

**IN THE MATTER OF THE POWERS OF THE
NATIONAL ASSEMBLY FOR WALES TO REFUSE TO
ENTER CHARDON LL ON THE UK NATIONAL LIST**

OPINION

Introduction

1. We are asked to provide an Opinion for Friends of the Earth (“FOE”) as to whether the National Assembly for Wales (“the Assembly”) can lawfully refuse to enter Chardon LL genetically modified (“GM”) T25 maize onto the UK National List of agricultural plant varieties. We understand that this Opinion may be forwarded to members of the Assembly and to the Assembly’s civil servants.

2. Junior Counsel has already advised on this matter and drafted a written opinion for Friends of the Earth in March 2000 which was provided to members of the Welsh Assembly. The most relevant developments since March 2000 are (1) changes to the Seeds Regulations; (2) commencement and completion of the Chardon LL public hearing; (3) the replacement of the then deliberate release directive (Directive 90/220) with the new (Directive 2001/18); (4) the replacement of the then common catalogue directive (70/457) with the new Common Catalogue Directive (2002/53) and (5) Wales’ invocation of Art. 16 of Directive 90/220 to impose particular restrictions on the cultivation of ChardonLL in Wales.

Summary of Opinion

3. Our opinion is that there are a number of grounds upon which the Assembly could and/or should refuse to accept Chardon LL for the National List if the evidence of FOE and/or other experts (in particular those who gave evidence at the recent hearing (described below) is accepted. These are

- that the variety does not satisfy the criteria for value for cultivation and use;
- that the requirements of Art 4(4) of the Common Catalogue Directive 2002/53 (that all appropriate measures have been taken to avoid adverse effects on human health and the environment) have not been complied with;
- that the requirements of regulation 5(4)(b) of the Seeds (National List of Varieties) Regulations 2001 (cultivation of the variety could be harmful, in relation to plant health, to the cultivation of other varieties or species) have been met.

4. We draw specific attention to the independent role of the National Assembly for Wales (“NAW”) in deciding whether the Chardon LL variety should be listed.

Update

The regulations

5. The Seeds (National List of Varieties) Regulations 1982 (in respect of which junior Counsel previously advised) were replaced by the 2001 Regulations of the same name (SI 2001/3510) (‘the Regulations’). For the purposes of this Opinion only the new regulations are now of direct relevance.¹ The key changes to the Regulations, for the purposes of this Opinion, are the replacement of Reg. 12 (1982 Regs) which provided two mandatory grounds for refusal of listing with Reg. 5 of the regulations which sets out a number of mandatory grounds for refusal (Reg. 5(3)) and two discretionary grounds (Reg. 5(4)). In addition, the new Regulations contain limited specific provisions in relation to GM seeds including the requirement that no GM seed may be listed unless it has been

¹ The relevant transitional provision is contained at Reg. 24(12)

accepted for marketing under the Deliberate Release Directive: see reg. 5(3)(d) of the Regulations.

The Assembly's previous decision

6. At the time of junior Counsel's previous opinion in March 2000, the Welsh Assembly (amongst others) were considering whether to propose ChardonLL for addition to the National List. In the event, that proposal was made and gave rise to a lengthy public hearing under the provisions of the Regulations.

The hearing

7. That hearing was completed in June 2002 under the chairmanship of Alun Alesbury and a 'themed summary' or 'digest' by Mr Alesbury of the evidence given at that hearing was provided to the Ministers and the devolved authorities at the end of December 2002. The Secretary of State and the devolved authorities are considering that summary (together with the evidence submitted at the hearing) and will then make a decision as to whether or not to list to list.

8. Under Regulation 16(8) of the Regulations the National Authorities shall not take a decision until they have considered any oral or written representations made at the ChardonLL Hearing or made to them by way or written representations. It is noteworthy that Mr Alesbury states in his report at para 5.14 of the Introduction that following such consideration the National Authorities

...had to take an entirely fresh decision, in the light of all of the new material on either side produced through the written and oral representations and evidence...I expressed the view that in the new situation (whatever may have been the case at the "proposed decision" stage), the ...National Authorities had moved into something of a "quasi-judicial" position, rather than one of being (as it were) advocates for one particular result

The decision to list

9. Seeds matters generally are devolved issues and under the Regulations the functions of the National Authorities are stated to be exercisable by the devolved authorities in relation to each of the devolved regions (Reg. 2(4)). However, there remains only one National Seed List for the whole of the UK and the term

National Authorities is specifically defined to mean each of the relevant devolved authorities “*acting jointly*” (reg. 2(1)).

