Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto[1]

(Question N° EFSA-Q-2003-078)

Opinion adopted on 11 February 2004

SUMMARY

This document provides an opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on genetically modified oilseed rape GT73 and derived products for feed use. The opinion is based on a question raised by the Commission related to the notification for the placing of the oilseed rape on the market by Monsanto under the Directive 2001/18/EC on the release of genetically modified organisms (GMOs) into the environment (EC, 2001).

The GMO Panel was requested to consider whether there is any scientific reason to believe that the placing on the market of GT73 oilseed rape, for import and processing, is likely to cause any adverse effects on human health and the environment. The question followed a scientific assessment which was initially made by the competent authority of the Netherlands and subsequently evaluated by all other Member States. An assessment of the GT73 oilseed rape was requested by the Commission because of questions raised by several Member States following the evaluations at the national level. When this is the case, the EU legislation requires that EFSA carries out a further assessment and provides an opinion.

In delivering its opinion the GMO Panel considered the notification and additional information provided by the applicant and the specific questions and concerns raised by the Member States. Specific objections raised by the competent authorities of the Member States included potential allergenic risk of GT73 oilseed rape, issues of pesticide residues, clarification of data obtained from rat feeding studies and the potential need for additional feeding studies using the actual animal species which would be fed the GM product commercially. Some Member States also requested a more detailed environmental monitoring plan.

The risk assessment process was conducted using scientific guidance published by the EC Scientific Committees (EC, 2003). It included examination of the DNA integrated into GT73 using *Agrobacterium*–mediated transformation, the nature and safety of the target proteins produced by the transgenic event and the possibility that the genetic modification may have influenced the safety (including allergenicity) in comparison with conventional oilseed rape.

[1] For citation purposes: Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of glyphosate-tolerant oilseed rape event GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto, *The EFSA Journal* (2004) 29, 1-19.

The GT73 oilseed rape has been genetically modified to provide tolerance to the herbicide glyphosate. The stated purpose of the modification is to allow farmers to manage weeds more effectively in oilseed rape fields during cultivation. The GT73 oilseed rape has been planted for field trials within the EU and has been marketed in several countries outside the EU. The present notification concerns import and processing, but not cultivation. If approved it would therefore make it possible to import, process and use GT73 oilseed rape and derived products as animal feed. This is in addition to the present use of oil derived from GT73 for food purposes, which was notified in 1997 under the Regulation (EC) 258/97[2].

The oilseed rape was genetically modified with two genes encoding proteins conferring glyphosate tolerance. One of the proteins is glyphosate tolerant 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. strain CP4 (CP4 EPSPS). The EPSPS activity is needed for the biosynthesis of aromatic amino acids in plants and in micro-organisms; the plant enzyme is usually sensitive to glyphosate, thereby causing the plants to be killed by the herbicide. The second protein is glyphosate oxidoreductase (GOX) which acts by breaking down glyphosate.

Molecular analysis showed that GT73 contains a single inserted copy of the DNA present in the construct used for the transformation. There are some molecular changes at the insertion site, which do not lead to new traits and are not considered to pose a safety risk. In the unlikely event that a new peptide or protein is introduced as a consequence of the insertion event, bioinformatics analysis showed that these would have no homology to known toxins or allergens.

The Panel has considered all the studies provided by the applicant and concludes that since there are no indications of relevant compositional differences, additional animal feeding studies are not necessary. The wholesomeness of GT73 oilseed rape is confirmed by animal feeding trials.

The notification C/NL/98/11 for GT73 oilseed rape only concerns import and processing for feed use. There is therefore no requirement for scientific information on possible environmental effects associated with the cultivation of GT73 oilseed rape. The GMO Panel agrees with the conclusions of the environmental risk assessment by the applicant that the likelihood of unintended environmental effects due to the adventitious release and spread of GT73 oilseed rape will not be different from that of traditionally bred oilseed rape. The monitoring plan provided by the applicant is in line with the intended uses of the GMO.

In conclusion, the GMO Panel has considered all the evidence provided and is of the opinion that GT73 oilseed rape is as safe as conventional oilseed rape and therefore the placing on the market of GT73 oilseed rape for processing and feed use is unlikely to have an adverse effect on human or animal health or, in the context of its proposed use, on the environment.

Key words: GMOs, *Brassica napus*, oilseed rape, GT73, herbicide tolerance, glyphosate, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), glyphosate oxidoreductase (GOX), food safety, feed safety, human health, environment, import, Directive 2001/18/EC.

