

Chardon LL Hearing

**CHANGES TO THE REGULATION OF THE ENVIRONMENTAL SAFETY OF
RELEASING
GENETICALLY MODIFIED ORGANISMS
INTO THE ENVIRONMENT SINCE DECEMBER 1998**

Proof of Evidence

of

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On behalf of Friends of the Earth

October 2000

This evidence was submitted at the National Seed List Hearings which ran from October to November 2000 in Manchester and London, England. In April 2000 the UK Government proposed to add the genetically modified maize seed, Chardon LL, to the UK National Seed List. Chardon LL is a variety of T25 maize developed by Aventis. The hearings considered public objections to this government proposal. On 15 November 2000 the National Seed List Hearings were indefinitely suspended by the UK Government.

This is part of a series of evidence submitted. For the rest of the evidence and for Friends of the Earth's case against Chardon LL maize see:

www.foe.co.uk/campaigns/food_and_biotechnology/information/gm_food/

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**CHANGES TO THE REGULATION OF THE ENVIRONMENTAL SAFETY OF
RELEASING GENETICALLY MODIFIED ORGANISMS INTO THE ENVIRONMENT
SINCE DECEMBER 1998**

Dr. Susan Mayer

1. Introduction and Conclusion

- 1.1 I have a first class honours degree in Pharmacology, a degree in Veterinary Science and a PhD in veterinary cell biology/immunology. I am currently Executive Director of GeneWatch UK and an Honorary Research Fellow at the University of Lancaster. I have been studying and undertaking research on the science and regulation of genetically modified (GM) foods and crops for ten years. I am also a member of the Government's Agriculture and Environment Biotechnology Commission.
- 1.2 I have been asked by Friends of the Earth to advise on the differences in the regulation of marketing consents for the release of genetically modified organisms (GMOs) before and after December 1998 and the implications of any differences for the consent to market genetically modified T25 maize produced by Aventis.
- 1.3 I conclude that if the application to market the T25 maize had been made after December 1998 the original dossier would not have been acceptable. More data would have been required including about the potential for indirect environmental impacts particularly under the actual conditions of use and the safety of using the variety as an animal feed. A monitoring plan would also have to have been provided. Because this information has not been presented, questions remain over the environmental safety of marketing T25 maize and it cannot be concluded that all appropriate measures have been taken to avoid adverse effects.
- 1.4 Claims that there is no change to the information requirements needed to assess the safety of T25 before and after December 1998 are not supported by the evidence which shows significant changes to the principles and practice of the risk assessment process have taken place in the UK.

2. The risk assessment process for marketing consent for GM crops in general before and after December 1998

2.1 The release to the environment of genetically modified organisms (GMOs) is covered by the Deliberate Release Directive (90/220/EEC). This is implemented in the UK by regulations brought under Part VI of the Environmental Protection Act 1990.

¹ The approach to risk assessment taken in the regulations is to divide the evaluation procedure into two parts. The first part relates to experimental, small-scale releases of GMOs and the second to marketing of GMOs. The theory is that the data acquired during the small-scale trials will inform the decision about safety of releasing GMOs on a large scale. All assessments are made on a case-by-case basis.

2.2 However, there has been considerable difficulty in gaining agreement between Member States of the European Union on the safety of marketing GMOs. There has been disagreement about the scope of the risk assessment and what determines an adverse effect. The outcome of this debate has been the recognition that the risk assessment process under the existing Deliberate Release Directive is inadequate to ensure environmental safety and that the Directive should be revised. In particular, it has been acknowledged that indirect effects of releasing GMOs must be included in the scope of the risk assessment and that monitoring and traceability are needed to ensure that environmental safety is being properly evaluated. Therefore, in 1998, the European Commission made a proposal for a Directive to amend Directive 90/220/EEC on the deliberate release into the environment of GMOs (COM (1998) 85 final) (CHD 12, page 632 onwards; FOE File 4, Tab 31).

2.3 The UK agreed that changes were needed to make the environmental risk assessment of GMOs more rigorous and, in relation to the UK's role in the revision of the Deliberate Release Directive, on 21st October 1998 the Environment Minister, Michael Meacher, said that:

*“the UK is seeking to make sure that the scope of the Directive and of the environmental risk assessment are well-defined and broad enough to cover indirect as well as direct effects of GMOs”*² (CHD 15, page 8 @ 9, first full paragraph; FOE File 5, Tab 1).

