

# Sound science?

**The evidence against  
Aventis' GM maize**

**February 2001**

FRIENDS *of the*  
**earth**  
*for the planet* for people

# Executive Summary

In April 1998 the European Commission instructed the French Government to allow the agricultural company Aventis to legally market, import and grow seeds and grains of their genetically modified (GM) maize, called T25. France did so in August 1998. Earlier the same year, under the fast-track substantial equivalence procedure, Aventis had notified the EC that it intended to market processed foods derived from T25 maize. This meant that Aventis was able to market these T25 foods without the need to do a full safety assessment.

For reasons set out in this document, Friends of the Earth argues that the marketing of both T25 maize and its processed foods should be immediately suspended. We regard the weight of these reasons to be overwhelming; and, sadly, to reflect a superficial, lax and unimpressive performance on the part of public bodies and advisers. We summarise these reasons below.

## **I. Why the marketing consent for T25 maize should be suspended**

1. Aventis' marketing consent application reveals the following information, which indicates that the absence of acceptable risk to human health and the environment has not been reliably demonstrated:

(1) **Significant compositional differences found and important data missing:** significant differences were found in amino acid, fatty acid, fat, carbohydrate, protein and fibre content of T25 maize and the non-GM equivalent; along with the absence of data for levels of two amino acids;

(2) **Limited, illogical and inadequate consideration of anti-nutritional substances:** consideration of anti-nutritional substances was limited to one such substance, phytic acid, relevant to monogastric animals but measured in silage, a feed for ruminants, in such few samples that only a greater than 100% difference would have been detected;

(3) **Toxicity determined without testing the maize plant on any species and experiments used which were not realistic or of adequate scope:** safety of the novel PAT protein was determined by in vitro simulation of digestion of the same protein extracted from oilseed rape; and by feeding the same protein extracted from oilseed rape to rats for 14 days, where the number of rats used was too small and their starting weights too varied to show differences of less than 20%. The EU's Scientific Committee on Plants has pointed out the inadequate nature of this approach;

(4) **The single, inadequate experiment using whole T25 maize grains showed suspicious trends which were not further investigated:** the only feeding study of whole T25 maize grains was to chickens in 1996. In this study, greater variations in all weight and other measurements were recorded for chickens who were fed the GM grains compared with those fed the non-GM grains, and twice as many died (although this was not statistically significant). Scientists commissioned by FOE have analysed

this research and concluded that it was not of a standard that would be acceptable for publication in a scientific journal. They reported that the trends for variations and higher mortality in the GM-fed birds were “suspicious” and were surprised that such a “poor study should have been presented as evidence and accepted as evidence in the first place.”

(5) **Inadequate examination of environmental impacts:** these were considered on just one page of 85, with no mention of contamination of non-GM maize supplies, the impact of the herbicide tolerant crop on agricultural biodiversity or of the impacts of the herbicide and the GM maize on soil eco-systems - i.e., the key indirect effects of the GM maize or the effects of changes in agricultural practices.

2. **The application would not be approved now.** T25 maize was approved before the EU Council of Ministers agreed in December 1998 that the risk assessment procedures for GM crops were inadequate and needed “rapid revision...in order to have in place an effective and predictable regime to secure protection of human health and the environment”. New provisions of relevance to T25 include addressing potential gene transfer under conditions of planting and possible immediate and/or delayed, direct and indirect environmental impacts of specific cultivation and management techniques; and the need for a post-marketing monitoring plan.

3. Criticisms are made in the document about the failure to have resolved several of the objections raised by various Member States during the approval process; and of the speedy consideration of the dossier by the EU Scientific Committee on Plants, their inaccurate understanding of the potential for gene transfer, their failure to characterise precisely - and to distinguish between different strains, and of types within strains, of - the bacterium from which the inserted pat gene is derived and other criticisms including their failure to demonstrate that they considered, for example, the compositional differences, missing data and experimental inadequacies referred to in paragraph 1 above.

## **II. Why the marketing of T25 maize processed food should be suspended**

On 8<sup>th</sup> January 1998, Aventis notified the Commission that it was placing on the market certain maize processed food derived from T25. This fast-track procedure allows marketing of GM food, without a full safety assessment under the Novel Food Regulation 258/97, if ‘substantial equivalence’ is established. Aventis relied on a report by the UK’s Committee (ACNFP) to establish this. No full safety assessment under the Novel Food Regulation has been carried out.

The marketing of T25 maize processed food must be suspended for a full safety assessment to be carried out. The grounds for this, in addition to points 1(1)-(4), are as follows:

1. **Additionally inadequate scientific assessment:** the UK Committee that cleared T25 maize food as ‘substantially equivalent’ did so having seen only an incomplete draft of the rat study, and 9 months before the chicken study was even made available to the UK government;

2. **The EU Scientific Committee on Food (SCF) has not considered the evidence provided by Aventis on the safety of T25 maize:** the SCF’s Opinion of 7 September 2000

on Italy's submissions was limited to those submissions and to the opinion of the UK Committee and the EU Scientific Committee on Plants. It did not consider, and has not considered, the Aventis evidence.

**3. Suspicious timing by Aventis of Article 5 notification:** Aventis notified the Commission *one week before* Member States decided that several of their products would need a full safety assessment and would not qualify for fast-tracking; and *five weeks after* the UK Committee concluded the same thing.

### **III. Why the marketing of T25 fodder maize should be suspended**

**1. Limited GMO marketing consent:** The Commission Decision of April 1998 is limited to "seeds and grains" of T25 maize. It does not extend to silage.

**2. No examination for ruminant safety:** Aventis has already developed at least two fodder maizes from T25 maize (Chardon LL and Sheridan). These will be used to produce whole plant silage and fed to cattle. Despite the fact that fodder maize could make up to 75% of a cows diet, there is no evidence that Aventis examined the safety of T25 maize for ruminant livestock.

**3. Recommendations for cattle feeding studies ignored:** Key Government and independent experts have called for feeding studies on cattle. However, these have been ignored. With the effects of BSE highlighting the need for precaution, to allow marketing of T25 fodder maize with no evidence of its possible effects on one of the main target species, seems a reckless and fundamental error.

# EU Approvals of T25 maize

## 1. Introduction

Aventis 'T25' maize is genetically modified to be tolerant of the herbicide glufosinate ammonium (marketed as Liberty) which is also produced by Aventis. The GM maize contains the *pat* gene, taken from the bacterium *Streptomyces viridochromogenes* var. Tu 494. This gene causes the plant to produce the novel protein Phosphinothricin Acetyl Transferase (PAT), allowing the GM maize to break down the herbicide glufosinate ammonium, which is otherwise toxic to plants. The *pat* gene is under the control of the viral '35S' promoter from the Cauliflower Mosaic virus (CaMV). Additionally, T25 maize contains part of an ampicillin resistance gene (approximately 25% of this gene is missing in the GM maize).

In 1995, Aventis (then called AgrEvo) applied to France for consent to market T25 maize in the European Union as laid out in Part C of Directive 90/220/EEC. The application was considered by all the member states. In April 1998, the European Commission made a decision approving T25 maize and, as is laid down by the directive, France granted a formal consent to market the crop in August 1998. This 'Part C' marketing consent allows the GM maize to be imported into the EU, grown in the EU, processed in the EU and marketed. In addition, the European Commission has ruled that such marketing consent could cover the use of the GM crop in animal feed. In this document, FOE will argue that the consideration given to T25 in the EU approvals process was not thorough enough. In particular:

- Serious deficiencies in the evidence presented by Aventis in support of T25 were not picked up, or were ignored
- The safety of T25 maize for livestock was not given anything more than a cursory consideration, despite recommendations from various scientific advisers.
- No consideration was given to the indirect impacts of T25 maize to the environment, despite this being raised by several member states

In addition, during the course of 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). This was due to an emerging consensus with EU member states that the safety provisions within 90/220 were inadequate. In December 1998, the EU Council of Environment Ministers met and agreed that procedures to make the risk assessment of GM crops more rigorous should be adopted immediately, in advance of new legislation. This occurred only 4 months after France gave marketing consent to T25 maize, and FOE will show in this document that had the application for T25 maize been made under the more rigorous procedure it would not have been found acceptable, and T25 maize would not have been approved on the basis of that application.

Approval for the use of GM crops in human food is covered by European Commission regulation 258/97. Within this regulation there are two forms of approval. The first is full approval, which enables all member states giving consideration of the GM crop for use in food

– so far, no GM crop has gained approval by this mechanism. The second form of approval is laid out in Articles 3.4 and 5 of the regulation. This allows for the fast track ‘notification’ of GM foods that are derived from, but not containing, GM crops *and* that are considered to be ‘substantially equivalent’ to non GM food. Using this mechanism, if the ‘Competent Authority’ of one member state gives a favourable opinion of the GM derived food, the company wishing to market it simply notifies the Commission of the favourable opinion and of their intention to start marketing. There is no formal mechanism for other member states to be consulted on the notification, or to object to it.

In January 1998, Aventis notified the Commission that it intended to start marketing processed products, derived from T25 maize, for use in food. The products of T25 maize that were notified were starch and derivatives, oil and “all heat processed or fermented products obtained from hominys, grits and flour (dry milled fragments). The notification was based on a favourable opinion produced by the UK’s Competent Authority on GM foods, the Advisory Committee on Novel Foods and Processes (ACNFP). This was delivered in 1996, under voluntary consultation procedures operating in the UK prior to the introduction of the EU Novel Foods Regulation 258/97. In this document, FOE will show that just 8 days after Aventis notified the Commission of the T25 products they intended to market, the Standing Committee on Foods ruled that such products were ineligible for this route and that they should undergo a full safety assessment. FOE will also show that the ACNFP opinion upon which the notification was based was not sufficient to show safety of these products and that serious deficiencies in the evidence provided by Aventis were ignored. FOE will argue that T25 maize should be recalled and required to undergo a full safety assessment.