2 According to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council (EC, 1997), novel foods or novel food ingredients may follow a simplified procedure, only requiring notification from the company, when they are considered by a national food assessment body as 'substantially equivalent' to existing foods or food ingredients (as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein). Notification 'Refined oil from glyphosate tolerant oilseed rape line GT73' (EC, 1998) was considered by the UK Advisory Committee on Novel Foods and Processes (ACNFP, 1995).

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BACKGROUND

The Commission received the notification (Reference C/NL/98/11) for the placing on the market of glyphosate-tolerant genetically modified (GM) oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC (EC, 2001) from Monsanto, on 16 January 2003, following a positive assessment from the lead Member State (The Netherlands).

In accordance with the Directive 2001/18/EC, the notification was then transmitted to the competent authorities of other Member States, a number of which raised objections during the statutory 60-day period. The applicant provided the Member States with additional information in response to the objections raised during this 60-day period. The Member States had until 6 October 2003 to confirm or lift their objections. Where these objections are maintained, the Commission is required to consult the relevant Scientific Committees for opinion, now represented by the EFSA. Some Member States maintained specific objections.

Article 18(1) of Directive 2001/18/EC states that the period of time during which the Commission is awaiting the opinion of the Scientific Committee shall not exceed 90 days. The evaluation by EFSA started on 29 October 2003, after receipt of the complete background information (request from the Commission, dossier of the applicant and final objections maintained by the Member States). During the 90-day period, EFSA requested further clarifications from the applicant; this procedure, in agreement with the Commission, extended the final deadline set for the delivery of this opinion.

TERMS OF REFERENCE

EFSA was requested, under Article 29(1) and in accordance with Article 22(5)(c) of the Regulation (EC) No 178/2002 (EC, 2002), to provide a scientific opinion as to whether there is any scientific reason to believe that the placing on the market of the GT73 oilseed rape, for import and

processing, is likely to cause any adverse effects on human health and the environment within the scope of Directive 2001/18/EC.

In particular, EFSA was requested to take account of the scientific objections raised by the competent authorities of the Member States.

EFSA was not requested to give an opinion on the non-scientific objections raised by the competent authorities in their replies, either within the context of the entry into force of forthcoming legislation or following requests for further legislative/implementing measures.

ASSESSMENT

1 Introduction

The assessment conducted by the GMO Panel took into account the intended uses of the GM oilseed rape and followed the principles laid down in the guidance document for the risk assessment of genetically modified plants and derived food and feed (EC, 2003).

2 Molecular characterisation

2.1 Issues raised by the Member States

During the statutory 60-day period, some Member States requested additional information on the molecular aspects of the dossier, including clarifications of Southern blots (insert copy number, restriction sites) and DNA sequence/bioinformatics analysis of the insert and 3' and 5' flanking regions. The applicant provided additional information which addressed the objections raised. All of this information has been used to deliver the present opinion. Comments raised by the Member States on specific molecular detection methodologies are presently not within the scope of the GMO Panel remit.

2.2 Relevant background data

2.2.1 Transformation process and vector constructs

The parental variety Westar is a spring oilseed rape (*Brassica napus*) best suited to Canadian environments. Westar oilseed rape was transformed with *Agrobacterium tumefaciens* harboring plasmid vector PV-BNGT04. The vector includes two genes that encode proteins conferring glyphosate tolerance, i.e. *cp4 epsps* from *Agrobacterium* sp. strain CP4, and *goxv247* from *Ochrobactrum anthropi* (variant 247 of the original *gox* gene with enhanced efficiency of glyphosate degradation). The corresponding proteins are 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) and glyphosate oxidoreductase (GOX). Both genes have a modified figwort mosaic virus promoter (P-CmoVb) and an N-terminal chloroplast transit peptide (CTP) sequence from *Arabidopsis* (AEPSPS/CTP2 [used with CP4 EPSPS] or Arab-SSU1A/CTP1 [used with GOX]). CTP targets the proteins to the chloroplast. The *goxv247* has a pea polyadenylation site (E9 3').

The rationale of developing glyphosate-tolerant oilseed rape was as follows. Glyphosate acts by preventing the biosynthesis of aromatic amino acids in the plant. The herbicide specifically inhibits

EPSPS enzyme activity in glyphosate-sensitive plants. The CP4 EPSPS differs from the sensitive forms of the enzyme, being highly insensitive to glyphosate, and thus restoring the biosynthesis of aromatic amino acids in the genetically modified plant treated with glyphosate. The GOX protein acts by breaking down glyphosate to less toxic aminomethylphosphonic acid (AMPA) and glyoxylate. AMPA is the principal breakdown product of glyphosate (also in non-GM plants) and is degraded by several micro-organisms, while glyoxylate is commonly found in plant cells and is broken down by the glyoxylate pathway.