10. As a result no decision to add ChardonLL to the National List under Reg. 5 may be made without the agreement of all of the relevant authorities. The decision will be the first proposed National List decision in the UK on a GM variety. The variety has been “approved” for deliberate release into the environment and marketing in 1998 using the risk assessment process laid down in the Directive 90/220.

11. The National Listing procedure is explained in the civil service briefing paper for the Agriculture and Rural Development Committee meeting on 1 March 2000 thus

National Listing (NL) is a UK regulatory system which stems from a range of EC Directives. All varieties of the main agricultural and vegetable species, including genetically modified varieties, must be on the UK List or EU Common Catalogue before they may be marketed in the UK. Addition to the UK National List requires that the candidate varieties show they are Distinct Uniform and Stable (DUS) and have a Value for Cultivation and Use (VCU) in the UK. Those assessments are made in growing trials, usually over two years, on the basis of which a recommendation is made by crop experts, from a range of technical and scientific committees, about whether these requirements are met.

Statutory framework

12. In relation to the European legislation Council Directive 2002/53 (the Common Catalogue Directive²) is important. In its initial form Art 4(1) deals with the acceptance of a variety for “inclusion in a common catalogue” (see Article 1). It reads

Member States shall ensure that a variety is accepted only if it is distinct, stable and sufficiently uniform. The variety must be of satisfactory value for cultivation and use.

13. Directive 2002/53, by Art 24 of the Directive, is specifically said to be

² Directive 2002/53 is a consolidating directive bringing together the numerous amendments to the original Common Catalogue Directive (70/457) including those introduced by Directive 98/95 which first brought GM considerations within the seed listing regime.

without prejudice to the provisions of national laws justified on grounds of the protection of health and life of humans, animals or plants or the protection of industrial and commercial property

14. Article 4(4), a version of which was first added to the 1970 Directive in 1998 by Directive 98/95, provides that

In the case of a genetically modified variety ... the deliberate release into the environment of the variety shall be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment.³

15. However, this is the current wording as included in the current, consolidating directive 2002/53. As originally worded by Directive 98/95, Article 4(4) reads

In the case of a genetically modified variety...the variety shall be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment.

16. It seems to us, especially given that Directive 2002/53 is a consolidating directive⁴ that the new wording is a mistaken transposition of the original amendment introduced by direction 98/95 and we understand that FOE have written to the Commission seeking a Corrigendum to the new Directive⁵. This opinion proceeds on the assumption that the original wording is correct.

17. The Regulations transpose to an extent the relevant European directives on listing. Reg. 5 of the Regulations sets out the basis on which a plant variety either shall (reg. 5(3)) or may (reg. 5(4)) be refused for addition to the National List.

18. The key terms of Regulation 5 are as follows. Subsection (3) reads

“(3) The National Authorities shall not accept a plant variety on to a National List unless they are satisfied that -

³ Paragraph 14 of the preamble to Directive 98/95 states that Member States, when determining whether to accept GM varieties under Directive 70/457 “should have regard to any risk related to their deliberate release into the environment...”

⁴ Recital (1) states “...For reasons of clarity and rationality the Said Directive should be codified.”

⁵ The letter from Friends of the Earth notes that the argument that the new wording is simply a mistaken transposition is supported both by (1) various other language versions of the Directive; and (2) the terms of the vegetable seed ‘sister directive’ (2002/55, Art. 4(2)).

- (a) the variety is a variety of a species specified in Part I of Schedule 1;
- (b) [relates to DUS which is not in issue here];
- (c) in respect of any variety other than a variety referred to in Part III of Schedule 2, the variety is of satisfactory value for cultivation and use as described in Part II of that Schedule;
- (d) in respect of a genetically modified variety, it has been accepted for marketing in accordance with Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms;”

19. Subsection (4) reads

- (4) The National Authorities may refuse to accept a plant variety on to a National List, whether or not they are satisfied of the matters in respect of the variety specified in paragraph (3) above, if they are satisfied that -
- (a) the refusal is required by virtue of any provision of national law justified on grounds of the protection of health and life of humans, animals or plants; or
 - (b) cultivation of the variety could be harmful, in relation to plant health, to the cultivation of other varieties or species

20. The relevant wording of Schedule 2, Part II is:

“The value of a variety for cultivation or use shall be regarded as satisfactory if compared to other varieties accepted in a National List its qualities taken as a whole offer, at least as far as production in any given region is concerned, a clear improvement either for cultivation or as regards the uses which can be made of the crops of the products derived from the crops.