Friends of the Earth argues that there are serious procedural irregularities with the approvals of T25 maize which require that it be reconsidered.

## 2. The evidence from Aventis in support of T25 maize

On 26 February 1996, AgrEvo France submitted an application for marketing consent under EU Directive 90/220/EEC for T25 maize (reference C/F/95/12-07) to the French government's Competent Authority for the assessment of GMOs. On May 24 1996 the French government forwarded this application to the European Commission Directorate General XI, which then passed it to the other member states' Competent Authorities for their consideration. The marketing consent application presented by Aventis covered the following:

### The Composition of T25 maize grain

One of the concerns about GM crops and the foods derived from them is that the insertion of novel genes creating novel proteins may disrupt the genetics of the crop and its basic biochemistry - this could change the nutritional composition of the GM crop. Aventis presented compositional analyses of T25 maize which they used as a basis for their claim that:

*“Analyses showed that GTC [glufosinate tolerant corn] silage and grain are not materially different from current commercial varieties in essential nutrients or antinutrients”<sup>1</sup>.*

But in fact, their own analyses of T25 maize grown in the United States found significant differences in fat and carbohydrate content between the GM and non GM maize grains<sup>2</sup>. In addition, a more detailed analysis found differences in the levels of three amino acids, arginine, histidine and lysine between the GM and non GM maize. Analysis of fatty acid composition found stearic acid, linoleic acid and arachidic acid to be significantly different from the non GM maize<sup>3</sup>, and Aventis state in a document submitted to the UK's ACNFP that the levels of the linolenic and arachidic acids were outside the range of values reported in any other study<sup>4</sup>.

Dr Vyvyan Howard, Head of the Fetal and Infant Toxicology-Pathology Group at the University of Liverpool, and a Fellow of the Royal College of Pathologists, examined this evidence for Friends of the Earth. He was particularly concerned about the amino acid analysis, commenting that:

*“The amino acid assay for substantial equivalence showed statistically significant increases in the levels of the amino acids arginine, histidine and lysine. This is interesting in itself because these three amino acids are similar in chemical composition, possessing an additional NH<sub>2</sub> group. No further analysis was made into this difference, despite the fact that the introduced PAT-protein is an N-acetyl transferase, an enzyme that might be expected to react with such molecules. It is*

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<sup>1</sup>Submission for placing on the market (in accordance with the Part C of the Directive 90/220/EEC) of Glufosinate Tolerant Corns (*Zea mays*) Transformation Event T25”, submitted by AgrEvo France. Reference C/F/95/12-07. Page 40

<sup>2</sup> page 43, Figure C 3

<sup>3</sup> Page 44, Figure C 4

<sup>4</sup> “Safety, Compositional and nutritional aspects of glufosinate resistant corn transformation events T14 and T25”, produced in 1995 by AgrEvo USA page 31

*possible that the increased levels of these three amino acids are connected to the introduction of the PAT protein.”*

*“Strangely, no analysis was made for the levels of the amino acids asparagine and glutamine or, if this was done, no data are presented. These amino acids also have an additional NH<sub>2</sub> group”<sup>5</sup>*

AgrEvo France also submitted compositional analysis on GM and non GM grains grown at field trials in France. However, in this case only a very crude compositional analysis was conducted – examining moisture, crude nitrogen, crude fat, crude cellulose and crude starch contents and no differences were observed.

### **Consideration of Anti nutritional compounds**

The marketing consent application includes a consideration of an anti-nutritional factors found in maize. This is normally done to establish whether the levels of naturally occurring anti nutrients or toxins have been altered by the genetic modification. However, Aventis stated in the marketing consent application that

*“The possible presence of anti-nutritive substances which occur naturally needs to be taken into consideration with respect to animal feed. An example of naturally occurring nutritive substances are phytates, which bind phosphorus and other minerals making them unavailable to monogastric animals (Ensminger et al., 1990). All silage evaluated in this study had less than 1.15% phytate content and there was no statistical difference between GTC and its counterpart”<sup>6</sup>*

In other words, Aventis identified an anti nutritional factor that is of importance to monogastric animals, such as pigs, and then measured its levels in animal feed (silage) which is only ever fed to ruminant livestock (such as cattle), for whom phytic acid is not important anyway.

In addition, it has been noted by the UK’s ACNFP, the UK’s Interdepartmental Group on New Feed Developments and FOE’s independent expert Dr Vyvyan Howard, that the results of the phytic acid analysis were so variable, with so few samples taken, that the experiment could only have detected a difference in phytic acid levels between the GM and non GM maize if this was greater than 100%<sup>7 8 9</sup>.

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<sup>5</sup> Paras 2.2.1, 2.2.2

<sup>6</sup> Safety, Compositional and Nutritional Aspects of Glufosinate Resistant Corn Transformation Events T14 and T25, page 28. Submission for placing on the market (in accordance with the Part C of the Directive 90/220/EEC) of glufosinate tolerant corns (*Zea mays*) transformation event T25, page 41-42

<sup>7</sup> Letter from MAFF to Agrevo, 1 April 1996 2<sup>nd</sup> page, 2<sup>nd</sup> para.

<sup>8</sup> Letter, with writer and recipient removed, dated 1 July 1996 and entitled “AgrEvo’s Glufosinate Tolerant Maize” provided by the UK Food Standards Agency

<sup>9</sup> Analysis of key documents relevant to the safety of Chardon LL for animal feed purposes. Proof of

(continued...)

## Examination of the safety of the novel protein PAT

T25 maize has been genetically modified with a gene from a rare (Tu 494) strain of the soil bacterium *Streptomyces viridochromogenes*, found in Cameroon. The gene causes the GM plant to produce the novel protein Phosphinothricin Acetyl Transferase (PAT). PAT is an enzyme that breaks down the herbicide glufosinate ammonium, which is otherwise toxic to plants.

When the EU Scientific Committee on Plants (SCP) examined T25 maize, they noted that this is a truly novel protein, in that

*“The protein product of the phosphinothricin acetyltransferase gene is not present in humans, animals, intestinal micro-organisms or in traditional food and feed plants.”*

So it would be reasonable to assume that its safety would be thoroughly assessed, as it is extremely unlikely that any humans or animals would have been exposed to this protein prior to its introduction into GM crops.

A preliminary test of the safety of a novel protein is to examine how quickly it is broken down in the intestine. This is because many proteins (although not all) that cause allergies resist breakdown in the intestine. Aventis state in their marketing consent application that

*“AgrEvo Gmbh has confirmed experimentally that PAT protein and pat DNA in glufosinate resistant canola [oilseed rape] is degraded in vitro by the gastric juices from swine, chicken and cattle (bovine rennet-bag fluid and paunch)”. (p 31) .*

However, when Dr Vyvyan Howard, Head of Fetal and Infant Toxicopathology at the University of Liverpool and a member of the Royal Society of pathologists examined this study for Friends of the Earth he commented that

*“With respect to the gastric juices of monogastric animals, the pH of 1.5 quoted on page 35 will only be present in the fasting condition. It is well understood by nutritional physiologists that the pH of the stomach rises after ingestion of food, definitely higher than pH 5.5, the highest pH tested in these experiments. It remains elevated above pH 4 in the contents for a considerable time. The experiments do not represent a realistic assessment of the likely degradation of PAT protein in real animals.”<sup>10</sup>*

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<sup>9</sup>(...continued)

Evidence of Dr CV Howard, MB. ChB. PhD. FRCPath on behalf of Friends of the Earth. October 2000.

<sup>10</sup> Analysis of key documents relevant to the safety of Chardon LL for animal feed purposes. Proof of Evidence of Dr CV Howard, MB. ChB. PhD. FRCPath on behalf of Friends of the Earth. October 2000. Para 2.3.2

In other words, examining the breakdown of PAT protein in very acidic conditions means that it appears to break down more rapidly than it will do in reality.

The EU's Scientific Committee on Plants has stated that

*“The use of in vitro simulation of gastric and intestinal digestion of the gene product should be considered supplementary to in vivo experiments” because “Isolated proteins are known which are fully degraded in the simulated gastric system but survive gut passage intact when fed as part of a normal diet”<sup>11</sup>.*

But unfortunately, this statement was made after T25 maize was granted marketing consent.

In addition to the in vitro studies, a 14 day toxicity study was carried out on rats using PAT protein extracted from GM oilseed rape - “RCC Project 616307. PAT protein – Repeated Dose oral toxicity (14-day feeding) study in rats”.

In their marketing consent application, AgrEvo France stated that

*“Based on the results of this study, with histopathology still pending, there is no evidence of toxicity for PAT-protein when administered to rats in their feed in dietary concentrations up to 50 000 ppm for a period of 14 days” (p 50)*

Dr Vyvyan Howard Head of the Fetal and Infant Toxicology-Pathology Group at the University of Liverpool, and a Fellow of the Royal College of Pathologists, examined this report for Friends of the Earth and made the following comments:

*“By feeding the purified PAT-protein, rather than the whole plant, this experiment is specifically designed to NOT detect the pleiotropic effects which should be anticipated.”*

Because the study examined the PAT protein in isolation, rather than looking at the safety of the whole GM maize, it is therefore very limited in scope. Dr Howard went on to state that

*“There is no specific statement as to the provenance of the PAT protein made in the Report. However, by inference it appears that it came from purified Canola meal [oilseed rape] (page 18 of the report). An implicit model assumption is made that the toxicology of PAT-Protein from Canola is identical to that from ...maize ... There is no evidence presented to support this assumption. The folding of the protein in the two species, which will not necessarily have the same chaperone proteins, may not be identical.”*

Dr Arpad Puzstai, formerly of the Rowett Research Institute, also examined this report and made the following comments:

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<sup>11</sup> Scientific Committee on Plants. *Guidance document to facilitate notifiers in the preparation of plant GMO dossiers for consideration by the Scientific Committee on Plants (SCP/GMO/103-Final)* 18 December 1998.

