unless these core principles are met fully. Equally, in considering options for change the Government remains absolutely committed both to a robust, open and transparent review of GM safety and to public engagement in decision making on GM safety issues.

9. We have looked carefully at all of the options for change, which fall into 4 broad categories:

i) Make no change to the current arrangements

We think this option is unsustainable. The current systems are not sufficiently effective in providing opportunities for public involvement at the appropriate points in the decision-making process, are costly to the taxpayer, and objectors have to pay statutory fees.

ii) Remove the right to Representations and/or a Hearing altogether

The provision of what amounts to a 2 to 3 stage appeals process (ie Written Representations, a Hearing *and* a separate Tribunal) is unique to this legislation and derives from its original intent as described above. It would be possible to bring the processes in this sector into line with the generality of such arrangements by removing the facility of a Hearing and/or Written Representations and relying on objectors appealing direct to the Plant Varieties & Seeds Tribunal. However, both the Representations and the National List Hearing mechanisms have been viable and cost-effective options for the resolution of technical matters on eg conventional seeds and plant variety issues in the past.

iii) Restrict the right to make Written Representations and/or apply for a Hearing to the seeds industry

This would return the system to the purpose for which it was originally designed, but runs counter to the Government's stated policy of openness and transparency and therefore is completely unacceptable.

iv) Change the public consultation arrangements both under the regulatory controls on GM safety and under the National List legislation

This would ensure that public concerns on safety can be raised before safety decisions are taken. The experience with the Chardon Hearing emphasises the need to have a clearer distinction between the National List process – which is substantially about seeds issues - and the separate regulatory controls under EU Directive 2001/18/EC and the Novel Foods Regulation dealing with GM safety issues.

10. In our view, option iv) is the best route to achieve the Government's objective of facilitating transparent, open and timely debate on GM issues. The precise changes proposed are set out below in greater detail.

¹ Unless the context implies otherwise, references to 'Government' includes the Devolved Administrations.

Proposals for Change

11. It is proposed that statutory public representations on GM crop safety issues should be made much earlier in the development of a new GM crop to the experts whose statutory role is to advise Ministers on GM safety issues. The proposals would form part of the current implementation of Directive 2001/18/EC on the deliberate release of GMOs (which updates the old Directive 90/220/EEC). In implementing Directive 2001/18/EC, the Government is proposing to improve substantially the statutory arrangements for public consultation (see Annex A).

12. The key elements of the proposed new approach to public consultation on the GM crop approvals process are summarised below:

Before decisions on experimental GM releases

- a mandatory public consultation on applications for part B consents lasting a minimum of 48 days, which requires Ministers to invite the public and others to make representations to them on any risks of damage being caused to the environment by the proposed release;
- relevant representations must be considered in making decisions; and
- this is linked to a new requirement to advertise proposed releases in a major newspaper (as opposed to local) thus significantly improving the opportunity to make representations, and the fact that a public consultation will be held by the Government.

Before decisions authorising commercial releases

(An important factor is that these decisions are taken at European Community level, not by individual Member States. This means that the process is managed by the Commission.)

- under the new Directive, the Commission must consult the public (for two separate periods of 30 days) while the application is being considered;
- responses are copied to all Member States;
- the Commission and Member States then make a collective decision on the application, and a Part C consent is either granted or refused; and
- in the UK, we intend to advertise the fact that such consultations are being held by the Commission, and relevant representations by the public will inform the UK position in making a collective decision in Europe.

13. **As under the current arrangements, any person affected by a National List decision may submit an appeal to the Plant Varieties & Seeds Tribunal at a minimal cost of £10 per appeal. Such appeals may be on any basis relevant to National List proposed decisions. The National List decision is then suspended until the appeal has been determined.**

How will the new system be implemented?

14. The arrangements under Directive 2001/18/EC are set out at Annex A. In the case of GM foods, the procedures for assessing their safety for human health and the environment under the Novel Foods Regulation are the same as under Directive 2001/18/EEC.

