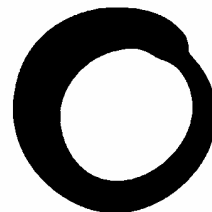


March 2004

Legal Briefing



**Friends of
the Earth
Cymru**

**Cyfeillion
y Ddaear
Cymru**

Proposed decision to add ChardonLL to the UK National List of Varieties

**Briefing for members of the Environment, Planning and
Countryside Committee of the National Assembly for Wales**

The purpose of this briefing is to summarise the various legal grounds upon which the Assembly either may or must lawfully refuse to add ChardonLL to the UK National List and to highlight some of the evidence that would allow the Assembly lawfully to make such a decision.

I. Introduction

ChardonLL is the first GM seed variety to have been proposed for addition to the National List of Seed Varieties in the UK ('the List'). Addition to the National List represents one of the final regulatory hurdles for this seed variety before it may be commercially planted and grown throughout the UK. In order for Chardon LL to be commercially grown in the UK, the Government will also have to confirm that the GMO marketing consent granted for T25 maize in 1998 is still valid after the publications of FSE results and other new scientific information (particularly that which emerged during the Chardon LL hearings). In addition to GMO approval, an authorisation for glufosinate ammonium to be used on GM maize is also required before full commercial growing can commence.

Friends of the Earth Cymru provided a briefing to members of the Agricultural and Rural Development Committee ('ARD') in March 2000 concerning the question at that time of whether to propose to add ChardonLL to the National List of Seed Varieties. At the time of that briefing much important information that is now available concerning ChardonLL was not yet in the public domain. That information has come into the public domain as a result of the public ChardonLL hearing which took place in two stages in Autumn 2000 and again in Spring 2002. Furthermore, since the date of that briefing the law has changed at the European and domestic levels¹.

¹ In particular, the replacement of the 1982 Seeds (National List of Varieties) Regulations with the 2001 regulations of the same name and the replacement of the old GM deliberate release directive (Directive 90/220)

As a result of these developments, and because Wales is now called on again to make a final decision as to listing of ChardonLL, Friends of the Earth Cymru is providing EPC Committee members with an updated legal briefing together with a small bundle of relevant documentation which it is hoped the members of the EPC Committee will find of assistance in their decision making.

II. Background

Despite a clear recommendation by the ARD Committee that ChardonLL should **not** be proposed for listing the then Agriculture Secretary (Christine Gwyther) decided to agree to the *proposal* to add ChardonLL to the List. As set out below, we suggest that that decision was made at least in part on the basis of an incorrect legal analysis by the Office of the Counsel General ('OCG').

Following the proposal to add ChardonLL to the List a public hearing was called for by over sixty individuals and organisations most of whom gave evidence and many of whom called witnesses to be examined. The applicant company (Aventis CropScience, now called Bayer CropScience) refused to give oral evidence to the hearing or to open itself up to cross-examination or to cross-examine the willing witnesses for the objectors. That hearing concluded in June 2002 and the report of the Chairman, Mr Alun Alesbury, was provided to the NAW and to the other UK authorities in October 2002. During the hearing considerable new evidence was provided which strongly supports the view that ChardonLL should not be added to the List both from a GMO perspective and also a seed and agronomy perspective.

The National Authorities are now required to consider the evidence submitted to the ChardonLL hearing and make a decision as to whether to add ChardonLL to the List.

Importantly, any decision to list must be made unanimously by all four regional authorities. As there is only one National List for the whole of the UK it is not possible to protect the Welsh environment by having ChardonLL added to lists for the other three regions alone. If the Welsh Assembly wishes to protect its environment from commercial growing of ChardonLL and, in accordance with its policy, of operating the most restrictive GMO policy possible within the framework of European legislation then it should refuse the addition of ChardonLL to the National List.

The purpose of this briefing is to summarise the various legal grounds upon which the Assembly either may or must lawfully reject ChardonLL and to highlight some of the evidence that would allow the Assembly lawfully to make such a decision. A more detailed analysis of the Assembly's legal powers is contained in the attached opinion of Counsel. A very detailed analysis of the evidential grounds on which the application for listing should be refused is contained in the *Final Submissions of Friends of the Earth to the ChardonLL hearing* which are available on request and which can be viewed on Friends of the Earth's website².

with a new GM deliberate release directive (Directive 2001/18). In addition, the European Common Catalogue (Seed Listing) Directive has been consolidated in a new legal instrument (Directive 2002/53).