¹ The Genetically Modified Organisms (Deliberate Release) Regulations 1992 and The Genetically Modified Organisms (Deliberate Release) Regulations 1995

²Opening statement by Michael Meacher to the House of Lords Select Committee on Agriculture, 21 October 1998

- 2.4 The Revised Directive is now in its final stages and is expected to be agreed later in 2000. It has had two readings in the European Parliament and is shortly to be considered again by the Council of Environment Ministers. It is unlikely that there will be significant changes to risk assessment process in the existing text before it is finalised.
- 2.5 When comparing the existing and revised Directives there are clear differences in the risk assessment process.
- 2.6 The existing Deliberate Release Directive, in Article 2(8), defines the environmental risk assessment as meaning:
“ ..the evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOs’”
- 2.7 In the still-unfinalised revised Directive, as set out in the Common Position adopted by the Council on 9th December 1999 (CHD 12, page 689 @ 693; FOE File 4, Tab 31), the risk assessment is defined in Article 2(8) as:
“ .. the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or placing on the market of GMOs may pose and in accordance with Annex IF”.
- 2.8 How this change to definition of the risk assessment process affects the process has been summarised by the Joint ACRE Secretariat at the Department of the Environment in paragraph 18 of a recent paper for the Agriculture and Environment Biotechnology Commission³ (CHD 12, page 751 @ 755; FOE File 4, Tab 33):
“The technical annex formalises some important principles, which reflect existing best practice among EU Member States. These include:
That potential adverse effects may be direct, indirect, immediate or delayed;
The risk assessment should be carried out on a case by case basis; this implies that the

³ Agriculture and Environment Biotechnology Commission. Risk assessment for releases and marketing of GMOs in the European Union. Background paper by the secretariat to the Joint Regulatory Authority and ACRE, DETR. AEBC 00/6.

required information may vary depending on the type of GMOs concerned, their intended use and the potential receiving environment, taking into account, among other things, GMOs already in the environment;

If new information on the GMO and its effects on human health and the environment becomes available, the risk assessment should be re-examined;

That the information required in notifications must include possible impacts of the specific techniques used for the management of GMO where these are different from those used for non-GMOs. **This particular principle is a new addition to GMO risk assessment**” (emphasis added).

2.9 Therefore, there are changes both in content and emphasis of the risk assessment process in the revised Directive. On 5th November 1998, Michael Meacher announced that, in order to reflect this change in advance of the revised Directive being formally adopted and to ensure improved environmental protection from any adverse effects of releasing GMOs to the environment in the UK, that:

*“In future we shall be seeking advice from ACRE not only on the direct and indirect effects of genetically modified organisms into the environment but also on the possible resultant changes in agronomic practice and the subsequent effects on biodiversity”*⁴.

(CHD 12, page 758 @ 759 (title of question only) and 760 (text of question and answer); FOE File 4, Tab 34).

2.10 As a result, in December 1999, the Department of the Environment, Transport and the Regions (DETR) and the Advisory Committee on Releases to the Environment (ACRE), published new guidance on the application of the underlying principles for risk assessment and monitoring⁵ (CHD 12, page 618; FOE File 4, Tab 30). In their introduction to this guidance (on page 622), the DETR and ACRE state that:

“At the Environment Council in December 1998, EU Ministers agreed that there was a need for rapid revision of Directive 90/220 in order to have in place an effective and predictable regime to secure protection of human health and the environment from the

⁴ Michael Meacher, Response to Parliament Questions from Alan Simpson, Hansard 5th November 1998.

⁵ DETR/ACRE Guidance Note 12. Guidance on principles of risk assessment and monitoring for the release of genetically modified organisms. December 1999.

release and marketing of genetically modified organisms”.

2.11 The new guidance goes on, in the third and fourth paragraphs on page 622, to say that:
‘The UK will therefore ask, with immediate effect, applicants for consent to release or market GMOs to apply the approach for risk assessment set out in Annex A to this note’

and

‘From now on, holders of consents to market GMOs will be required to monitor the performance of their product and verify that the assumptions in the risk assessment supporting the application are borne out in practice’.

2.12 Therefore, a company or individual applying for consent to market a GMO before or after 1998 would have a significantly different system to comply with. After 1998, the risk assessment process was more rigorous and included monitoring as well as broader risk assessment.

3. T25 and the differences in risk assessment before and after December 1998

3.1 Aventis’ ‘T25’ genetically modified (GM) glufosinate tolerant maize, of which Chardon LL is one variety, was granted EU approval for cultivation and sale by France in August 1998. This consent was given under the provisions laid out in EU Directive 90/220 on the deliberate release into the environment of genetically modified organisms (GMOs).