15. The National List Regulations apply to the whole of the United Kingdom. They would be amended to provide that, when any variety (GM or otherwise) is proposed for addition to the National List, any person who would be affected by it (which effectively means anyone with a concern about the possible growing of the new crop) may apply to make Written Representations or participate in an oral Hearing, **but only in relation to the core subject matter of National Listing referred to in regulation 5(3)(b) and (c) of the current regulations: that is, whether the variety is distinct, uniform and stable; and whether it is of satisfactory value for cultivation and use.** This would have the effect of excluding evidence relating specifically to GM consents granted under other legislation; and safety issues governed by other provisions of national law or where cultivation of the variety could be harmful in relation to plant health. GM issues bearing on the core National List criteria of DUS and VCU would continue to be admissible grounds for making Written Representations and/or requesting a Hearing.

16. **No change is proposed to the rights of any affected person to appeal against a proposal to add a plant variety (GM or conventional) to the National List direct to the Plant Varieties & Seeds Tribunal. There are no limitations in the legislation on the subject matter that may be considered by the Tribunal and the decision of the Tribunal is binding on Ministers.**

17. **The proposed changes to the National List written representations and hearings procedures will not be brought into effect before the introduction of the new consultation arrangements under Directive 2001/18/EC.**

GM public debate

18. The Scottish Executive recognise that there is a genuine concern about the growing of GM crops in the UK. After receiving advice from the independent Agriculture and Environment Biotechnology Commission, the Executive has confirmed that it supports a wide-ranging public debate on the issues raised by the possible commercialisation of some GM crops. This will precede formal decisions on the possible commercialisation of those GM crops being grown in the Farm Scale Evaluations. The debate will start officially in the autumn. The Executive want an open and balanced dialogue in which all voices can be heard, to deepen understanding of the issues and enable people to reach their own judgements. Fuller details of the GM public debate will be announced shortly.

Conclusion

19. The changes proposed in this consultation letter, together with the work being taken forward in parallel on the implementation of Directive 2001/18/EC, will target GM safety issues at the proper fora and provide statutory, wide-ranging and cost-free rights for the public to comment on GM authorisations **before** decisions are made on whether to grant or refuse authorisation. They maintain a right for any affected person to submit an appeal against a National List proposed decision to the

Plant Varieties & Seeds Tribunal. **The changes proposed to the National List arrangements will not be introduced before the introduction of the new consultation arrangements under Directive 2001/18/EC.**

Comments

20. Comments on these proposals are invited by mail, fax or e-mail and should be sent by 16 December 2002 to:

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21. In order to help inform debate on the questions covered by this consultation letter, the Department intends to follow its normal practice of making available to the public, on request, copies of the responses received. The Department will assume, therefore, that responses can be made publicly available in this way. If respondents indicate that they wish all, or part, of their reply excluded from this arrangement, **its confidentiality will be strictly respected.**

8. Copies of the responses made available to the public, will be held on an "open file" kept in the Library at Saughton House, Edinburgh. Copies of documents from the "open file" will be forwarded to members of the public on request. A charge will normally be levied to cover the cost of copying.

22. The Department for the Environment, Food and Rural Affairs, the Welsh Assembly Government Agriculture and Rural Affairs Department, and the Department of Agriculture and Rural Development in Northern Ireland are conducting separate consultations in their own areas.