² http://www.foe.co.uk/resource/evidence/chardonll_final_submission.pdf

The specific points of evidence summarised below are summaries only of a list of more than ninety questions that Friends of the Earth posed at the ChardonLL public hearing and which we submitted needed to be answered both by the applicant for consent and the National Authorities if ChardonLL were to be added the List. Those questions remain unanswered. That list of questions is also available on request and can be viewed on Friends of the Earth's website³.

Each of the grounds set out below would entitle the Assembly lawfully to reject the application for listing. Furthermore, two of the grounds are mandatory and (if the Assembly is satisfied as to the evidence in support of those grounds) then Wales (and the other nations) must refuse to add ChardonLL to the List.

³ http://www.foe.co.uk/resource/evidence/chardonll_question_aventis.pdf

III. The Grounds

The Mandatory Grounds for Refusal

Two grounds on which the National Assembly **MUST** refuse the application to add ChardonLL to the National List

1. It cannot be said that “*all appropriate measures have been taken to avoid adverse effects on human health and the environment*” in accordance with Art. 4(4) of Directive 70/457 (as amended); and
2. ChardonLL is not of satisfactory value for cultivation and use (Reg. 5(3)(c) of the Seeds (National List of Varieties) Regulations 2001).

Ground 1

All appropriate measures have not been taken to avoid adverse effects on human health and the environment

The background paper provided to the ARD for its discussion on 1 March 2000 (ARD 03-00) stated that “*The [National List] process has no role in assessing the environmental or safety aspects of genetic modification and is therefore the same whether a GM or non-GM variety is involved.*” With respect, that is incorrect. Since 1998 there has existed a listing specific additional legal requirement for any application for a **GM** seed variety. This requirement is in addition to other general requirements that apply to all applications (GM or non-GM).

The requirement is that⁴:

“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.” (Art. 4(4))

That requirement is specific to the seed listing and **must** be satisfied for any GM seed that is to be added to the National List. In March 2000 the OCG argued⁵ that the requirement for *all appropriate measures* to have been taken was simply a repetition of the separate legal requirement for a GM consent to have been granted. For the reasons set out in the attached opinion of Mr Nick Cooke QC and Mr Stephen Cragg⁶ FOE believes that view to be incorrect. As a result, at a minimum, the Welsh Assembly (and the Minister) has a duty to consider whether “*all appropriate measures have been taken to avoid adverse effects on human health and the environment*”. If, on the basis of the evidence adduced during the course of the ChardonLL hearing, it is accepted that further appropriate measures could and should

⁴ The specific requirement of Art. 4(4) was inserted into Directive 70/457 (the European Directive which sets out the overarching legal framework for Seed Listing and which provides the basis for the domestic regulations) by Directive 98/95.

⁵ Advice of OCG to the ARD dated 29 March 2000 (ARD 05-00 (p.5))

⁶ See Paragraphs 29 – 37

be taken in order to avoid adverse effects on human health and the environment then the Assembly is legally obliged to refuse to add ChardonLL to the List.

As a result of the evidence given at the ChardonLL hearing Friends of the Earth believes that it is clear that it cannot yet be said that “*all appropriate measures have been taken to avoid adverse effects on human health and the environment*”. In particular, the Members of the National Assembly will note that⁷:

- a. although ChardonLL is a fodder maize variety specifically designed to be fed to cattle and although ChardonLL silage is likely to make up the majority of their diet, no studies have been published showing the effect of feeding ChardonLL to the intended target species⁸;
- b. the ACAF GM sub-group (the only body with a specific remit to advise on animal feed issues) has stated that there are some statistically significant differences between the GM and non-GM varieties and that the substantial equivalence of T25 to non-transgenic maize should be confirmed *before it may be concluded with confidence* that T25 silage poses a low risk;
- c. the evidence relating to anti-nutritional compounds supplied by Aventis in support of their application for T25 marketing consent is patently inadequate;
- d. even in 1996, the Scientific Committee on Plants (SC-Plants) stated (with reference to the T25 dossier) that “*the applied in vitro methodology to study the survival of the PAT can be improved.*” and that the ACAF GM sub-group was expressly “*critical of some features of*” one of the key supporting studies (*the rat study*);
- e. even the ACAF GM sub-group was critical of features of the Rat Study in their 2001 report saying that “*in particular the origin of the PAT protein fed was not clear and the use of activity units and weight of PAT protein did not allow the level of exposure to be determined accurately*”;
- f. the Chicken Study relied on by Aventis has been demonstrated to be of little or no scientific worth. In particular, expert evidence to the hearing demonstrated that:
 - i. The number of birds was far too few to provide independent measurement.
 - ii. There was no positive control.
 - iii. The reporting of the statistical analysis was inadequate.