*"no valid conclusions can be drawn from a feeding study carried out with five rats per group in which the starting weight of the rats varies by more than  $\pm 20\%$  (53-82g for males and 52-74g for females) (page 15), because ... for any differences to reach significance, they must exceed  $\pm 20\%$ . To achieve this in a 14-day study should require catastrophic conditions in the experiments, which would, in any case, not be allowed by Home Office rules in [the UK]"<sup>12</sup>*

In other words, so few rats were used and their weights were so varied to start with, that after the 14 days of the study there would have to be have been weight differences between the test groups of greater than 20% to register as a difference.

### **Examination of the whole maize grains**

Aventis submitted, in support of the EU marketing consent application, a report entitled "The effect of Glufosinate Resistant Corn on Growth of Male Broiler Chickens" produced by the Department of Animal and Poultry Sciences at the University of Guelph, dated July 12, 1996. This report was examined for Friends of the earth by Dr Steve Kestin and Dr Toby Knowles of the Department of Clinical Veterinary Science at the University of Bristol.

The report documents a small trial where two groups of broiler chicken were fed different diets, one based on normal maize, and the other based on GM T25 maize. The growth and performance of the broilers to 42 days was measured. The objective of the study seems to be set out in the introduction, where it is stated that *"This study was conducted to compare the performance of broiler chickens fed glufosinate resistant corn with a standard commercially available corn hybrid"*.

After examining the report, Drs Kestin and Knowles noted that whilst there were no statistically significant differences between the birds fed GM and non GM grains, there was a trend showing greater variation in all measurements for those birds fed GM grain.

*"This is not a statistically significant effect, but is a trend which is suspicious and could be because of flaws in the design or execution of the study, or, alternatively, a real difference in the effect of the diets though the exact cause is impossible to say with any degree of certainty."*

They also noted that twice as many birds died when fed the GM maize as those fed non GM maize, commenting that

*"The trend for higher mortality in the GM fed birds - 10 birds, as against 5 birds - is also suspicious. Again, as for weight and other variables, it suggests either a fault in the study or a real effect of diet. At this point, however, it is impossible to say which with any degree of certainty."*

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<sup>12</sup> Evidence presented by Dr Arpad Pusztai to Ministry of Agriculture Fisheries and Food public hearings on the proposed addition of the genetically modified maize variety Chardon LL to the UK National List. Tuesday, 24 October 2000.

They went on to criticise the design and execution of the study, noting that

- there was no positive control group of birds, meaning that *"it is not possible to say whether a nil finding would have been real, or a function of poor experimental control."*
- that there were not enough replicates in the trial (4 as opposed to a minimum of 14) meaning that *"only very large effects on live weight could have been detected."*

They concluded that

*"Put simply, this study as reported is inadequate in terms of providing any evidence or conclusions. It is not of a standard that would be acceptable for publication in a scientific journal."*

*"It follows that neither do we consider the study as reported to be adequate for being taken into account as evidence of safety in connection with decisions to approve the use of the relevant GM maize. If anything, the results as reported arouse suspicions of real differences between the treatments. This should act as a spur to further investigation..."*

Dr Knowles, commenting on the study, stated that

*"We are very surprised that such a ... poor study should have been presented as evidence and accepted as evidence in the first place. From a point of view of a statistician ... the reporting and the design are wholly inadequate and this became really obvious after only five minutes of reading."*

*"It is very basic science that has fallen down at this stage, and I am amazed that it has not been picked up".<sup>13</sup>*

### **Examination of the environmental impacts of T25 maize.**

In Section C1 of Aventis marketing consent application for T25 maize, the company examines the "Environmental Impact of the product". In this section, which covers only 1 page out of the 85 page application, two areas are covered. Firstly, Aventis covered the "Likelihood of the GMP [Genetically Modified Plant] becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats", in other words, whether or not GM T25 maize is likely to become a problem weed, which Aventis claim it will not. Secondly, Aventis cover the "Impact on the agricultural practices", in which they state that

- T25 maize provides *"a valuable new weed management tool"*

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<sup>13</sup> Evidence of Dr Toby Knowles at the UK MAFF public hearings on the proposed addition of the genetically modified maize variety Chardon LL to the UK National List. 3 November 2000.

- Glufosinate ammonium is highly biodegradable, has no residual activity and has a very low toxicity for humans and wild fauna
- That it *“can positively impact current agronomic practices by participating in the shift from pre emergence herbicide to post emergence herbicide use”*
- *“Volunteer corns (sic) are very rare in Europe and there is no likelihood of interspecific exchange of genetic material”*

No mention is made of the contamination of non GM maize supplies, of the impact of the herbicide tolerant crop on agricultural biodiversity or of the impact of the herbicide and the GM maize on soil ecosystems. In other words, no mention is made of the indirect effects of the GM maize, or of the effects due to changes in agricultural practice.

### 3. Consideration of T25 maize in the EU for Approval under Directive 90/220

Over the summer of 1996, the Commission received various objections to the application by Aventis for T25 maize by various member states:

On the 1<sup>st</sup> of July, the Austrian government notified the Commission that it objected to the marketing of T25 maize.<sup>14</sup> Comments included:

*“The detailed study of the “Wissenschaftszentrum Berlin” on herbicide resistant plants (WZB Berlin 1993, 1994, 1995) comes to the conclusion that especially in the case of frequent growing of herbicide resistant maize – compared to other plants or other crop rotations – severe ecological consequences have to be expected. Seeds of other plants in the agroecosystem will be irreversibly destroyed with obvious negative effects on the biological diversity.”*

*“The Austrian Competent Authorities hold the opinion that an assessment of the potential environmental impact of the herbicide and its metabolites should form an integral part of the assessment of a transgenic herbicide resistant plant. As Basta [glufosinate ammonium] is not only a herbicide but also has antimicrobial activity, the notification should be supplemented by an assessment of the effects of Basta on soil microorganisms”*

*“the overall statement of the notifier that Basta is an “environmentally friendly” product has to be questioned.”*

*“The question of persistence and residues of BASTA and its main metabolites in the plant and soil – also after acetylation by PAT – have to be clarified”*

*“What is missing in the dossier is an assessment of the following aspect: The pat gene is occurring naturally in soil microorganisms and its gene product fulfills a certain function (inactivation of PPT-like substances which are antimicrobial). If more Basta is applied, a selection pressure on pat-expressing bacteria and on those which have received the pat-gene after gene transfer might be higher. The effects on soil microbial diversity and soil microbial ecology could be significant and should be assessed”*

On the 19<sup>th</sup> of July 1996, the Norwegian government (then considering entry into the European Union) notified the European Commission that it objected to the marketing of T25 maize<sup>15</sup>. Comments were that:

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<sup>14</sup> Letter from the Bundesministerium für Gesundheit und Konsumentenschutz to EC DG IX, 1 July 1996.

<sup>15</sup> Letter from the Norwegian Ministry of the Environment to European Commission Directorate

(continued...)

*“if the Commission decides to submit a favourable draft decision, we would like to suggest that the applicant as a condition for a provisional consent, have to establish a scientific monitoring program [on pesticide usage]”.*

*“Antibiotic resistant marker genes should be eliminated in commercial products intended for food and feed production”... “We find it particularly unfortunate that a part of the ampR gene is present in the plant”*

*“The exact position of the inserted genes in the genome is not known, and possible unexpected effects of gene expression e.g. affecting production of toxins or vitamins, are not examined. The genetically modified corn is not tested on animals, and the protein pattern is not examined. The documentation necessary for a complete health assessment is not present in the dossier”*

On the 7<sup>th</sup> of August 1996, the Italian government notified the Commission that it would not object to the marketing of T25 maize, but added that

*“we want to point out that it would be very important that the Company designs information strategies for a proper use of the GMP [genetically modified plant] in combination with herbicides”*<sup>16</sup>.

On the 9<sup>th</sup> of August 1996, the German government notified the European Commission that it objected to the marketing of T25 maize because:

*“The use of phosphinothricin [herbicide] in genetically modified, tolerant maize cultures can result thus in metabolites, which correspond to L-phosphinothricin in their physiological effect, but could lead to higher amounts of residues than with the previous use of phosphinothricin in the cultivation of maize. It appears therefore necessary to fix the indication of the use of phosphinothricin in the cultivation of maize specifically for such maize lines, which are tolerant to phosphinothricin based on the pat-gene”*

and that the labeling of the GM seeds should be changed to reflect restrictions on the use of the herbicide to which T25 is tolerant.<sup>17</sup>

On the 9<sup>th</sup> of August 1996, the Swedish government notified the European Commission that it objected to the marketing of T25 maize because of a lack of clarity over the legislation pertaining to herbicide tolerant GM crops<sup>18</sup>. Specifically, they commented that:

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(...continued)

General IX, 19 July 1996.