2.2.2 Transgenic constructs in the genetically modified plant

Evidence is provided which shows that GT73 oilseed rape has a single copy insert (Southern blot, *Eco* R1 or *Spe*I digests) containing the *cp4 epsps* and *gox* genes. All of the genetic elements present between the left and right borders of the transformation vector pMON 17327 are present in GT73 and with the same organisation of DNA (confirmed by sequencing of the insert). The sequencing of 3' and 5' flanking regions revealed that 40 base pairs (bp) of parental (Westar) DNA is absent from GT73, and that GT73 contains 22 bp of DNA adjacent to the 5' insert/plant junction which is not present in Westar. Bioinformatic analysis presented in the notification indicated no homologies between inserted sequences, flanking sequences and known toxins/allergens/pharmacologically active molecules.

2.2.3 Inheritance and stability of inserted DNA

The inserted DNA is inherited in a stable fashion in a nuclear chromosome as indicated by a number of parameters, e.g. predicted Mendelian segregation ratios (over several generations) from crosses between GT73 and conventional oilseed rape.

2.3 Conclusion

The Panel is of the opinion that sufficient molecular characterisation has been carried out. The data do not indicate any significant risks.

3 Comparative analysis

3.1 Issues raised by the Member States

Some Member States requested additional information concerning e.g. the possible use of the herbicide during cultivation and the glucosinolate content of the GT73 oilseed rape. The applicant provided additional information which has been taken into consideration in delivering the present opinion.

3.2 Relevant background data

3.2.1 Choice of comparator

As the spring oilseed rape variety Westar was the parental cultivar/line used in the development of GT73 oilseed rape, Westar was chosen as the non-modified cultivar in all studies for comparison (Klassen et al., 1987). The heterozygosity of the plant population that constitutes the cultivar Westar was estimated by Agriculture Canada to be in the range of 10-15%.

3.2.2 Field trials and compositional analysis

The aim of the compositional analysis is to provide evidence of whether the genetic modification has resulted in any unintended effects being introduced into the GT73 oilseed rape. The assessment was based on comparisons of data obtained with GT73 with the range measured for the parental line Westar, as well as data available in the literature.

Kernels from oilseed rape (GT73, Westar and other commercial varieties) were obtained from field trials in Canada (1992 [7 sites], 1993 [5 sites]), 1997 [4-19 sites per variety]) and Europe (1994 [3 sites], 1995 [3 sites]). Crops grown in the 1992 field trials were not treated with glyphosate, but all trials performed thereafter included crops both treated and not treated with glyphosate. Analysis of kernels included proximates (oil and protein, fibre, ash, moisture), fatty acid and amino acid profiles, and glucosinolate composition. From the samples of Canadian field trials during 1992 and 1993, chlorophyll and sinapine were also measured. Additional data on glucosinolate levels were provided for GT73 oilseed rape from trials conducted in Chile in 1996, as well as for hybrids derived from the transgenic oilseed rape.

Kernels from the Canadian field trials in 1993 were processed into toasted meal, and the meal was analysed for proximates (protein, ash, moisture, fat, fibre and N-solubility), amino acid profile, glucosinolates, phytic acid, and minerals. In addition, CP4 EPSPS and GOX proteins were measured from seeds of the various field trials and toasted meal. No CP4 EPSPS and GOX enzymatic activities were detected in the toasted meal.

The results of numerous analyses of the chemical and nutritional composition of GT73 oilseed rape over several years and across diverse geographies indicated that the constituents measured were within the ranges reported for conventional oilseed rape varieties and that GT73 is substantially equivalent to Westar in protein content, proximate values and amino acid composition. Fatty acid composition was also the same except for a very slight reduction in the level of linolenic acid. There was no indication that treatment with glyphosate had any impact on the composition of the harvested seeds.

Compared to the OECD consensus document on rapeseed (OECD, 2001), the applicant has analysed all compounds except for sterols, tocopherols and pheophorbide pigments, and tannins.

Glucosinolate level

Glucosinolates are monitored in oilseed rape due to their reported antinutritional properties. Some glucosinolates produce goitrogenic compounds upon hydrolysis by myrosinase present in *Brassica* seeds. When seeds are crushed, this enzyme acts upon glucosinolate to yield isothiocyanates, thiocyanates and possibly nitriles, some of which might be harmful. During oilseed rape meal processing, myrosinase is inactivated by heat treatment, leaving glucosinolates intact. Oil produced from oilseed rape varieties low in erucic acid and glucosinolates is the only oilseed rape product considered fit for human consumption. Maintaining low glucosinolate level is a basic breeding objective. In oilseed rape breeding, up to nine glucosinolates are monitored.