⁷ The following matters are very limited ‘highlights’ only of the evidence adduced at the ChardonLL hearing and referred to both in FOE’s final submissions to the ChardonLL hearing and more specifically in FOE’s list of questions to the Hearing (both of which documents are attached to this briefing).

⁸ Although there is no definition within Directive 98/95 (or 70/457) 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 explicitly linked) that risk to “*the environment*” includes risk to “*plants and animals*” (Art.2(8) 1990/220) (See para. 32 of Counsel’s Opinion). It must therefore be understood that the obligation to ensure that all appropriate steps are taken to avoid adverse effects on human health and environment includes an obligation to avoid adverse risks to animals (and therefore in the current case, particularly, risk to the cattle to whom ChardonLL silage will be fed).

- iv. There was a trend for high mortality in the GM fed birds which was not investigated.
 - v. There was a trend for greater weight variance in GM fed birds which was not investigated; and
 - vi. *When the current Chairman of ACRE has himself stated that the way that the Chicken Study was analysed “doesn’t enable us to draw any conclusions.”*
- g. despite serious concerns about cross-pollination (a matter especially sensitive in the context of the Welsh environment) Aventis’ application for marketing consent of T25 maize contains no information about the risk of contamination of other varieties from cross-pollination other than to note that *“the wind can cause pollen from plants to fall on the silks of other adjoining plants”* and despite the fact that expert evidence to the ChardonLL hearing concluded that *“the available data indicates that 200m is unlikely to be a satisfactory separation distance if 0.1% or even 1% are the maximum levels of acceptable contamination.”*; and when a recent report published by the European Environment Agency and the European Science Foundation describes maize as a *“medium to high risk crop for gene flow from crop to crop”* and notes that there is evidence *“that GM maize plants would cross pollinate non-GM maize plants up to and beyond their recommended isolation distances of 200m.”*; and when the United Kingdom (on behalf of the Welsh Assembly) has declared (by way of an Art.16 notification) that the risk from cross pollination of non-GM maize by unrestricted release of T25 crops would involve a *“risk to the environment”* .
- h. Aventis failed to make any mention whatsoever of Horizontal Gene Transfer (HGT) in their Part C marketing notification. Furthermore, evidence adduced at the ChardonLL hearing strongly indicates that information provided by them since that date is inaccurate. In particular, expert evidence to the ChardonLL hearing concluded that HGT from T25 maize products is likely to occur and that the acquired sequences will then spread further by gene transfer and that this is particularly likely if Glufosinate Ammonium is being used in conjunction with the crop (as will be the case here). The same witness commented that numerous safety questions remain unanswered in this regard and noted that essential and specified research ought to be undertaken before ChardonLL is put into commercial planting.
- i. there have been clear failings in the regulatory approvals process with respect to the clearance of T25 maize. In particular
- i. The advice given initially by the ACRE secretariat to ACRE in June 1996 was incomplete and, in some places, incorrect.
 - ii. The written comments made by members of the ACRE committee (the only formal result of ACRE’s consideration of the T25 dossier) ranged from cursory to non-existent with the result that Aventis’ application dossier was in effect passed by ACRE ‘on the nod’.

- iii. The only three experts consulted at the time whose remit was directly relevant to feed safety issues (i.e., prior to ACAF's very recent involvement) raised very serious concerns about T25 all of which were ignored.
- j. the risk assessment carried out for the marketing approval of T25 maize is not up to current minimum requirements under directive 2001/18⁹. In particular, an expert witness (member of the Agriculture and Environment Biotechnology Commission) at the ChardonLL hearing concluded that "*if the application to market the T25 maize had been made after December 1998 the original dossier would not have been acceptable*". That expert stated that, in particular, new information would have been required on:
 - i. Environmental effect of the use of GA in conjunction with T25;
 - ii. Monitoring and testing assumptions contained in the risk assessment;
 - iii. Effects on animal health and consequences of introduction into the food chain;
- k. the United Kingdom (acting on behalf of the Welsh Assembly) has already notified the Commission under Art. 16 (90/220) that it considers that the unrestricted release of T25 (of which ChardonLL is a variety) represents a risk to the environment. Should ChardonLL be added to the List then the opportunity to restrict the release of ChardonLL in the Welsh environment will be further diminished.

The Farm Scale Evaluations

ChardonLL has specifically been engineered to be used with the Bayer herbicide product 'Liberty' ('LL' standing for Liberty Link). The active chemical substance in Liberty is Glufosinate Ammonium.

The environmental effects of using the pesticide Glufosinate Ammonium in conjunction with T25 maize are now required to be considered as part of the risk assessment of Directive 2001/18. It was for this reason that T25 maize was included in the Farm Scale Evaluations ('FSE') from 2000-2003.