<sup>16</sup> Letter from Dipartimento della Prevenzione e dei Farmaci, Ministero della Sanita to the EC DG IX, 7 August 1996

<sup>17</sup> Letter from the Robert Koch Institute, Berlin, to EC DG IX, dated 9 August 1996

<sup>18</sup> Letter from the Swedish Board of Agriculture, Department for Crop Production to EC DG IX. 9 August 1996

*“Sweden has previously, with emphasis, questioned the use of herbicide-tolerance, since the long-term environmental effects of herbicide tolerant crops are not known. Sweden, therefore, strongly urges that a programme is initiated to evaluate these effects”*

*“The disrupted copy of the ampR (ampicillin resistance) gene is of no significant value to the final product irrespective of the field of application. Sweden is of the opinion that the selective breeding programme should be structured in such a way that the gene for resistance to antibiotics is not present in the final product”*

*“The current provisions of Directive 90/220/EEC do not provide sufficient basis for requiring the product at issue to be labelled”.*

On the 12<sup>th</sup> of August 1996, the Danish government notified the Commission that it objected to the marketing of T25 maize because “the product is not labelled in a satisfactory manner”<sup>19</sup>

Clearly, the various competent authorities raised a range of issues and concerns about T25 maize, several of which are still unresolved:

- labeling of GM seed
- the effect of growing herbicide tolerant maize and its associated herbicide on agricultural biodiversity,
- the environmental and health impacts of glufosinate ammonium herbicide and the metabolites produced in the GM maize
- the impact of the herbicide, and transfer of the pat-gene to micro-organisms, on soil microbial ecosystems
- impact on pesticide usage in agriculture
- the presence of the disrupted ampicillin resistance gene in the GM maize
- the possibility of unexpected allergens and toxins, and the quality of screening for these

Correspondence shows that Aventis provided a small amount of additional information in respect of these concerns, and on 18 March 1997, Member States voted in favour of giving marketing consent to T25 maize. There was still significant delay to the consent procedure as by this time, the French Government was conducting a national debate on GM crops. It has been stated by the secretariat of UK ACRE that the reason that T25's consent was delayed was this debate <sup>20</sup>.

However, this does not fully explain why, if Member States were content with the safety of T25 maize, it was referred by the Commission to the EU Scientific Steering Committee for their consideration (who then passed it to the Scientific Committee on Plants) at the end of 1997. In fact, only after T25 maize had been considered by the Scientific Committee on Plants

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<sup>19</sup> Letter from the Ministry of Environment and Energy, Danish Environmental Protection Agency to DG XI, dated 12 August 1996

<sup>20</sup>“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 Agriculture and Rural Affairs Committee, March 2000. ARD 05-00 Section 1.2

did the European Commission issue a decision, on 22<sup>nd</sup> of April 1998, in which they granted consent to place onto the European market

*“Seeds and grains of genetically modified maize (Zea mays L) with increased glufosinate ammonium tolerance derived from the maize line HE/89 transformation event T25...”<sup>21</sup>.*

But when the French Government did issue the consent, on the 3<sup>rd</sup> of August 1998, they unilaterally widened the consent to cover “genetically modified maize”<sup>22</sup> rather than just the seeds and grains.

### **Consideration of the Environmental impacts of T25 maize in the UK.**

In the UK, the Advisory Committee on Releases to the Environment is responsible for examining the environmental risks of GM crops. The secretariat for ACRE at that time was the Biotechnology Unit of the Department of the Environment (DoE). On June 3 1996, the DoE received an application for marketing consent for T25 maize under EU Directive 90/220/EEC, which had been forwarded to the UK for consideration by the Commission’s Directorate General DG XI<sup>23</sup>. Other member state’s Competent Authorities would also have received it at around this time.

On 20th June 1996, the Biotechnology Unit at the DoE, secretariat to ACRE, produced

“Advice of the Advisory Committee on Releases to the Environment to the Secretary of State” which stated that

*“the product notified by the French competent Authority does not pose a risk in terms of human health and environmental safety for the United Kingdom. They have no objection to the product being placed on the market”<sup>24</sup>.*

This advice was then circulated to other Government departments along with the application<sup>25</sup>. But on the 20<sup>th</sup> of June, the ACRE members themselves had not yet even seen the application.

In fact, the application for marketing consent for T25 maize was circulated to committee

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<sup>21</sup>Commission Decision 98/293/EC

<sup>22</sup> Order of 3 August 1998 giving consent in writing pursuant to Article 13(4) of Directive 90/220/EEC of 23 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L T25 and Mon 810) NOR: AGRP9801537A

<sup>23</sup> DETR Biotechnology Unit date stamp on Aventis’ application

<sup>24</sup> ‘Draft’ ACRE advice, dated 20 June 1996

<sup>25</sup> Letter from Additives and Novel Feeds Division of MAFF to the Biotechnology Department of the DoE, 15 July 1996 states that “we are content for a favorable response to be forwarded to the Commission provided that your advice is in line with the draft ACRE advice circulated in your letter of 19 June”

members the day after the secretariat produced ACRE's 'advice'<sup>26</sup>. Committee members were also supplied with a paper produced by the secretariat, outlining its assessment of the application<sup>27</sup>. In the section headed "Risk Assessment" the paper states that

*"The main issues of concern are:*

- the environmental risk from survival and spread of herbicide tolerant maize*
- the transfer of the herbicide tolerant traits to compatible species"*

*"Risk of Spread: Maize has several characteristics, such as the retention of seeds, that make establishment and spread beyond agricultural land extremely unlikely. Maize is dependent on human intervention to ensure its survival in agricultural situations. The genetic modification will not confer an added competitive advantage over indigenous plants or increase the likelihood of maize spreading beyond the release sites."*

*"Risk of transfer of traits: Pollen grains (100 microns in diameter) are rarely transported over long distances by wind and shed pollen typically remains viable for 10-30 minutes. Insects do not play a significant part in pollen dispersal in maize. There is no evidence for hybridisation between maize and any British species (DOE GMO Research Report No 1). Thus, the risk of transfer of herbicide tolerance to other plant species is effectively zero."*

*"Summary of Risks to UK Environment: Maize is not grown extensively in the UK for climatic reasons (DOE GMO Research Report No 1) although use for animal fodder is increasing. Restricted use of maize in the UK, together with the very low risk of spread and gene transfer to near relatives indicates that the probability of the risks being realised in the UK are effectively zero"*.

It should be noted that some of the information provided to the ACRE members on this issue is of doubtful accuracy. The ACRE secretariat states that maize pollen is rarely transported over long distances and that pollen is only viable for 10 to 30 minutes (see above). However, Professor Jean Emberlin, Director of the National Pollen Research Unit in the UK, has pointed out that in fact maize pollen has a viability period of between 3 hours and 9 days, depending on environmental variables<sup>28</sup>. In addition, she has commented that the most comprehensive available study indicates that maize cross-pollination occurs at levels greater than 0.1% between two fields of maize at 200m distance from each other. Professor Emberlin has calculated that at wind speeds of 2m/s, with convection currents keeping pollen aloft, maize

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<sup>26</sup> Letter from Chemicals and Biotechnology Division, Department of the Environment, Transport and the Regions to Friends of the Earth, 11 September 2000.

<sup>27</sup> ACRE Secretariat, June 1996. Paper ACRE/96/P10 *Advisory Committee on Releases to the Environment. The Genetically Modified Organisms (Deliberate release) Regulations 1992 Application for consent from AgrEvo France to market Genetically Modified Maize – C/F/95/12-07*

<sup>28</sup> Chardon LL Hearing. Proof of evidence of Professor Jean Emberlin, Director, National Pollen Research Unit, University College, Worcester UK, on behalf of Friends of the Earth, October 2000. "An assessment of the outcrossing in maize, relevant to the proposed decision to add GM maize variety Chardon LL to the National List."

pollen could travel 7.2km a day.

However, there is no evidence that the ACRE members questioned the information that they were provided with by the secretariat, nor that they considered issues additional to those raised by the secretariat. Written documents relating to consideration by individual ACRE members have been provided to Friends of the Earth for seven of the members on this committee in 1996. There is no mention of these environmental issues in their comments. Only one member even mentions the environmental implications of growing T25 maize, stating that

*“As with other maize applications, the risk to the UK natural or agricultural environment through increased weediness [of the GM maize] or any risk of spread from the cultivated or semi managed situation is minimal”<sup>29</sup>*

On the 19<sup>th</sup> of July, the ACRE committee considered T25 maize at their meeting. The minutes state that, with regard to the UK’s consideration of the marketing consent application,

*“...members have not raised any concerns and provided MAFF are content with food and feed safety, the Secretariat do not propose to raise any objections.”<sup>30</sup>*

and on 24 July 1996 the Department of the Environment notified the European Commission that the UK had no objections to T25 maize being placed on the European market<sup>31</sup>. Interestingly, the Environment Division of the Welsh Office did not inform the DoE that they had no comments to make on the marketing consent application until the day after the UK notified the Commission<sup>32</sup>.

## **Changes in Risk Assessment**

Only five months after T25 maize was approved the environmental safety assessment for GM crops was significantly strengthened. According to the UK’s Department of the Environment Transport and the Regions (DETR)

*“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 release and marketing of genetically modified organisms”<sup>33</sup>*

The text of the Ministerial agreement reads

*“Without prejudice to the expeditious revision of Directive 90/220, noting especially*

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<sup>29</sup>Written Evaluation of Consent Application by ACRE, C/F/95/12-07, Dr J Macleod, 8 July 1996

<sup>30</sup>Minutes of the 40<sup>th</sup> ACRE meeting at the Department of the Environment. 19 July 1996. Para 3.2.6

<sup>31</sup> Letter from the Biotechnology Unit of the Department of the Environment to DG IX, dated 24 July 1996

<sup>32</sup> fax from Welsh Office, Environment Division to the DoE, dated 25 July 1996.

<sup>33</sup> DETR/ACRE Guidance Note 12. Guidance on principles of risk assessment and monitoring for the release of genetically modified organisms. December 1999.

*the need to further strengthen risk assessment, as also pointed out by the European Parliament, and monitoring procedures, the Member states intend already now when applying the existing Directive 90/220 to take into account the underlying principles for risk assessment and monitoring resulting from the work done in preparation of the Council”*<sup>34</sup>

As a result, the environmental risk assessment required for GM crops was made significantly more rigorous, and a requirement for monitoring was introduced. So, for example, as a direct result of this decision, the UK DETR produced new guidance for applicants for marketing consent in 1999. This widened the scope of the risk assessment to include indirect and delayed effects on the environment as well as introducing a requirement to monitor GM crops. New provisions of relevance to T25 maize included

*“Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting”*

*“Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP [Genetically Modified Higher Plant] where these are different from those used for non-GMHP”*

These two issues in particular, the contamination of other maize crops and the effects on biodiversity from changes in crop management are of great concern around Europe and yet were not addressed in the initial submission by Aventis or, apparently, by the SCP. In addition, Aventis did not submit a monitoring plan, as required under these increased requirements.