3.2 However, as described above, the approach to the risk assessment process that was used in giving the approval of T 25 has changed in significant ways in the UK since December 1998. In particular, there are several areas where further information would be required if an application for marketing approval had been made since 1998. The most obvious of these changes are:

How the growing of T25 and the use of glufosinate (to which T25 has been genetically modified to be tolerant) would affect the environment. This is because the specific techniques used for the management of T25 would be different from those used for

non-GM maize. This is the data that arises from the ‘new principle’ embedded in the revised Directive where the specific techniques used for management of the GMO are different than those used for non-GMOs (see para 2.8 of my Proof) and now included in the DETR/ACRE Guidance Note 12 (see para 4.9 of my Proof).

Details of mechanisms for monitoring and testing assumptions contained in the risk assessment. Again this is data which is required as a result of alterations to the Deliberate Release Directive and included as a new Annex in the DETR/ACRE Guidance Note 12 (see para 2.11 of my Proof).

A requirement (introduced under DETR/ACRE Guidance Note 12) for the assessments of effects on animal health and the consequences of the introduction of the GMO into the food/feed chain if it is to be used as an animal feed. Since the variety Chardon LL of T25 is intended to be used as feed for cattle, this is a change which is directly relevant and where new data would be required.

3.3 I have examined the application to market T25 maize (C/F/95/12/07) submitted by AgrEvo (which is now part of Aventis) (CHD 12, page 10 onwards; FOE File 4, Tab 2). Nowhere in the application to market the maize is there consideration of the first two areas. In relation to animal feed safety, there is no information on the safety of feeding T25 maize to cattle.

4. Official justifications of ‘no difference’ in the risk assessment process

4.1 Despite the clear and obvious differences which are now embedded in the risk assessment process for marketing consents of GMOs in the UK, there have been claims by the Department of the Environment that these would have made no difference to the assessment of the T25 maize.

4.2 For example, in section 3.1 of their paper to the Welsh Assembly’s Agriculture and Rural Affairs Committee in March 2000, the DETR’s ACRE Secretariat said in relation to the new Guidance Note 12 issued in 1999

⁶ (CHD 11, page 32 @ 40/1; FOE File 2, Tab 5):

“This new guidance makes little or no practical difference to the risk assessment procedures already practised in the UK. The harmonisation and clarification of risk assessment adopted by Environment Minister simply brings many other Member States into line with the UK; indeed UK Government scientists and ACRE have been pivotal in guiding the revisions. It follows therefore that if T25 maize came forward for Part C approval again today, the risk assessment procedure in the UK would be to the same standard and rigour as was applied in 1996.

It has been suggested that the revisions to the Directive have introduced major changes to risk assessment since T25 maize was approved. As discussed above, this is not so – in the UK at least. It has further been suggested that the farm scale evaluations (see annex for background) raise new issues about the safety of T25 maize that were not considered in 1996. This is also not correct. The indirect effects of GMOs has always been part of the assessment, but the purpose of the farm scale evaluations is to test the effect on farmland biodiversity of changes in management practices associated with the use of herbicide tolerant crops. This is not a GM issue and it is irrelevant whether the crop is GM or not. In fact there are several herbicide tolerant crops under development that are not GM and have been produced by conventional plant breeding. The same biodiversity issues apply to these.”

- 4.3 This is in contradiction to the explanation given to the AEBC where the DETR’s ACRE Secretariat explicitly state that the changes include the introduction of a new principle, not simply a harmonisation as suggested to the Welsh Assembly.
- 4.4 Furthermore, it is clear from the minutes of the Advisory Committee on Releases to the Environment (ACRE), the Government’s statutory advisors on environmental safety of releasing GMOs to the environment, that the increase in scope of their evaluation would

⁶ Regulatory evaluation of herbicide tolerant maize (T25) under Directive 90/220/EEC. Assessment of safety to human health and the environment. A paper by the ACRE Secretariat to the Welsh Assembly’s Agriculture and Rural Development Committee, August 2000. This paper appears at Vol 3 Page 361 of the written representations, as Appendix 11 to the written representations of Aventis.

alter the information requirements for marketing consents. Item 2.1 of the minutes of their 10th November 1998 meeting states

⁷ (CHD 12, page 763 @ 764; FOE File 4, Tab 35):

“The Secretariat explained that this does not alter the terms of reference of the Committee but it does extend the Committee’s advice to cover more indirect environmental impacts of releasing GMOs. With the effect from the next application put before ACRE, the Committee will now advise ‘not only on the direct and indirect effects of releasing GMOs into the environment but also on the possible resultant changes in agronomic practice and the subsequent effects on biodiversity’ (ibid). In this context the wider issues paper will help focus on the issues which need addressing. The Committee discussed the possible changes that this would entail, not only for ACRE and the Secretariat but also for those applying for deliberate release consents. The Secretariat clarified that the new requirements would, in practice, only apply to Marketing applications because those for experimental releases (Part B) are small scale, transient and usually have specific risk management requirements as a condition of the consent”.