The average level of glucosinolates in GT73 oilseed rape was consistently slightly higher than in Westar in several initial trials conducted in Canada in 1992 and 1993. The differences were statistically significant. Data obtained from field trials in Canada in 1997 indicated somewhat lower alkyl glucosinolate levels in GT 73 oilseed rape (10.37 μmol/g defatted meal; range 8.21-14.45) compared to levels in standard varieties (10.93 μmol/g; range 6.46-16.37), but no statistical analysis was provided. Comparison of alkyl glucosinolate levels showed no differences between GT73 (mean *ca.* 11.2 μmol/g defatted meal; range 9.9-12.9) and Westar (mean 10.6 μmol/g

defatted meal; range 9.6-11.4) in European field studies conducted in 1994. In the 1995 field studies there were greater differences between GT73 (mean *ca.* 11 µmol/g defatted meal; range 9.8-12.6) and Westar (mean *ca.* 7.9 µmol/g defatted meal; range 3.9-10.0), but without statistical analysis. In 1996 the variety RU3 (produced by backcrosses of GT73 to the non-modified variety Alliance) was grown in field trials together with the control line Alliance in Chile and a number of commercially available oilseed rape varieties in Canada, France, Germany and the United Kingdom. The commercial varieties were selected to have a broad variation in the glucosinolate levels but still represent the range of commercially acceptable quality in rapeseed meal. The alkyl-glucosinolate level in RU3 was somewhat higher (10.4 µmol/g) than that of the control line (7.8 µmol/g), but lower than in the Canadian (15.3 µmol/g) and European (22.1 µmol/g) varieties. The applicant provides two possible explanations for the higher glucosinolate level in GT73. 1) The Westar variety of oilseed rape is a population of different individuals. Considering the glucosinolate levels in oilseed rape, any progeny may differ from the average of the Westar population. Because the genetic transformation of Westar to produce line GT73 represents the selection of one cell of a single individual from a Westar population, it is not unexpected to observe different levels of constituents such as glucosinolates in GT73. 2) It is also possible that the slightly elevated levels of glucosinolates found in GT73 result from variation induced by tissue culture during the genetic modification process. Tissue culture is known to induce genetic variability (somaclonal variation), which can also be exploited by plant breeders (Jain, 2001). Variation of glucosinolate levels has been observed, for example, between individual plants of the same population as well as between somaclonal variants of e.g. another *Brassica*, Indian mustard (Palmer et al., 1988). The Panel considers that these are reasonable explanations.

The maximum glucosinolate content set by the European Commission for certified seed of "double zero" varieties listed in the Common Catalogue of Varieties of Agricultural Plant Species is 25 µmol/g seeds (moisture content 9%) (EC, 1999). The applicant has not provided data on total glucosinolates in whole seeds. According to the analyses reported, the seeds of oilseed rape contain ca. 45-50% fat, and alkyl glucosinolates represent 40-50% of total glucosinolates. Thus 25 µmol glucosinolates/g seeds is approximately equivalent to 20 µmol alkyl glucosinolates/g of defatted meal. The glucosinolate levels reported are thus clearly below the maximum content set by the European Commission.

3.3 Conclusion

The data provided on the crops grown during the seasons 1992 to 1996 indicate no compositional changes as a result of the genetic modification, except for the intentionally expressed novel proteins, glucosinolate level and the minor alteration in the linolenic acid level. The company has given a plausible explanation for the altered level of glucosinolates. The altered level of linolenic acid is not considered to be biologically relevant. The average glucosinolate levels remained well below the maximum glucosinolate content set by the EC. Although the notification has not been updated to include all relevant constituents suggested by OECD (2001), the GMO Panel accepts the data provided since all key components have been considered. Comparative measurements of these compounds do not indicate that the genetic modification produced compositional changes indicative of unintended effects. The compositional analysis indicates that, with the exception for the introduced proteins, there are no differences between GT73 oilseed rape and its appropriate comparators which would indicate the need for additional toxicological testing.

4 Food/feed Safety Assessment

4.1 Issues raised by the Member States

Some Member States maintained that insufficient information was presented to entirely rule out a potential allergenic risk of the product. Data on the levels of glyphosate/AMPA residues were requested. A satisfactory explanation was sought for the potentially adverse effect observed in one of the three rat feeding studies. A feeding study on mice provided with feed products derived from GT73 oilseed rape was requested. Feeding studies were requested using typical target animals which reflect the commercial use of the product. Finally, one Member State requested, as a principle, a comprehensive toxicological risk assessment instead of deciding case-by-case which toxicological tests might be appropriate to perform a safety assessment. It should, however, be kept in mind that the notification concerns import, processing and feed use. The only oilseed rape product for human use is the refined oil, which has already been notified within the EU in 1997 (EC, 1998).