Therefore, had Aventis presented their original application for T25 after December 1998, it would not have been acceptable and it is highly improbable that T25 would have gained approval on the basis of the information provided. After 1998, the risk assessment process was more rigorous and included monitoring as well as broader risk assessment.

Finally, it is clear that the Austrian government’s wide ranging concerns were not satisfied, because on April 14 2000, they invoked the ‘Safeguard Clause’ (Article 16) of Directive 90/220 which allows member states to adopt unilateral bans on GMOs. In addition, Italy invoked the safeguard clause of the Novel Food Regulation 258/97 in 2000 to prevent T25 food products from being sold.

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<sup>34</sup> DETR/ACRE Guidance Note 12. Guidance on principles of risk assessment and monitoring for the release of genetically modified organisms. December 1999.

## 4 Consideration of T25 by the EU Scientific Committees

On 21st November 1997, the Scientific Steering Committee mentioned that their advice had been requested by the European Commission on T25 maize and 3 other GMOs. Their consideration was to cover “the potential risk of these plant varieties for food safety or consumer health in its widest sense”. The SSC then “decided that the Scientific Committee for Plants would act as leading Committee for this specific issue”, and suggested that they drew up a working group to examine the four GMOs in question.

In fact, at their very first meeting on November 11 (ten days before the SSC met) the SCP was informed by the secretariat that they would be considering these GMOs as a matter of high priority.

On the 22<sup>nd</sup> December 1997, the Working Group membership of 15 members of different EU Scientific Committees was confirmed, and within this the group was broken down into four sub groups covering biotechnology, toxicology and residues, environment and food and feed issues. Their remit was to examine the large dossiers covering all four GMOs under consideration, including T25. In the Scientific Steering Committee’s meeting on 21<sup>st</sup> November 1997, they suggested that

*“As it is expected that many similar requests for scientific advice related to GMOs will be received, the SC-Plant was requested to gain, from the analysis of these first 4 dossiers, the experience for establishing standardised analysis criteria, evaluation methods and risk assessment approaches, to be applied to future dossiers.”*  
(Emphasis added)

The examination of T25 was to be an exercise for the SCP, from which they would gain experience.

The SCP completed their task with incredible speed - in fact, on the 10<sup>th</sup> of February 1998 (only 7 weeks later), the SCP delivered its official opinion on all four GMOs. At the meeting of the Scientific Steering Committee on 19-20 February

*“the chairman congratulated the SC-Plants for having succeeded in handling the 4 large dossiers within such a short period and having prepared the 4 opinions earlier than expected.”*

Considering the speed with which the four opinions were delivered, and also that the majority of committee members had full time jobs apart from their duties on the Scientific Committees, there must be a question over how much time was devoted to the examination of T25 and the other GMOs.

### The SCP’s consideration of T25 maize

Various member state’s Competent Authorities raised issues of concern about T25 maize. Whilst it is not clear that it is the SCP’s responsibility to examine the concerns raised by member states (as they are in fact answerable to the European Commission) it is interesting to

note whether these concerns were addressed. Of the seven concerns raised, 3 are not even mentioned:

1. the effect of growing herbicide tolerant maize and its associated herbicide on agricultural biodiversity (raised by Austria, Sweden and Norway) was not mentioned in their opinion.
2. the impact of the herbicide, and transfer of the pat-gene to micro-organisms, on soil microbial ecosystems (raised by Austria) was not addressed by the SCP in their opinion.
3. The impact on pesticide usage in agriculture (raised by Sweden and Italy) was not addressed by the SCP in their opinion.

And in this section it is argued that many of the issues that were examined by the SCP were not adequately addressed.

The Scientific Committee on Plants stated on 10 February 1998 that

*“after examining and considering the existing information and data provided in the dossier, against the background of available knowledge in the areas concerned, considers that there is no evidence to indicate that the use of the genetically modified maize as any other maize, is likely to cause adverse effects on human or animal health and the environment”*

*“The weight of evidence provided by the company and available elsewhere concerning the safety leads the Committee to conclude that there is no significant risk to humans or livestock following ingestion of the gene product”*

It is not obvious however, that their consideration of T25 can support these statements.

## **Potential for Gene Transfer**

Regarding the potential for gene transfer from the GM maize to bacteria in the guts of animals or humans, the SCP states that, with regard to the pat gene,

*“the gene is under the control of a plant promoter which is not functional in bacteria. Consequently, in the unlikely event of gene transfer from the transgenic maize to intestinal bacteria, expression of the pat gene would not occur.”*

In fact, the CaMV promoter has been proven to be functional in bacteria<sup>35</sup> and so the pat gene can be expressed by bacteria which obtain it. Research proving that the CaMV 35S promoter is functional in bacteria was published in 1991 and so it would seem reasonable that the SCP should have been aware of this fact, which is fundamental to the safety of the inserted gene.

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<sup>35</sup>Assaad FF, Signer ER (1990). Cauliflower mosaic-virus p35S promoter activity in *Escherichia coli*. *Molecular and General Genetics* 223(3): 517-520. Lewin A, Jacob D, Freytag B, Appel B (1998). Gene expression in bacteria directed by plant-specific regulatory sequences. *Transgenic Research* 7(6): 403-411

The SCP goes on to state that

*“Even if it is assumed that, due to genetic recombination events, the gene would be expressed in intestinal micro-organisms or in human or animal cells (the probability of which is remote), no negative effects are expected since the only known substrate of phosphinothricin acetyltransferase (PAT) is the herbicide glufosinate ammonium”.*

But Dr Ricarda Steinbrecher, a molecular geneticist who examined this issue for Friends of the Earth, notes that *“the assertion that no negative effects can be expected from intestinal micro-organisms expressing the pat gene has not been tested with gut bacteria and so is really only conjecture”* and that *“no mention of horizontal gene transfer to soil micro-organisms has been made.”*<sup>36</sup>

### **The origin of the novel PAT protein**

The SCP states that

*“The protein product of the phosphinothricin acetyltransferase gene is not present in humans, animals, intestinal micro-organisms or in traditional food and feed plants”* (6.2.2).

In other words, it is a protein that is entirely novel to both the food and feed chain. Then they go on to state that

*“The gene encoding PAT has been isolated from the gram positive soil actinomycete Streptomyces viridochromogenes. The bacterium is not pathogenic for humans or animals”*

It is commonly held that if the source organism of a novel protein holds no risk to humans, then the novel protein taken from it is less likely to be dangerous. However, as has been pointed out by Dr Steinbrecher

*“In fact, the pat gene is derived from strain Tu 494 of S. viridochromogenes, found in a soil sample taken from Cameroon. But not all S. viridochromogenes strains contain the pat gene, not even all of the strain Tu 494. In fact only the mutant variant type ESI of the Tu 494 strain was found to contain a functional pat gene.”*

*“when scientists tried to find the pat gene in other micro-organisms, especially in soil bacteria, they had little success”*

This means that the fact that *S viridochromogenes* as a whole is non-pathogenic is not relevant to whether or not the PAT protein, taken from a rare mutant strain, is toxic.

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<sup>36</sup> Risks posed by horizontal gene transfer with regard to Chardon LL maize. Proof of Evidence of Dr Ricarda Steinbrecher on behalf of Friends of the Earth, October 2000.

## The safety of T25 maize for humans and animals

The SCP states that

*“Sequence comparisons show that the PAT protein does not have homology to known allergens” (6.2.2).*

A 1999 review article by Dr JM Wal of the Laboratoire d’Immuno-Allergie Alimentaire (part of the French INRA)<sup>37</sup>, who works extensively on food allergens, highlighted the failings in such an approach. He states that

*“the absence of common or similar sequences... does not strictly guarantee safety, because the available information in databanks is limited to a small fraction of allergens. For example, bovine  $\gamma$ -Lactoglobulin is not listed as an allergen in data banks and it would not be recognized as an allergen from its amino acid sequence through a search employing these criteria” (3.2.3, 2<sup>nd</sup> para)*

It is possible that this finding was unknown when T25 maize was considered by the SCP, but in addition there are some obvious failings in their assessment of the food and feed safety of T25 maize:

- They apparently did not question that the PAT protein used in the acute toxicity test was taken from GM oilseed rape, not GM maize, and they were apparently unconcerned that the study was so designed that it would only be able to measure “catastrophic” results.
- They accepted the conclusions of this study, despite themselves noting that “the use of the isolated protein in toxicity studies does not adequately model degradation of the same protein when fed as an integral component of the diet”.
- They apparently did not pick up that the feeding study on broiler chickens showed suspicious trends in variables measured, including mortality. Or that the study was so badly designed that errors were obvious “after only five minutes reading”<sup>38</sup>.
- They commented that “the nutritional composition and the content of the natural anti-nutritional factors are within the normal range”, apparently failing to note that there were significant differences in carbohydrate, amino acid and fatty acid composition, with two fatty acids being outside the range found in other published studies. Nor did they notice that only 18 out of 20 amino acids were measured.
- They also appeared unconcerned that the analysis of the anti nutritional factor used so few samples, of such variability, that only a difference of greater than 100% would be detectable.

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<sup>37</sup>Wal JM. 1999. Assessment of allergenic potential of (novel) foods *Nahrung* 43(3): 168-174

<sup>38</sup>Evidence of Dr Toby Knowles at the UK MAFF public hearings on the proposed addition of the genetically modified maize variety Chardon LL to the UK National List. 3 November 2000.