The results of the FSE showed that biodiversity in GM maize fields represented an improvement on the current weed management in fodder maize. However, serious concerns about the validity of the FSE results for maize have been raised. These cover the following areas and are subject to a separate briefing from Friends of the Earth¹⁰:

1. In the FSE, the comparison herbicide used on the non-GM half of the experiment was Atrazine. However, Atrazine was banned by the EU in

⁹ This point is broadly the same as the point made in FOE's original legal briefing (para. 7). The point was originally made on the basis of proposals for improvement of the risk assessment procedure. Those proposals have subsequently crystallised in the form of Directive 2001/18.

¹⁰ *GM Fodder Maize: Why ChardonLL should not become the UK's first Commercial GM crop*, March 2004, available from Friends of the Earth Cymru.

2003 and may not be used beyond 2005. Thus no comparison between conventional weed control to be used in the future and the GM regime has been made. It is therefore not possible to judge for the purposes of the Directive 2001/18 risk assessment what the relative impact on farmland biodiversity of the two systems will be.

2. GM maize yields were not measured accurately to ensure that a commercial yield had been achieved. The FSE researchers chose height as the only direct measurement of maize yield. Height does not correlate well with final yield and quality and in National List Trials it is specifically not designated as a character of “major” importance.
3. Failure to measure yield accurately has cast doubt on whether the GM maize was sprayed as required by normal agronomic practice or whether it was managed primarily to enhance biodiversity for the purposes of the FSE comparison. Advice on spraying times was given by Bayer CropScience to the FSE farmers via a draft label for glufosinate ammonium and verbal advice. At least one farmer (in Oxfordshire) has reported that he was told not to spray the GM crop. Pictorial evidence from this site shows a clear and dramatic difference in yield between the two halves of the experiment with the non GM regime producing the greater crop.

Ground 2

ChardonLL is not of Value for Cultivation and Use

Value for Cultivation and Use (‘VCU’) is a specific mandatory requirement of both the originating European Directive and also of the domestic regulations¹¹. No seed variety may be added to the national list unless it can demonstrate a clear improvement for cultivation and as regards the uses which can be made of the crops or the products derived from the crops.

Considerable evidence was adduced at the ChardonLL hearing that demonstrates that ChardonLL is not VCU and in particular that ChardonLL does not have Value for Use. In particular, the Members of the National Assembly will note that:

- a. value for use cannot be shown as no tests have been carried out to establish that ChardonLL is safe for its only intended use, i.e., to be fed to cattle;
- b. expert evidence adduced at the ChardonLL hearing demonstrated clearly that even within the UK’s own VCU testing guidelines ChardonLL does not meet the VCU requirements because the overall score for ChardonLL based on the five major and intermediate characteristics chosen was incorrectly assessed as +2 rather than 0;

¹¹ Regulations (Reg. 5(3)(c))

- c. the same expert evidence shows that the statistical analysis carried out in respect of VCU was unsound and that the approach used was not in accordance with usual statistical practice;
- d. the raw data for Cob Ripeness shows that ChardonLL performed very badly and never scored better than any other variety even when harvested late;
- e. the VCU trials were conducted in wholly unrealistic conditions – notably they were conducted without the application of Glufosinate Ammonium which is the very *raison d'être* of ChardonLL. It is impossible to demonstrate value for cultivation in such an unrealistic testing context;

The Discretionary Grounds for Refusal

In addition, the National Assembly for Wales MAY lawfully, on the evidence before them, refuse to add ChardonLL to the National List because:

- 1. The cultivation of ChardonLL could be harmful, in relation to plant health, to the cultivation of other varieties or species (Reg. 5(4)(b) of 2001/3510); and**
- 2. The National Assembly for Wales retains a residual discretion (outside of the provisions of Reg. 5 of the 2001 Regulations) which is sufficiently wide to allow them to do so.**

Ground 3

The cultivation of ChardonLL could be harmful, in relation to plant health, to the cultivation of other varieties or species.

Regulation 5(4)(b) provides that the National Authorities may refuse to accept a variety onto a National List where the cultivation of that variety could be harmful, in relation to plant health, to the cultivation of other varieties or species. This requirement provides the National Assembly with a broad discretion as to whether or not to add ChardonLL to the List. In particular, and in accordance with the precautionary principle there is no requirement that it be demonstrated conclusively that cultivation would be harmful to the cultivation of other varieties or species, merely that it *could* (realistically) be so. The evidence adduced at the ChardonLL hearing is more than sufficient to satisfy that burden.¹²

In particular we would ask the Committee to consider the matters raised by one expert witness in relation to Horizontal Gene Transfer ('HGT') to soil bacteria. We highlight that expert's conclusion that "*horizontal gene transfer of [the pat] gene would introduce a new gene into the agricultural soil microbial population without any knowledge of its consequences*" and that "*soil is a living system and integral to plant health and plant growth*" (emphasis added).