4.2 Relevant background data

4.2.1 Toxicology

Test material

Structural and functional identity of the CP4 EPSPS and GOXv247 proteins produced in recombinant *Escherichia coli* and in GT73 oilseed rape was shown by analyzing the gene sequences, protein approximate molecular weight and glycosylation, N-terminal amino acid sequence, enzymatic activity and immunological properties.

Safety of the novel proteins

In vitro digestibility. In vitro studies showed that the transgenic protein GOXv247 is readily degraded in simulated gastric fluid containing pepsin. The degradation was demonstrated by Western blotting (>90% degraded in 15 sec) and enzyme activity (>96% loss of activity within 1 min). These two methods were also used to demonstrate degradation in simulated intestinal fluid (>90% protein degraded within 30 sec, and >95% loss of enzymatic activity within 1 hour).

With regard to the digestibility and degradability of the CP4 EPSPS protein, it was shown that this protein is rapidly degraded *in vitro* in simulated gastric fluid (<15 sec), and intestinal fluid (<10 min). The *cp4 epsps* gene has been introduced into crops that previously received a positive opinion from the EFSA GMO Panel (EFSA, 2003) and competent Scientific Committees of the European Commission (SCP, 1998a, b).

Acute toxicity. Mice (10 animals/sex/group) were administered, by gavage, single doses of preparations containing 1, 11 or 104 mg of GOXv247 per kg body weight. Control mice were of two types, animals gavaged with preparations obtained from *E. coli* genetically modified with a vector from which the GOXv247-encoding sequence had been deleted, and animals gavaged with a buffer solution. The study was terminated 7 days after dosing. Parameters studied included food consumption, body weight gain, and gross necropsy. No substance-related effects were noted.

An acute oral toxicity study on CP4 EPSPS in mice showed no adverse effects following a dose of 572 mg/kg body weight applied by oral gavage.

4.2.2 Allergenicity

The strategies used in assessing the allergenic risk concentrate on characterisation of the source of the recombinant protein, the potential of the newly expressed protein to induce *de novo* sensitisation, or to elicit allergic reactions in already sensitised persons, and whether the transformation may have altered the allergenic properties of the modified food. A weight of evidence approach is recommended, taking into account all of the information obtained with various test methods, since no single experimental method yields decisive evidence for allergenicity (EC, 2003; CAC, 2003).

EPSPS protein

An allergy risk evaluation of CP4 EPSPS protein has been completed recently for a previous notification evaluated by the GMO Panel (EFSA, 2003) using the guidelines proposed by Metcalfe et al. (1996). These included the absence of known allergenicity of the source, absence of sequence homology with known allergens and rapid and extensive degradation by proteolytic enzymes. The Panel is not aware of any new information on allergenicity which requires a change of this opinion. Nor is the Panel aware of any new tests which produce more relevant or accurate information on possible allergenicity of the protein and which provide a higher guarantee of safety.

The applicant has provided a bioinformatic analysis of potential allergenicity, as well as toxicity and pharmacological activity, of putative peptides encoded at the 3' and 5' junctions of the GT73 event and plant genomic DNA. Sequences spanning the junction were translated from stop codon to stop codon in all frames and each frame compared to appropriate sequence databases including those for allergens and toxins. Data provided demonstrate that in the unlikely event that junction polypeptides were translated they would not share a sufficient degree of sequence similarity or identity to known allergens or toxins.

GOX protein

The amino acid sequence of the GOXv247 protein was compared in the notification to the sequences of known allergens. The FASTA algorithm was used to align the transgenic and database-stored structures with each other. No identical sequences containing at least eight contiguous amino acids were observed.

A test (Soeria-Atmadja et al., 2004) based on a method that combines FASTA alignment with supervised classification algorithms was performed at a request of the GMO Panel. The test identified the GOXv273 protein as non-allergen-related. Prediction of allergenicity based on identity over six consecutive amino acids was found to be unspecific[3]. Calculations showed that 73% of non-allergenic sequences are incorrectly detected as allergens. Corresponding miss-classifications using seven or eight amino acids in sequence were 21% and 4%, respectively. Similar data have been published by others (Goodman et al., 2002; Hileman et al., 2002).

[3] It has been shown recently that the GOX protein shares a 6-amino acid sequence present in a 9-amino acid epitope from the major shrimp allergen tropomyosin which binds IgE in sera of shrimp allergic patients (Kleter and Peijnenburg, 2002). Another recent publication by Ivanciuc et al. (2002) describes the 9-mer peptide as potentially cross-sensitising, given the presence of similar sequences in various other allergens. Since the presence of the GOX protein in GT73 derived oil meant for human consumption cannot be excluded, the relevance of such a finding should be assessed according to existing guidelines (CAC, 2003).