## Cross pollination

The SCP states that

*“The risk of genetic escape from modified plants will be limited by poor dispersal and the absence of sexually compatible plants either of the same or different species”.*

Whilst it is correct that there are no other sexually compatible species within Europe, sexually compatible plants of the same species (ie maize crops) are grown widely, and T25 can cross breed with these. Evidence presented by Professor Jean Emberlin, Director of the National Pollen Research Unit, for Friends of the Earth shows that maize pollen is not limited by poor dispersal. In fact, maize is an outbreeding species that produces very large amounts of pollen. Dr Emberlin pointed out in her evidence that

*“The most comprehensive available study on cross-pollination (Jones and Brooks, 1950)<sup>39</sup> indicates that:*

- (1) cross-pollination between two fields of maize at 200m occurs at levels greater than 0.1%;*
- (2) for one of the three years in the study, cross-pollination of 2.47% was recorded at 200m from the source; and*
- (3) a three-year mean of 1.19% cross pollination, over 11 times more than 0.1%, suggests that cross-pollination above 0.1% is a typical rather than an exceptional occurrence.”<sup>40</sup>*

And that factors “such as scale of pollen emissions or recipient field shape can significantly increase the level of cross-pollination.”

There is every reason to assume that widespread production of T25 maize will led to contamination of non-GM maize crops.

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<sup>39</sup>Jones, M.D. & Brooks, J.S. (1950) Effectiveness of distance and border rows in preventing cross-pollination in corn. Oklahoma Agricultural Experimental Station. Bulletin no. T-38

<sup>40</sup>An Assessment of outcrossing in maize, relevant to the proposed decision to add GM maize variety Chardon LL to the National List. Proff of Evidence of Professor Jean Emberlin BSc (Hons), PhD, Director, National Pollen Research Unit, University College, Worcester on behalf of Friends of the Earth, October 2000.

## 5 Novel Food approval for T25 maize

Approval for the use of GM crops in human food is covered by European Commission regulation 258/97. Within this regulation there are two forms of approval. The first is full approval, which entails all member states giving consideration of the GM crop for use in food – so far, no GM crop has gained approval by this mechanism. The second form of approval is laid out in Articles 3.4 and 5 of the regulation. This allows for the fast track ‘notification’ of GM foods that are derived from, but not containing, GM crops *and* that are considered to be ‘substantially equivalent’ to non GM food. Using this mechanism, if the ‘Competent Authority’ of one member state gives a favourable opinion of the GM derived food, the company wishing to market it simply notifies the Commission of the favourable opinion and of their intention to start marketing. There is no formal mechanism for other member states to be consulted on the notification, or to object to it.

In 1998, Aventis notified the Commission that it intended to start marketing processed products, derived from T25 maize, for use in food. The products of T25 maize that were notified were starch and derivatives, oil and “all heat processed or fermented products obtained from hominys, grits and flour (dry milled fragments). The notification was based on a favourable opinion produced by the UK’s Competent Authority on GM foods, the Advisory Committee on Novel Foods and Processes (ACNFP). This was delivered in 1996, under voluntary consultation procedures operating in the UK prior to the introduction of the EU Novel Foods Regulation 258/97.

The ACNFP’s opinion on T25 maize was published in their 1996 Annual Report, and their consideration took place in 1996, two years before Aventis notified T25 maize products. In addition, it is clear from documentary evidence that when ACNFP considered the evidence presented to them, not all of it was available.

### The Quality of the ACNFP assessment of T25 maize

The Advisory Committee on Novel Foods and Processes (ACNFP) advises the UK government on the safety of novel foods, including those derived from GM crops. In November 1995, Aventis (then AgrEvo) submitted an application for food approval to the UK’s Ministry of Agriculture Fisheries and Food (MAFF) for two types of maize, genetically modified to be tolerant to the herbicide glufosinate ammonium. These were referred to as ‘T14’ and ‘T25’. The application was made under the UK Government’s voluntary procedure for the approval of foods derived from GM crops, which operated prior to the adoption of the EU Novel Foods Regulation 258/97.

The ACNFP met to discuss the application on 22 February 1996 and 30 May 1996 and there is no evidence that they discussed this at any later date. In fact, the minutes of the meeting of the 30<sup>th</sup> record that the Committee’s Chairman concluded the discussion and “*suggested that line T25 be cleared*”<sup>41</sup>. This means that key evidence was unavailable to them. Firstly, the final version of the acute toxicity test of PAT protein in rats was unavailable at that time. In fact,

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<sup>41</sup> Minutes of ACNFP meeting, 30 May 1996

AgrEvo GmbH only provided the UK Government with a final version of this report in November 1996, claiming that

*“Because of failing administrative procedures, and a broken computerdisk (with subsequent incomplete recovery of the data) the final report of “PAT-PROTEIN - repeated Dose Oral Toxicity Study in Rats, RCC Project 616307” did not contain all the pathology data, necessary to justify the conclusions in the report”*<sup>42</sup>

The finished and complete report was only provided to the UK government 6 months after the ACNFP had concluded its assessment of T25 maize.

In addition, the report *“The effect of Glufosinate Resistant Corn on Growth of Male Broiler Chickens”* and produced by the Department of Animal and Poultry Sciences at the University of Guelph, (dated July 12, 1996) was forwarded to the UK Competent Authority by the European Commission in February 1997, nine months after the ACNFP’s consideration of the safety of T25 maize for use in food

A paper by the ACNFP secretariat, produced in March 2000, states that

*“The data on a wide range of other compositional factors satisfied the Committee that there had been no unintentional changes in the composition of the grain or plants as a result of the genetic modification”*<sup>43</sup>

Yet clearly the same issues are raised here as for the EU Scientific Committee on Plants. So, for example, the analysis of fatty acid composition found that the levels of steric, linolenic and aracidic fatty acids were statistically significantly different from the non-GM counterparts, with the levels of linolenic and aracidic fatty acids having values outside the literature value range. The amino acid assay for substantial equivalence showed statistically significant increases in the levels of the amino acids arginine, histidine and lysine while no data was presented of the levels of the amino acids asparagine and glutamine.

It is not clear why the ACNFP ignored this evidence, as this contradicts their conclusion of *“no unintentional changes”* for T25 maize. However, it would appear from minutes of their discussions, that the ACNFP were unsure how to examine for unintentional changes in GM crops at this time. On the 22<sup>nd</sup> of February, it was minuted as follows<sup>44</sup>

*“A member stated that it was a general concern in some quarters that when an organism is transformed, it may have an effect on the metabolism of that organism.”*

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<sup>42</sup>Letter from Dr Jan Bremmer, Hoechst Schering AgrEvo, Frankfurt to “Recipients of the report” dated 12/11/1996

<sup>43</sup> Paper to the Welsh Assembly Agriculture and Rural Affairs Committee, March 2000. Assessment of T25 genetically modified maize by the Advisory Committee on Novel Foods and Processes. ARD 05-00

<sup>44</sup> Minutes of ACNFP meeting , 22 February 1996

*“The Chairman agreed that ‘A member’s’ points were valid, and agreed that this was a generic issue which had not previously been addressed by the committee.*

*“A member felt that this was an issue which was fundamental to the committee’s use of substantial equivalence when considering submissions, and was therefore an issue which ought to be clarified...*

*“...An official pointed out that some previous applications had already addressed this point.*

*“A member replied that whereas in the past only the composition of the finished product (ie oil from oilseed rape) had been considered, the issue now, was that of the whole crop plant”*

Clearly, from this discussion, the Committee members were unclear about the use of substantial equivalence for assessing GM crops and perhaps this can explain why they ignored evidence showing differences in the GM maize.

### **The Legality of Aventis’ notification of T25 maize**

The ACNFP produced a report on T25 maize which was published in their 1996 Annual Report and is the also the opinion submitted by Aventis when they notified the marketing of T25 maize products to the European Commission. Because Aventis used this route, other member states have no legal right to consultation or objection to the GM food.

On the 8<sup>th</sup> of January 1998, Aventis notified the Commission that it would be placing processed products of T25 maize (including flour) onto the European market, as laid down under Article 3 and 5 of Regulation 258/97. At this time, the European Union had not clarified a definition for “substantially equivalent” as laid down in the Regulation. However, the European Commission has informed Friends of the Earth that at a meeting of the Standing Committee for Foodstuffs (one week later) on 15 January 1998,

*“The British Delegation informed that the British Advisory Committee on Novel Foods and Processes (ACNFP) concluded at its meeting on 4 December 1997 that “highly refined foods derived from GM crops, such as hot pressed oil, white sugar and starch, would be suitable for substantial equivalence evaluations on the grounds that neither DNA nor any proteins would be expected to be present...” “...all other ingredients derived from GM crops, such as flours and protein extracts, should be given a full safety evaluation as they may not have been subjected to the processing associated with highly refined products and could therefore contain novel DNA, in either an intact or a degraded form, and protein products denatured to varying extents” “This advice has been accepted by UK Ministers. [Denmark] and [Netherlands] shared the British view. [Germany] proposed to ask for the opinion of the [Scientific Committee on Food] if there is disagreement of the substantial*

*equivalence of a novel food or food ingredient to existing foods and food ingredients. The Committee agreed to that view”<sup>45</sup>.*

In other words, one week after Aventis notified T25 maize products to the European Commission, member states decided that several of the products notified (flours and dry milled fragments) should not qualify under this route. Aventis avoided a full safety assessment, and the consideration of T25 maize by member states, by using this approach.

On 16<sup>th</sup> December 1999, the Italian Superior Health Council (Consiglio Superiore di Sanita) of the Italian Ministry of Health issued an opinion that 7 products notified under Article 5 of the Novel Foods Regulation

*“should not be regarded as substantially equivalent in terms of their composition, as they contain proteins which are an expression of introduced genetic modification. For this reason, the recourse to the simplified procedure envisaged in Article 5 for notification made by the applicant, who approached the relevant agency in the United Kingdom for this purpose, does not seem to be lawful”<sup>46</sup>*

In other words, the Italian government considered that Aventis acted unlawfully when it notified that it was going to start marketing T25 maize products in the EU, because this option is only available for food products considered to be “substantially equivalent”.