Where other superior characteristics are present individual inferior characteristics may be disregarded.”⁶

21. Although the new Regulations in 2001 were made primarily to give effect to the amending provisions of Directive 98/95 (now contained in 2002/53), it is important to note that certain key provisions of that Directive (notably Art. 4(4)) are not transposed in the Regulations. That fact is recognised in the second paragraph of the Explanatory Note to the Regulations which states that:

Certain requirements of Council Directive 98/95/EC have not been transposed in full in these Regulations where there is existing provision in the Environmental Protection Act 1990 (c. 43). Part VI of that Act makes

⁶ The regulation talks about cultivation and use, whereas the schedule uses the disjunctive “or” (as to which see para. 25 (below)).

general provision for preventing damage to the environment from the release of genetically modified organisms. Relevant provisions include carrying out environmental risk assessments for genetically modified plant varieties, imposition of conditions appropriate for their cultivation and prohibition of their use where their cultivation could be harmful.”

22. Instead of transposing Art. 4(4), the drafters have included only a requirement (reg. 5(3)(c)) that a GM variety may not be accepted for addition to the list unless it has obtained a consent under the deliberate release directive (90/220, now 2001/18). As noted below, Reg. 5(3)(c) in fact transposes a distinct provision of the Directive, namely 7(4)(b).

Opinion

Value for cultivation and use (VCU)

23. In relation to VCU we are aware that FOE has argued that the variety should not be listed on the basis that expert evidence in the hearing has demonstrated non-compliance with the technical VCU requirements (see e.g., Alesbury 8.6.1 – 8.6.48) . We make no further comment about this but note only that if the Assembly accepts this evidence and is not satisfied that VCU requirements are satisfied then it cannot accept Chardon LL onto the list: regulation 5(3)(c).

24. In addition, FOE advance an argument which depends on the correct interpretation of the Regulations requiring both value for cultivation and value for use (rather than for one of these to be sufficient). The argument is that although (subject to the technical arguments set out above) it may the case that value for cultivation can be shown, VCU has not been satisfied because no clear improvement can be shown for the only intended real life *use* of ChardonLL (i.e., as silage for cattle). This is primarily, but not exclusively, because no published target species animal feed safety studies have yet been carried out in relation to ChardonLL.

25. We note that the requirement of the Directive 2002/53 as set out in Art.4(1) is that “*The variety must be of satisfactory value for cultivation and use.*”⁷

⁷ The conjunctive wording is supported by Recital (6) to the Directive which also refers to “*satisfactory value for cultivation and use.*”

(Emphasis added). The requirement of Reg. 5(3)(c) of the regulations also uses the conjunctive ‘*and*’, although the schedule referred to uses the disjunctive “or”. There is clearly some confusion on this point, but it is our view that, in order to satisfy the terms of Reg. 5(3)(c), especially when read in conjunction with the Directive, it must be shown that the variety is of satisfactory value for cultivation and value for use, and if the NAW accepts FOE’s argument on “use” then it cannot list Chardon LL.

Discretionary requirements

26. While the previous regulations contained no specific grounds (other than failure to satisfy technical requirements such as VCU and DUS) upon which the National Authorities could decline to list a variety the present regulations do contain such provisions. Specifically, under reg. 5(4)(b) the National Authorities may refuse to accept a plant variety onto a National List where they are satisfied that “*cultivation of the variety could be harmful, in relation to plant health, to the cultivation of other varieties or species*” (emphasis added).

27. Of particular importance in this context is the word “*could*”. It is clear, in our view, that there is no need to demonstrate conclusively that cultivation would be harmful to plant health, but merely (and in accordance with the precautionary principle⁸) that such a result is a realistic possibility.