GT73 oilseed rape or processed products

The objection raised by one Member State on a possible unintended effect of the genetic modification which would alter the allergenicity of GT73 oilseed rape is a relevant general issue for which there is no general answer. This would apply to allergy that has been reported on inhaled dust/flour derived from oilseed rape seeds (Suh et al., 1998; Monsalve et al., 1997). In the case of GT73, there is no information whether the genetic modification might alter the allergenicity of the GM oilseed rape.

4.2.3 Feed safety and nutritional assessment

Heat-processed oilseed rape meal is used solely as a protein-rich livestock feed and is not consumed by humans. The major uses of compound animal feed containing oilseed rape meal are in poultry, pig and cattle production. The safety and wholesomeness of GT73 oilseed rape meal were further confirmed in various animal species including short-term feeding studies on rat and quail.

Rat

Safety and wholesomeness of GT73 oilseed rape was investigated in three 28-day rat feeding studies. The levels of oilseed rape meal fed to the animals ranged from 8 to 13 g/kg body weight/day.

In the first study (1994), unprocessed or processed oilseed rape meal (GT73, which after the end of the study was found to be inter-mixed with another glyphosate-tolerant line, GT200, in a ratio of approximately 1:1) was fed to rats at dietary levels of 5 and 15%. Ten rats/sex/treatment were used (age 6 weeks). There were no differences in body or liver weights between rats fed glyphosate-tolerant or control oilseed rape meal. Rats fed oilseed rape meal had higher liver to body weight ratio than rats fed diets not supplemented with oilseed rape. The Panel has not taken these data into consideration since the results are difficult to interpret because of the accidental mixing of two different GM oilseed rape meals.

The second study (1995) was carried out with GT73 and Westar (control). Processed oilseed rape meal was fed to rats at dietary levels of 5 and 15% (corresponding to a mean daily intake of about 4.3 and 13 g/kg, respectively). Ten rats/sex/treatment were used. No differences in body weight gain were observed. However, the relative liver weights were slightly, but significantly, increased by approximately 9-16% in rats fed the 15% (but not 5%) GT73 oilseed rape diet when compared to Westar controls. There were no apparent gross pathological changes in the livers following examination at necropsy. The Panel considers this as an incidental finding.

In the third comprehensive study (1996) GT73 oilseed rape meal, and oilseed rape meal from several varieties (5 Canadian, 3 European) was included in the diets at 10 % (corresponding to a mean daily intake of about 8 g/kg). Two replicates of 10 rats/sex/treatment were used. The study did not reveal any significant difference in weight gain, feed intake or organ (liver, kidney) weights between rats fed GT73 and the parental Westar line and the commercial lines. Closer examination of the data (Nickson and Hammond, 2002) indicated that liver weights varied considerably between replicates and between control groups fed different varieties of non-transgenic oilseed rape. The liver weights of the GT73 replicate groups fell well within the range of the responses for the different controls including Westar.

Rainbow trout

A 10-week feeding study (1994) in rainbow trout was carried out using diets which included processed meal (0, 5, 10, 15 and 20% of fish meal dry matter) from the intermixed oilseed rape lines GT73 and GT200 (same as in the first rat study). There was no statistically significant difference in body weight gain or feed conversion ratio between the groups receiving parental or glyphosate-tolerant oilseed rape. The Panel has not taken these data into consideration since the results are difficult to interpret because of the accidental mixing of two different GM oilseed rape meals.

In the second feeding study (Brown et al., 2003) juveniles were fed a diet containing 0, 5, 10, 15 or 20% processed oilseed rape meal (toasted meal incorporated into feed pellets) from GT73 or its parental Westar line for eight weeks (maximum levels of incorporation into diets for salmonids is usually less than 20% of the dry matter). All diets were fed to triplicate groups of fish. The mean weight gain, protein retention, and survival were not significantly different between fish groups given GT73 or Westar in their diets.

Quail

In the first feeding study (1993) thirty 10-day old bobwhite chicks of mixed sex were fed for 5 days on diets which included 20% unprocessed meal from the intermixed oilseed rape lines GT73 and GT200 (same as in the first rat study). Body weight gain and estimated feed consumption were comparable for quail fed oilseed rape meal from the glyphosate-tolerant lines and those fed the control (parental line) and basal diet. The Panel has not taken these data into consideration since the results are difficult to interpret because of the accidental mixing of two different GM oilseed rape meals.