In August 2000 the Italian Government invoked the “Safeguard clause” (Article 12) of the Novel Foods Regulation and issued a decree of 4 August 2000 suspending the trade and use of products of T25 maize, and three other types of GM maize which were notified via this route.

This matter was referred by the European Commission to the Scientific Committee on Food. The draft opinion of the Rapporteur for the Scientific Committee on Food, produced in September 2000, states that

*“Because the Committee had to consider the request as a matter of urgency, it was not possible to examine the original documentation provided by the applicants. The Committee, however, went through the ACNFP and SCP reports on the seven products and came to the conclusion that the ACNFP and the SCP undertook a full risk assessment procedure.”*

*“The safety evaluations by ACNFP and SCP, however, have been performed between 1995 and 1998 on the basis of methods and principles regarded as sufficient at that time. Therefore, the Committee feels (can not exclude) that additional evidence for safety would be considered desirable if the products would undergo a reevaluation”<sup>47</sup>*

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<sup>45</sup>Letter from the Food Legislation Unit, DG Sanco-02, European Commission to Friends of the Earth, London (Date?)

<sup>46</sup> Opinion of the Consiglio Superiore di Sanita, Italy, on “Transgenic food. Dossier submitted by the Associazione Verdi Ambiente e Societa”, 16 December 1999

<sup>47</sup>Draft Opinion concerning a submission from the Italian Authorities raising concerns for the safety

(continued...)

However, the final version of this opinion (published on 7 September 2000) makes no mention of these facts. Perhaps, if the Scientific Committee on Foods had considered all the evidence submitted by the applicants, they might have picked up the failings in the evidence submitted by Aventis, which were apparently overlooked by the ACNFP and SCP in their considerations.

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<sup>47</sup>(...continued)

of certain products approved under the notification procedure of the Regulation 258/97. Submitted by Prof W Grunow, 02/09/00

## 6 The Use of T25 maize in animal feed

In July 2000, the European Commission circulated a draft Directive on novel feeds. The Commission has already ruled that crops approved under Directive 90/220 would have feed approval pending the introduction of the Novel Feed Directive and currently 8 crops, including T25 maize, have novel feed approval via this route. The following section will show just how superficial and inadequate approval of T25 under Directive 90/220 has been in this regard.

First, the Commission Decision giving consent to market T25 maize states that

*“consent shall be given by the competent authorities of France to the placing on the market of the following product, notified by AgrEvo France (Ref. C/F/95/12/07):  
seeds and grains of genetically modified maize (Zea mays L.) with increased glufosinate ammonium tolerance derived from the maize line HE/89 transformation event T25 which has been transformed using plasmid pUC/Ac”*<sup>48</sup>.

According to the Commission Decision, approval has only been given to market seeds of Chardon LL and grains of Chardon LL. Silage is not covered by this.

In the draft novel feeds directive, Annex III lists “*Novel feed materials authorised before the implementation of this Regulation under Directive 90/220*”. In the case of T25 maize, the description and decision for the authorisation are given as

*“Maize (Zea mays L) grains genetically modified to confer increased tolerance to the herbicide glufosinate ammonium, authorised under Commission Decision 98/293/EC of 21 April 1998, and by-products thereof”*  
File 4 B26 Annex III

Maize grains and byproducts thereof are not the same as maize silage, which is the whole plant, and no mention of the whole plant is made.

### **The composition of T25 livestock feed**

In the same way that genetic modification has the potential to affect the nutritional value of the grain, it also has the potential to affect the nutritional and toxic compound composition of the whole plant. This is very important for maize, as the whole plant is used for cattle feed as ‘silage’. Aventis has developed at least two fodder maize varieties of T25 (Chardon LL and Sheridan) to be used to produce whole plant silage for cattle, which it is currently attempting to get onto the UK’s National Seed List.

Fodder maize is fed exclusively to ruminants, usually dairy and beef cattle. The whole plant is harvested and made into silage, which is then fed to the cattle. The ensiling process partially

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<sup>48</sup> Commission Decision 98/293/EC

ferments the maize plants, and cattle fed it commonly eat it as a large percentage of their diet, up to 75%. As has been pointed out by the US Food and Drug Administration,

*“Unlike a food in the human diet, an animal feed derived from a single plant may constitute a significant portion of the animal diet. For instance, 50 to 75 percent of the diet of most domestic animals consists of field corn [maize]. Therefore, a change in the nutrient or toxicant composition that is considered insignificant for human consumption may be a very significant change in the animal diet.”<sup>49</sup>*

Aventis own analyses found significant differences in the levels of fat, protein, Acid Detergent Fibre (ADF) and Neutral Detergent Fibre (NDF) between T25 maize silage and its non GM counterpart<sup>50</sup>.

When considering these results, a member of the UK Government’s Inter Departmental Group on Novel Feed Developments commented that:

*“I would consider the number of replicates generally to be insufficient to conclude substantial equivalence, and would expect to see the effects of location (only one site used) and season (data only from one year, 1994) to be compared before substantial equivalence could be claimed.”*

Aventis claimed in the marketing consent application that their results could not be compared with any other published study of silage composition because they had in fact analysed the composition of the maize before it was made into silage, while every other published study looked at the composition of the silage after it was made. But despite this, they state in the marketing consent application that

*“since the GTC and nontransgenic counterparts were harvested at the late milk to early dough stage, and the composition analyzed prior to ensiling, we cannot directly compare our analytical values to the literature values. However, the at harvest nutrient values for GTC and its counterparts do fall within the literature ranges for ensiled materials” (Page 40).*

In other words, having stated that no direct comparison could be made between their results and those already published, Aventis went on to do just that comparison. The paragraph is contradictory and the literature comparison meaningless because it was improperly done. This means that there is no way of establishing whether the values that Aventis found for the composition of their maize silage are in any way comparable to those found in non GM maize silage.

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<sup>49</sup> US FDA Statement of policy: Foods derived from New Plant Varieties. US Federal Register Part IX Department of Health and Human Services. 29 May 1992. Section IV(h)

<sup>50</sup> Submission for placing on the market (in accordance with the Part C of the Directive 90/220/EEC) of Glufosinate Tolerant Corns (*Zea mays*) Transformation Event T25”, submitted by AgrEvo France. Reference C/F/95/12-07. Page 41 Figure C 1

When questioned about this by the UK's ACNFP, Aventis stated that "we are aware that the comparison we made may not be valid".<sup>51</sup>

### **Consideration of Anti nutritional compounds**

The marketing consent application includes a consideration of an anti-nutritional factors found in maize. This is normally done to establish whether the levels of naturally occurring anti nutrients or toxins have been altered by the genetic modification. However, Aventis stated in the marketing consent application that

*"The possible presence of anti-nutritive substances which occur naturally needs to be taken into consideration with respect to animal feed. An example of naturally occurring nutritive substances are phytates, which bind phosphorus and other minerals making them unavailable to monogastric animals (Ensminger et al., 1990). All silage evaluated in this study had less than 1.15% phytate content and there was no statistical difference between GTC and its counterpart".<sup>52</sup>*

In other words, Aventis identified an anti nutritional factor that is of importance to monogastric animals, such as pigs, and then measured its levels in animal feed (silage) which is only ever fed to ruminant livestock (such as cattle), for whom phytic acid is not important anyway.

In addition, it has been noted by the UK's ACNFP, the UK's Interdepartmental Group on New Feed Developments and FOE's independent expert Dr Vyvyan Howard, that the results of the phytic acid analysis were so variable, with so few samples taken, that the experiment could only have detected a difference in phytic acid levels between the GM and non GM maize if this was greater than 100%<sup>53 54 55</sup>.

### **Requirements for testing the safety of T25 for animal feed have not been met**

Aventis has had marketing consent to sell T25 maize for use in animal feed since 1998. The varieties of T25 maize that Aventis has, so far, developed for production in the EU are fodder varieties, for which the whole plant is intended to be fed to cattle as silage. Yet nowhere, in

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<sup>51</sup> Letter from AgrEvo to MAFF 22 April 1996, para 7.1

<sup>52</sup> Safety, Compositional and Nutritional Aspects of Glufosinate Resistant Corn Transformation Events T14 and T25, page 28. Submission for placing on the market (in accordance with the Part C of the Directive 90/220/EEC) of glufosinate tolerant corns (*Zea mays*) transformation event T25, page 41-42

<sup>53</sup> Letter from MAFF to Agrevo, 1 April 1996 2<sup>nd</sup> page, 2<sup>nd</sup> para.

<sup>54</sup> Letter, with writer and recipient removed, dated 1 July 1996 and entitled "AgrEvo's Glufosinate Tolerant Maize" provided by the UK Food Standards Agency

<sup>55</sup> Analysis of key documents relevant to the safety of Chardon LL for animal feed purposes. Proof of Evidence of Dr CV Howard, MB. ChB. PhD. FRCPath on behalf of Friends of the Earth. October 2000.

any of the evidence presented, do Aventis specifically examine the safety of T25 maize for ruminant livestock, such as cattle. In fact, feeding trials have only been carried out on rats and chickens, which both have very different digestive systems to cattle. This is despite the fact that, as has been previously mentioned, cattle may consume maize as over 50% of their diet. It is also despite the fact that there is wide agreement about the type of testing that should be done for a GM crop intended for use as an animal feed, both from Government appointed experts and independent experts.