4.5 In their explanation to the Welsh Assembly, the ACRE Secretariat argue that effects on biodiversity as a result of the use of GMOs and altered agricultural practices has nothing to do with the genetic modification process. Yet such an assessment is to be expressly included in the revised Directive concerning the release of GMOs to the environment. Of course there are specific issues which have to be addressed in relation to the safety of the genetic modification technique in this context. For example, the foreign gene(s) may alter the performance of the GM crop in unpredicted ways because other genes are disrupted following transfer or there are effects on biochemical pathways. These effects (as a direct consequence of the genetic modification process) may not become evident until the plants are grown in a variety of different environments and when used in combination with the herbicide. There are already indications that such effects have been seen with GM herbicide tolerant cotton and soybean in the United States.

4.6 Monsanto's Roundup Ready soybeans have been found to suffer in hot weather, especially when soil temperatures reach 45EC. Research at the University of Georgia, prompted by farmer reports

⁷ Minutes of ACRE meeting 10th November 1998, Item 2.1 Draft discussion paper on effects of commercial use of GM crops on farmland biodiversity (ACRE/98/INF30).

of unexpected crop losses, found that in high temperatures the plants were stunted and that a higher percentage of stems were split leaving the plants open to fungal attack and yield loss. The researchers suggest that the added genes that make the crop herbicide tolerant also have the side effect of increasing lignin production and making stems more brittle⁸ (CHD 15, page 380; FOE File 5, Tab 31). In 1997, farmers on the Mississippi had problems when Monsanto's herbicide tolerant cotton failed to grow properly. The bolls, which provide the cotton, were deformed and many fell off prematurely⁹ (CHD 15, page 381; FOE File 5, Tab 31).

- 4.7 It is these sorts of effects associated with the interaction between the genetic modification and associated management practices that the new approach to risk assessment intends to address. In effect, the evaluation is being made more realistic. Comparison of the DETR's own Guidelines for the release of GM plants to the environment before and after December 1998 illustrate how they believe this changes the questions asked of applicants. For example, paragraph 39 of Annex 2 of Guidance Note 7 (CHD 12, page 568 @ 605; FOE File 4, Tab 29) requires information on¹⁰:

“Any selective advantage or disadvantage conferred to other sexually compatible plant species, which may result from genetic transfer from the genetically modified plant”.

- 4.8 This is expanded in section IV2.iii of Guidance Note 12 (CHD 12, page 618 @ 627; FOE File 4, Tab 30) to request information about the¹¹:

“Potential for gene transfer to the same or other sexually compatible plant species under conditions for planting the GMHP and any selective advantage or disadvantage conferred to those plant species” (emphasis added)

- 4.9 Furthermore, a completely new question is now asked in section IV2.ix (same reference) including about the:

“Possible immediate and/or delayed, direct and indirect environmental impacts of the

⁸ Andy Coghlan, 'Splitting Headache' New Scientist No.2213 (20 November 1999)

⁹ The Gene Exchange (Summer 1998), The Union of Concerned Scientists
<http://www.ucsusa.org/>

¹⁰ Guidance to the genetically modified organisms (Deliberate Release Regulations, 1995).
DETR/ACRE Guidance Note 7.

¹¹ Guidance on principles of risk assessment and monitoring for the release of genetically modified organisms. DETR/ACRE Guidance Note 12. December 1999.

specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs”

4.10 A whole new Annex in Guidance Note 12 (Annex B on page 628), addresses monitoring and how it should be undertaken, which links to the risks identified under the risk assessment process.

4.11 Therefore, it is impossible to conclude as the DETR have done in their evidence to the Welsh Assembly, that there is no difference between the evaluation process of marketing consents of GMOs before and after December 1998.

5. Conclusion

5.1 I conclude that if the application to market the T25 maize had been made after December 1998 the original dossier would not have been acceptable. More data would have been required about the potential for indirect environmental impacts particularly under the actual conditions of use, the safety of using the variety as an animal feed and a monitoring plan would have to have been provided. Because this information has not been presented, questions remain over the environmental safety of marketing T25 maize and it cannot be concluded that all appropriate measures have been taken to avoid adverse effects.

5.2 Claims that there is no change to the information requirements that would be needed to assess the safety of T25 before and after December 1998 are not supported by the evidence which shows that significant changes to the principles and practice of the risk assessment process have taken place in the UK.