28. It is our view that so long as the National Authorities exercise their discretion in regulation 5(4)(b) in accordance with general public law principles of, amongst other things, Wednesbury unreasonableness and/or proportionality then there is a broad residual power in the National Authorities not to list. We also note the particular power of the NAW to “consider, and make appropriate representations about, any matter affecting Wales” (s.33 Government of Wales Act (‘GWA’)).

⁸ We note the “Communication from the [European] Commission on the precautionary principle” dated 2 February 2000 which emphasises the view of the Commission that the principle is a “key tenet of its policy” and the EC Treaty incorporating provisions already introduced by the Maastricht Treaty of 1992 and more specifically Article 174 thereof which states “Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and the principles that preventive action should be taken that environmental damage should as a priority be rectified at source.”.

Art 4(4)

29. Directive 98/95/EC (which came into force in December 1998) amended the Common Catalogue Directive so as to impose additional requirements upon the relevant National Authorities when making a decision as to whether to add a variety to a National List where that variety is a genetically modified organism as defined in the Deliberate Release Directive (90/220/EC). This is because of the special concerns about risks to the environment and health that arise in the context of genetically modified organisms (“GMOs”). In particular, the consolidated Common Catalogue Directive 2002/53 contains two separate and additional requirements that are of direct relevance to the decision the Assembly will have to make.

30. First, there is a requirement to ensure that (under Art.7(4)) a risk assessment equivalent to that required for Directive 90/220 is carried out and that, until a procedure is established for ensuring that the risk assessment in question is equivalent to that under Directive 90/220, a GMO may only be accepted on to a National List where a marketing consent under the Deliberate Release Directive is in place.

31. Second, and separately, Art. 4(4) imposes a requirement in respect of genetically modified plant varieties that is directly related to the question of whether or not a variety may be added to a National List (rather than whether for example a marketing consent will be granted). In this context, we note that Article 4(4) is part of an article which deals directly with other listing specific mandatory requirements such as VCU and DUS. Thus, Art. 4(4) imposes a listing specific mandatory requirement with the result that unless all such appropriate measures have been taken to avoid adverse effects on human health and the environment then that variety must not be listed.

32. Although there is no definition within Directive 2002/53 of the term “*human health and the environment*”, it is clear from Article 2 of the Deliberate Release Directive (to which Art. 4(4) is specifically linked) that risk to “*the environment*” includes risk to “*plants and animals*”. (Art.2(8) 1990/220). It is our view therefore that the obligation to ensure that all appropriate steps are taken to avoid

adverse effects on human health and environment includes, amongst other things, an obligation to avoid adverse risks to animals (and therefore in the current case, for example, any risk to the cattle to whom ChardonLL silage will be fed).

33. What is required from a National Authority in order to comply with the requirements of Art. 4(4)? It has been argued by MAFF's lawyers and the OCG that the two requirements in Arts. 4(4) and 7(4) are, in effect, the same and that Art 4(4) requires no more than that the National Authorities confirm that a marketing consent under the Deliberate Release Directive is in place⁹. In our view this argument is misconceived. Art. 7(4) deals with the specific requirement to carry out a risk assessment in accordance with the Deliberate Release Directive. Art. 4(4) imposes a separate and far broader requirement that must be met before a GM variety is accepted onto a national list, and includes, amongst other things, consideration of factors which have come to light even after the marketing consent has been granted.

34. Had the drafters of Art 4(4) intended simply to state that a variety might not be accepted onto a National List in the absence of a 90/220 risk assessment then it would have been a simple drafting matter to do so and would not have required an obligation on member states to ensure that all appropriate measures had been taken *etc.*

35. On the facts of this case, the T25 Part C consent arises as a result of the Commission Decision (98/293) concerning the placing on the market of genetically modified maize T25 pursuant to Directive 90/220. Article 1 of that Decision is in the following terms:

“Without prejudice to other Community legislation, in particular Council Directive[s]...70/457/EEC, ..., and subject to paragraph 2 of this Article, Consent shall be given by the competent authorities of France to the placing on the market...[etc].”

36. The fact that the Commission Decision which led to the granting the marketing consent is specifically stated to be ‘without prejudice’ to the Common

⁹ See e.g., letter from MAFF's lawyers to FOE dated 22 September 2000 (CHD 11/431) and the advice of OCG to the ARD Committee dated 29 March 2000 (ARD 05-00 (p.5) para. 11-13)

Catalogue Directive indicates strongly that the requirements of that Directive (effectively the ‘dominant’ directive) may justly require things to be done that go beyond the requirements of 90/220. One of those things is compliance with the terms of Art. 4(4).