In the second quail feeding study (1994) thirty 10-day old bobwhite chicks of mixed sex were fed for 5 days a diet containing 20% unprocessed GT73 oilseed rape meal. All birds appeared normal when the study was terminated three days later. When compared to the parental control group, quails in the GT73 group exhibited a slight reduction in body weight gain during the exposure period (day 0 - day 5). However, there was no reduction in body weight gain for the entire test duration (day 0 - day 8). Feed consumption was comparable for all groups.

Chickens for fattening

Rapidly growing broilers (Ross x Ross 508) were used to compare diets containing GT73 oilseed rape with the parental and six commercially available oilseed rape varieties (Taylor et al., 2004). Broilers were fed diets containing 25% oilseed rape meal during the first 20 days and for the following 22 days diets with 20% oilseed rape meal. In 42 days broilers reach a market weight of approximately 2 kg and are considered to provide a sensitive test system to detect adverse dietary effects. The recommended inclusion rate for processed oilseed rape meal is 20% corresponding to an oilseed rape intake of 20 g/kg body weight/day. No significant differences were observed in the performance parameters (growth, carcass fat pad, breast meat, thighs, legs, wings, chill weight; percentage of moisture, protein and fat in breast or thigh meat) between the GT73 and parental oilseed rape groups. The values obtained for GT73 oilseed rape were all within the ranges obtained with the commercial oilseed rape lines.

Lamb

It has been shown recently that incorporation of 6.5% (typical level for finishing lamb diets in western Canada) GM oilseed rape meal (event GT73) in a barley-based diet for lambs did not alter feed digestibility (dry matter, fibre, nitrogen balance), feed intake, feed conversion ratio, daily

weight gain, carcass characteristics or meat quality of the lambs as compared to the diet containing the non-transgenic parent Westar (Stanford et al., 2003). Apparent digestibility of the diets was determined using eight mature wethers (67.8 ± 2.3 kg) in a replicated Latin square with four 21-day periods. The growth trial involved 60 early weaned Arcott lambs (30 ewes; 30 wethers; initial age approximately 2 months; initial weight 21.5 ± 1.0 kg). The lambs were blocked by weight and gender for assignment to treatments, and fed the diets until reaching or exceeding 45 kg body weight. At slaughter, liver, heart, spleen, lungs, reproductive tract, kidneys, kidney fat, head, abomasum, intestines and bladder were subjected to veterinary inspection for morphological abnormalities. Organ and tissue structure appeared normal and were not affected by dietary treatment.

Levels of oilseed rape recommended for other target species

For growing pigs, the recommended dietary inclusion rate for oilseed rape meal is 12%; at this inclusion rate, a 20 kg pig would eat 6 g/kg body weight/day oilseed rape meal. The recommended inclusion rate for oilseed rape meal is 20% grain/concentrate mixture for calves, 25% for dairy cows and 20% for cattle for fattening. At a recommended oilseed rape meal inclusion rate of 25% of concentrate, a dairy cow could consume 5 g/kg body weight/day at peak lactation. Thus rats (Section 4.4.1) were fed more GT73 oilseed rape meal on a g/kg body weight basis (8-13 g) than recommended rates for dairy cows or growing pigs.

4.2.4 Residues and metabolites of the herbicide applied

In the light of their possible effects on animal and human health, two Member States have raised the issue of the possible presence of residues of glyphosate and its metabolite (AMPA) in GT73 oilseed rape. Food and feed derived from any cultivated oilseed rape treated with herbicide may contain residues of that herbicide and its metabolites. In the notification for consent to place GT73 glyphosate tolerant oilseed rape on the market no information on this topic was included. In the response to Member State objections the applicant declared that residue data for GT73 glyphosate tolerant oilseed rape were presented within the framework of Directive 91/414/EEC concerning the placing of plant protection products on the market (EC, 1991). The Panel recognizes the importance of the issue and notes that the risk assessment of such compounds is carried out within the scope of Directive 91/414/EEC.

4.3 Conclusions

Evidence is provided that there is no acute toxicity from the CP4 EPSPS and GOXv247 proteins. The GMO Panel is satisfied that the structural and functional identities of these proteins produced in *E. coli* and in GT73 oilseed rape were established.

In case of feed use only, the GMO Panel considers that additional experimental data on possible allergenicity is not required. Since this notification is for import and processing only, and not for cultivation, pollen allergy is not considered relevant. During processing, occupational exposure to the oilseed rape may occur. The allergenic risk from inhalatory exposure therefore exists but the number of reported cases of occupational allergy to rapeseed meal is low. There is no evidence that the allergenic potency of the GM crop has changed due to any unintended effect. Assessing such possible change would be extremely difficult due to the low number of patients. Since cross-reactivity between GOX and tropomyosin is not ruled out completely, persons allergic to shrimp meal should be aware of the possibility of hypersensitivity reaction when working with GT73 oilseed rape.