Yours sincerely

Charles W Greenslade
Head of Plants, Horticulture and Potatoes

PUBLIC CONSULTATIONS ON SAFETY OF GM CROPS – DIRECTIVE 2001/18/EC

1. In parallel to the current revision of seeds legislation, the Government is taking forward work to introduce updated legislation on the deliberate release of GMOs. Among other things, this gives us an opportunity to review the way that public consultation on GM crops is conducted in the UK.
2. Before a GM crop can be released on a commercial basis in the EU (including in the UK) it must be assessed and authorised under at least two separate regulatory frameworks:
 - firstly, it must be rigorously assessed for **safety** to human health and the environment under the EU Directive on the deliberate release into the environment of GMOs before decisions are taken on whether or not to allow its release for either experimental or commercial purposes. This is currently Directive 90/220/EEC, which will be updated and replaced by Directive 2001/18/EC; and
 - secondly, and only after it has been approved on safety grounds under the deliberate release Directive, the proposed new GM agricultural crop must undergo at least two years of listing trials, with a view to being placed on the National List. The purpose of the listing procedure is to establish that the variety is **distinct, uniform and stable and, for agricultural species, has a value for cultivation and use** in the UK. The seeds for a GM crop cannot be marketed until it has been added to the UK National List of plant varieties or to the EU Common Catalogue (a compendium of EU Member States' national lists) – and it cannot be added to the National List until it has been approved as safe for placing on the market under Part C of Directive 90/220/EEC).
 - In addition to clearance of the GM crop itself, any foods obtained from the GM crop would have to be approved under the EU Novel Foods Regulation EC/258/97. The Food Standards Agency is the UK competent authority for this legislation.

Consultation under the current system

3. The UK has a good record of making information on GMO releases available to the public. The Government operates beyond the requirements of the old Directive 90/220/EEC, making details of any application to release GMOs in the UK available on a public register. In addition, we have always taken account of representations made to us by the public concerning safety issues to human health or the environment raised by proposed experimental (or “Part B”) releases, for which the Government is responsible. On proposed commercial (or “Part C”) releases, for which the European Commission is responsible, we have also made information available to the public.

Improved consultation under the proposed new system

4. The new EU Directive 2001/18/EC on the deliberate release into the environment of GMOs introduces substantial improvements to the deliberate release regime, including the introduction of **mandatory** public consultation before decisions are made on whether or not to allow the release of a GMO. SEERAD is currently holding a public consultation on draft legislation to implement the new Directive in Scotland. The other administrations will be conducting similar consultations in their

respective areas. A detailed description of the proposed new system can be found in the consultation paper (see <http://www.scotland.gov.uk/library5/environment/rdrgr-00.asp>). However, key aspects of the improved system are outlined below.

5. Under the Directive, decisions on whether or not to grant a commercial (Part C) consent are taken collectively by the European Commission and all Member States. Under the new Directive 2001/18/EC system, the Commission must now **hold two separate periods of 30 days public consultation on any Part C application** before any decision is made. Representations received under the new system must be copied by the Commission to all Member States, which ensures that public comments from all over the EU can be taken into account by all parties involved in making the decision. In the UK, we intend to advertise the fact that such consultations are being held by the Commission, and relevant representations by the public will inform the UK position in making a collective decision in Europe.

6. GM crops may also be authorised for National List field trials by an experimental (Part B) consent under Directive 2001/18/EC (although a Part C consent would be needed before the GM crop could be added to the National List itself). In implementing Directive 2001/18/EC, the Government proposes to build significantly on the current system of information and consultation. Under the proposed new system there will be a **mandatory public consultation lasting a minimum of 48 days on all Part B applications**. There will also be a statutory requirement for relevant representations from the public to be taken into account in making decisions on whether to grant or refuse a Part B consent. The UK Government is also taking forward work, in parallel to the implementation of Directive 2001/18/EC, to ask the European Commission to initiate proceedings to extend notification times of experimental plantings of GM crops under Commission Decision 94/730/EC (the “first simplified procedure”)¹.

7. The safety assessment of GM crops is not a fixed process. If a GMO is granted a consent for release under Directive 2001/18/EC, that consent can and will be reconsidered if significant new evidence comes to light that might prompt a different view of the safety risks. Therefore, in addition to the specific consultation provided for under Directive 2001/18/EC, the Government (and any other Member State in the EU) would be required to consider new information with a bearing on the risk assessment of a particular GMO. This would apply at any time before or after a Part B or Part C consent is granted. In the UK, if the independent Advisory Committee on Releases to the Environment advised that action needed to be taken, the Directive provides for the consent to be altered or revoked as appropriate.

Public debate

8. Before the possible commercialisation of GM crops in the UK the Government is also encouraging an open and informed public debate on GM issues, including the science surrounding people’s concerns on GM crops and food. This will provide a further opportunity for public views to be aired on GM safety issues.

¹ See the consultation document on the implementation of Directive 2001/18/EC for more details.