37. Thus, in our view, there is a strong argument that the requirement in Art 4(4) to ensure that all appropriate measures have been taken before a variety is ‘accepted’ is wholly separate from (and additional to) the specific requirement that a variety may only be added to the List when it has a Part C Consent under the Deliberate Release Directive.

38. There remains the question as to whether Art 4(4) has been given effect by the present regulations or otherwise, or whether it has “direct effect” and the Assembly must apply its terms as correctly interpreted in any event. The terms of the Explanatory Note as set out above (para 21) are unclear. If the position of the drafter is that Art. 4(4) is a provision already covered by the EPA, then in our view this is mistaken as it is quite clear that the variety listing specific provisions of Art 4(4) are entirely separate from the general provisions contained in the EPA.

39. It is our view therefore that Art 4(4) has not been fully and correctly transposed with the result that the 2001 Regulations do not explicitly include the broad duty that is imposed on Member States by Article 4(4). As a result, it is either the case that the provisions of reg. 5 must be interpreted sufficiently broadly to contain the obligation on the Member States contained in Art. 4(4) or that the provisions of Art. 4(4) must be treated as being directly effective. Irrespective of which approach is taken, failure to comply with the listing specific obligation set out in Art. 4(4) (in whatever manner) would be a breach of the UK’s obligations.

40. Practically speaking, we note FOE’s argument that a number of “appropriate measures” have not yet been taken in the case of ChardonLL relating principally to the following issues¹⁰:

- Animal feed safety;

¹⁰ These are set out in detail in FOE’s Oral Submissions contained at FOE91 in the Chardon Hearing Documents.

- Horizontal Gene Transfer;
- Pollen dispersal;
- Ensuring that that the variety would comply with the terms of the amended Deliberate Release Directive (2001/18) (in particular the risk assessment).
- Flaws in the regulatory process

41. We make no comment here in relation to the further measures that should be taken but it is our view that these are all matters and issues which should be taken into account, pursuant to Art 4(4) but also in deciding whether VCU (specifically ‘value for use’) is satisfied and whether the discretionary elements of regulation 5 should be used.

The National Assembly of Wales (“NAW”)

42. It is clear that the devolution of listing issues imposes a duty on the NAW to satisfy itself, within the law, that the listing of ChardonLL is correct, taking specific Welsh factors into account, and the views of other National Authorities and/or other EU countries cannot be determinative of the issue. We note in particular that Wales has a positive approach to “sustainability” built into its constitution under section 121 GWA, which states that “The Assembly shall make a scheme setting out how it proposes, in the exercise of its functions, to promote sustainable development”. It seems to us that the approach of ensuring that all appropriate measures must be taken before listing is consistent with the NAW’s policy of taking the most restrictive, in the sense of cautious, possible approach within the law, and we note the evidence of the NAW’s view of the gravity of the issue by the invocation of Art 16 of the Deliberate Release Directive.

43. Such an approach would also be consistent with giving the advice of ACRE / ACNFP (provided after the Chardon LL hearing and re-affirming that ACRE/ACNFP think there is no evidence that T25 maize poses a greater risk to human health or the environment than non-GM maize) the utmost scrutiny. So long, of course, that the NAW properly considers the advice of ACRE/ACNFP there is nothing in law, which prevents the NAW preferring the approach of other commentators and experts such as those who gave evidence in the Chardon LL hearing.

Conclusion

44. The decision of the NAW is clearly an important one, and it is our view that there are still a number of significant considerations to be taken into account before a decision can be made. We reject the view that the only role for the NAW is to consider whether the “technical” aspects of VCU and DUS have been satisfied. Rather it is our opinion that there are difficult questions of evidence, policy and law which go to the heart of the debate involving GMOs which the NAW must now consider independently before reaching their conclusions as to whether to list Chardon LL as a variety.

45. We are happy, of course, to be contacted further if any clarification of this opinion is required.

NICHOLAS COOKE QC

STEPHEN CRAGG

26 February 2003

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**Phil Michaels
Legal Adviser
Friends of the Earth
26-28 Underwood Street
London N1 7JQ
Tel: 020 7490 1555
Fax: 020 7490 0881**