We also note that expert's reference to the possible consequences of HGT to soil bacteria including "*shift in the current balance of organism in given ecosystems (potentially effecting plant/micro-organisms interactions, nutrient recycling, antagonistic control of pathogens etc.)*". In other words, HGT to soil microbes could affect the quality of the soil in precisely such a way as to be "*harmful*" (by interfering with soil ecosystems) in relation to the plant health (of plants to be subsequently planted on the same land) of other varieties and species. The evidence adduced at the ChardonLL hearing indicates that this is a real, and not a fanciful, risk to which the

¹² See paragraph 27 of the attached legal opinion which states that "*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 principle) that such a result is a realistic possibility.*"

various National Authorities should have regard.

Ground 4

The National Assembly for Wales retains a broad residual discretion (outside of the provisions of Reg. 5 of the 2001 Regulations) which is sufficiently wide to allow them to do so.

Reg. 5 of the List Regulations sets out the situations when a variety must be refused listing. In addition it provides for two situations in which a variety may be refused listing. Several of these have been considered above.

However, neither the mandatory nor the discretionary listing requirements are expressed to be exhaustive¹³ and we would suggest that the Assembly retains a broad residual discretion to refuse to add ChardonLL to the National List as long as its decision to do so is made in accordance with general public law principles e.g., it is reasonable and is made on a case by case basis. This issue is considered further in the Opinion of Mr Stephen Cragg and Nr Nick Cook QC.

¹³ The same point applies to the wording of the originating directive 70/457 although the wording used is different.

III. ACRE's Advice

Following publication of Alun Alesbury QC's report into the ChardonLL hearing a further report was published by ACRE. That report stated that it remained ACRE's view that there was no evidence that ChardonLL "*poses a greater risk to human health or to the environment than non-GM maize varieties*".

The Committee should note that ACRE's report is concerned only with the GM aspects of the ChardonLL (as a form of T25 maize) and is not concerned with its seed listing aspects. In any event, Friends of the Earth disputes many of the conclusions reached by ACRE for the reasons set out in very detailed evidence to the ChardonLL hearing. Friends of the Earth does not consider that the response from ACRE provides adequate evidence of the safety of T25 because:

- ACRE accepted that substantial equivalence of T25 silage should be confirmed.
- ACRE opinion on horizontal gene flow to soil microbes is contradicted by other published papers.
- ACRE failed to fully assess the consequences of horizontal gene flow to soil microbes.
- ACRE underestimated the time maize pollen remains viable in assessing the impacts of cross pollination.
- ACRE failed to respond adequately to the applicability of the rat study.
- ACRE conceded the design weaknesses in the chicken feeding study and its inappropriateness as a guide to cattle growth rates and productivity but failed to see the significance of this.
- ACRE and ACAF appeared confused about the need for cattle feeding studies to confirm the wholesomeness of T25.
- ACRE failed to refute criticisms of digestion studies on PAT protein.

For the purposes of this briefing though, Friends of the Earth simply refers to the paragraphs 42-43 of the attached legal opinion which set out the way in which the Assembly is entitled to approach ACRE's advice on this matter. In particular we note Counsel's Opinion that:

"42. ...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.” (emphasis added)

IV. Conclusion

For the reasons set out in Friends of the Earth’s final submissions to the ChardonLL hearing and summarised above, we consider that the case for refusal of the application to add ChardonLL to the National List is overwhelming and that the National Assembly is lawfully entitled to (and should) refuse to add ChardonLL to the List on the basis of the above referred grounds. In particular, there are two grounds on which the Assembly must refuse to add ChardonLL to the National List if it accepts Friends of the Earth’s factual evidence.

Furthermore, Friends of the Earth Cymru considers that a decision to add ChardonLL to the List at this stage will seriously hamper the Assembly’s stated policy in relation to GM and will undermine Wales’ positive approach to sustainability as built into the Government of Wales Act.

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**Friends of the Earth Cymru inspires solutions to environmental problems
which make life better for people.**

Friends of the Earth Cymru:

- is dedicated to protecting the environment and promoting a sustainable future for Wales
- is part of the UK’s most influential environmental campaigning organisation
- is part of the most extensive environmental network in the world, with over 60 national organisations across five continents
- supports a unique network of campaigning local groups working in communities across Wales
- is dependent upon individuals for over 90% of its income