The UK's Interdepartmental Group on Novel Feed Developments stated in 1996 that

*“At present the approach is to predict how the intended modifications might have affected the organism and carry out specific tests to assess these modifications. This approach cannot hope to identify unintended and unforeseen modifications in gene expression.”*

*“The comparative testing of modified and unmodified product in target species should be used to demonstrate that nutritional value and toxic thresholds have not significantly changed. This type of test is non specific but has the advantage over the current approach of assessing the overall response of target species. Although no such test would positively prove total absence of risk it would be a useful additional test of product safety and substantial equivalence.”*

*“Target species testing is a requirement of all new feed additives and ingredients therefore the inclusion of this as a mandatory part of GMO testing seems entirely justified.”*

*“The current concerns over BSE mean that MAFF must take the precautionary approach towards the introduction of feed ingredients into the food chain.”*

*“The extension of safety testing of GM products to include target animal assessment should be applied to Glufosinate tolerant maize and all other similar new products”<sup>56</sup>*

The IDG, whose remit was to coordinate policy on animal feedings, recommended that a precautionary approach be taken and that target species testing of GM animal feeds should be made mandatory. If this recommendation had been adopted, T25 maize would have to have been tested for its safety for ruminant livestock (cattle) before gaining approval for use in animal feeds or as whole crop silage.

However, this recommendation was not adopted. Friends of the Earth has questioned why not and has been informed by Sir John Krebs, Chairman of the UK Food Standards Agency (which now has responsibility for this area) that

*“the ACNFP had already considered T25 maize at its meetings on 22 February and 30*

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<sup>56</sup> Memo (recipient removed) entitled “Interdepartmental Group on Novel Food (sic) Developments: Glufosinate Tolerant Maize”. Dated 1 July 1996

*May 1996. The ACNFP had advised that the composition of the grain and silage did not differ from that of conventionally bred maize. On this basis it was concluded that there were insufficient grounds for requiring additional data for feed safety purposes”*<sup>57</sup>.

In other words, the Government asked the relevant body about its opinion on T25 maize, and then ignored its clear advice that further testing should be done. In addition, the ACNFP was not qualified to give an opinion on the safety of T25 maize as an animal feed. Not one member of the Committee at that time had any expertise in animal feed safety or animal nutrition<sup>58</sup>. In addition, their remit in 1996 was

*“to advise Health and Agriculture Ministers of Great Britain and the Heads of the Departments of Health and Social Services and Agriculture for Northern Ireland on any matters relating to the irradiation of food or to the manufacture of novel foods or foods produced by novel processes having regard where appropriate to the views of relevant expert bodies”*<sup>59</sup>.

No mention made of animal feed, and they are required to take regard of the views relevant expert bodies, such as the IDG.

When Friends of the Earth questioned this further, Sir John Krebs responded by stating that *“the advice of independent scientific experts was given more weight than internal comments from officials”*<sup>60</sup>. This would be sound policy, except for the obvious fact that in this case the independent scientific advisers were advising outside their remit and area of expertise. In contrast, the IDG was established (according to Sir John Krebs) *“to coordinate policy on animal feedingstuffs across Government”*<sup>61</sup> and so their advice on this issue would seem to be entirely consistent with their role.

With regard to the advice given by the IDG, that further testing should be done, Sir John stated that

*“the emphasis of target species testing for new crops, whether a GM or conventional variety, has not been to provide safety information but to provide data on the nutritional adequacy of the feed ingredient from an economic perspective.”*

This appears to contradict the IDG’s statement, that

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<sup>57</sup> Letter from Sir John Krebs, Chairman of the Foods Standards Agency to Friends of the Earth, 25 September 2000.

<sup>58</sup> ACNFP Annual Report 1996. “Membership of the Committee during 1996” pages 26-27

<sup>59</sup> ACNFP Annual Report 1996 “Remit” page 25

<sup>60</sup> Letter from Sir John Krebs, Chairman of the Foods Standards Agency to Friends of the Earth, 20 November 2000

<sup>61</sup> Letter from Sir John Krebs, Chairman of the Foods Standards Agency to Friends of the Earth, 20 November 2000

*“the comparative testing of modified and unmodified product in target species should be used to demonstrate that nutritional value and toxic thresholds have not significantly changed”*

- in other words, to test the safety of the GM crop for livestock.

In 1998, the EU’s Scientific Committee on Plants stated that

*“It is desirable that feeding studies with GM plants or by-products derived from GM sources should be performed, wherever possible, in the target animal”*<sup>62</sup>

In the case of the T25 fodder maize ‘Chardon LL’ the target animal would be a cow.

They went on to state that in those cases where the target animals were identified as being ruminants

*“It is also important that separate evidence of the extent of degradation in ruminants is obtained in vivo for all GM products or parts of products designed for use as rumen feeds”*.

In other words, there should be feeding studies specifically to see what happens to the GM feed in cattle or other ruminants.

When the UK’s Advisory Committee on Animal Feedstuffs came to examine this issue in 1999, their Secretariat noted that

*“Where materials are considered substantially equivalent except for certain defined differences, unless there are sound arguments not to do so, it might be considered prudent to carry out some form of target species tolerance study, particularly for target species which have digestive systems which differ significantly, such as polygastrics”*.<sup>63</sup>

The ACNFP and ACAF then went on to comment that “feeding trials carried out with monogastrics would not be directly applicable to ruminants”<sup>64</sup>.

In 2000, the ACAF secretariat and the Food Standards Agency commented that feeding trials

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<sup>62</sup> Scientific Committee on Plants. *Guidance document to facilitate notifiers in the preparation of plant GMO dossiers for consideration by the Scientific Committee on Plants (SCP/GMO/103-Final)* 18 December 1998. Section 3.4.3 “Target Animals”

<sup>63</sup> Discussion paper for joint meeting of ACNFP and ACAF. Approaches to assessing safety of materials for use as human food or animal feed. November 1999. Para 25

<sup>64</sup> Minutes of the Joint meeting of ACAF and ACNFP. 1 December 1999. Para 2.6

*“could be particularly relevant where the GM crop in question is specifically for animal feed use, such as fodder beef (sic) and forage maize for silage”<sup>65</sup>.*

The only feeding trials that have been conducted on T25 maize have involved monogastric animals (chickens, rats). No specific feeding trials using ruminants have been conducted either for Chardon LL or T25 type maize varieties.

FOE asked independent experts to examine the evidence presented by Aventis in support of its application for marketing consent, with respect to the assessment of the safety of GM feed for livestock and they came to almost identical conclusions as the SCP, ACAF and the Food Standards Agency:

Dr Vyvyan Howard said that:

*“The studies presented do not address the main question, namely “What is the effect of feeding glufosinate resistant corn to ruminants at >50% of the diet?” All the data that has been presented is just a surrogate for a well-designed feeding trial, which would be both relevant and informative”.*

*“We do not consider that feeding the PAT protein produced by a different plant species (Canola) to a non-relevant species (rat) is sufficient to prove the safety of this product. It should itself be fed, as a whole food, to the intended target species, in a relevant proportion of the diet, in a properly designed feeding trial.”<sup>66</sup>*

Dr Bob Orskov, Director of the International Feed Resource Unit, Aberdeen, who has worked for many years at the Rowett Research Institute, has published four books relating to the nutrition of ruminants and is a co-author of more than 500 published articles stated the following:

*“Feeding of forage to ruminants is a two stage system. Forages are not used directly by the animals but the microbes inhabiting the forestomach degrade the digestible part of the forage. The degradation products produced by the microbes, such as volatile acids and the microbes themselves, form the energy and protein source for the animals.”*

*“GM forages could therefore theoretically have undesirable effects both on the microbes and on the host animal metabolism due to the gene insertion or associated promoter.. These could give rise to plant secondary compounds in the GM feed, which may cause problems for microbial metabolism or host animal metabolism or both.”*

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<sup>65</sup> ACAF’s role in assessing GM material Paper produced by ACAF secretariat and Food Standards Agency, September 2000

<sup>66</sup> Analysis of key documents relevant to the safety of Chardon LL for animal feed purposes. Proof of Evidence of Dr CV Howard, MB. ChB. PhD. FRCPath on behalf of Friends of the Earth. October 2000

*“Before GM forages are introduced in animal feeding I would recommend that a very thorough test is carried out, both on the microorganisms and on the host animal metabolism. If the microbial trials are satisfactory, then controlled tests on animal feeding can be carried out.”*

*“(1) Obtain small samples of the GM forage and incubate in stomach juice - ie rumen fluid obtained from ruminant animals.*

*(2) Examine carefully the microbes and the microbial metabolism and end products of degradation in comparison with non GM forage as well as the extent of degradation.*

*(3) If the above tests are all satisfactory, feed to small number of cattle increasing amount of GM forage and observe palatability and measure digestibility in comparison with non GM forage.*

*(4) If stage 3 is satisfactory, feed the forage to beef and dairy cattle and observe beef and milk production and make quality assessment for human consumption.”*

*“Only by going through this process should we allow GM forage to be introduced in animal feeding.”<sup>67</sup>*

It is clear that despite widespread agreement between all regulatory authorities and independent scientific experts that GM feeds should be tested on those livestock species that are going to eat them, this has not been done for T25 maize. Those tests which have been conducted do little to inspire confidence and are clearly not sufficient to guarantee the safety of T25 maize and silage for livestock and especially cattle. It is vital that T25 maize is withdrawn from use in animal feed as it has not been adequately tested.

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<sup>67</sup>Statement on the required testing of GM forage for feeding to animals, relevant to the proposed decision to add GM maize variety Chardon LL to the national List, written by Dr Bob Orskov DSc., OBE, FRSE, Honorary Professor in Animal Nutrition at Aberdeen University. September 2000

For more information on Friends of the Earth's GM campaign see:

[http://www.foe.co.uk/campaigns/food\\_and\\_biotechnology/gm\\_food/](http://www.foe.co.uk/campaigns/food_and_biotechnology/gm_food/)

[http://www.foe.co.uk/campaigns/food\\_and\\_biotechnology/information/gm\\_food/index.html](http://www.foe.co.uk/campaigns/food_and_biotechnology/information/gm_food/index.html)

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