The Panel is of the opinion that the wholesomeness and absence of toxicity of feed in livestock is confirmed. The Panel has considered all the studies provided by the applicant and concludes that since there are no indications of relevant compositional differences, additional animal feeding studies are not necessary.

The panel recognises the importance of the issue concerning residues of glyphosate and its metabolite in GT73 oilseed rape and notes that the risk assessment of such compounds is within the scope of Directive 91/414/EEC concerning the placing of plant protection products on the market.

5 Environmental risk assessment and monitoring plan

5.1 Issues raised by the Member States

Several Member States felt that the monitoring plan was inadequate. The monitoring plan was requested on the basis that seed spillage could occur during import and transport, and that the GT73 oilseed rape may have a selective advantage in that this trait may spread to wild populations of the *Brassica* group. It was stated that Italy is a centre of origin of *Brassica* and that the issue of dispersal of transgenic oilseed rape was a particular concern in this country. Finally, a comprehensive environmental risk assessment was requested by one Member State.

5.2 Relevant background data

5.2.1 Environmental risk assessment

The notification C/NL/98/11 for GT73 oilseed rape is for import only, and thus there is no requirement for scientific information on environmental effects associated with the cultivation of GT73 oilseed rape. In the environmental risk assessment the applicant has indicated that oilseed rape is an out-crossing, open pollinating crop with effective dispersal systems for pollen. It also produces large quantities of small seeds. These seeds are very robust and can remain viable in soil for many years. Oilseed rape also exists as a weed in other crops and can colonise semi-natural habitats. It can also out-cross with other Brassicae especially *Brassica rapa* and disperse genes through this species (OECD, 1997).

Studies with GT73 oilseed rape have not shown any enhanced weediness or fitness, except when glyphosate herbicide is applied (Crawley et al., 2001). The environmental risk assessment concludes that the likelihood for unintended environmental effects due to the establishment and spread of GT73 oilseed rape will not be different from that of traditionally bred oilseed rape. Even if feral populations of GT73 oilseed rape were established and transgene flow occurs at a low frequency to cultivated oilseed rape and/or other Brassicae, a selective advantage only occurs if the complementary herbicide is applied. The GMO Panel agrees with this assessment. The Panel also took into account the fact that the notification did not include cultivation of the plants within the EU. Taking these factors into account the Panel considered that the statement that Italy is a centre of origin was not applicable in this case.

5.2.2 Monitoring plan

The objectives of a monitoring plan according to Annex VII of Directive 2001/18/EC are to (1) confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO, or its use, in the environmental risk assessment are correct, and (2) identify the occurrence of adverse effects of the GMO, or its use, on human health or the environment which were not anticipated during the environmental risk assessment. The scope of the monitoring plan provided by the applicant is in line with the intended uses for the GMO since the environmental risk assessment did not cover cultivation.

Additional information supplied by the applicant on the assessment of oilseed rape imported from North America into the European Union leads to the following conclusion: North American oilseed rape is imported into Europe and crushed either at certain seaports of discharge or at ports located along the river Rhine. Crushing plants away from rivers tend to supply themselves from domestic production. The crushing industry is HACCP (Hazard Analysis and Critical Control Point) compliant. Operators are trained to avoid or minimize spillage and to ensure that spills are cleaned up promptly. Oilseed rape plants eventually germinating in the crushing facility have to be removed in order to be in compliance. In the unlikely event that spillage, germination and flowering of a GT73 oilseed rape plant occurred in the ports and associated crushing plants, their location in industrial areas makes it highly unlikely that gene transfer to non-GM Brassicae would occur. The applicant therefore submits that case-specific monitoring for spillage and gene transfer are not required as conditions of any consent to import, handle and process GT73 oilseed rape. The GMO Panel agrees with this conclusion.

5.3 Conclusion

The GMO Panel considers the environmental risk assessment and monitoring plan acceptable in the light of the intended use of GT73 oilseed rape. The Panel advises that appropriate management systems should be in place to restrict seeds of GT73 oilseed rape entering cultivation, as the latter requires specific approval under Directive 2001/18/EC.

6 Other issues raised by the Member States

The traceability and labelling arrangements are considered inadequate. Conditions for co-existence with GMO-free production methods and the issues concerning liability should be resolved.

The Panel is not in a position to evaluate these issues which relate to risk management and not risk assessment.

CONCLUSIONS

In accordance with Article 29 (1) (a) of the Regulation (EC) No 178/2002, the European Commission has requested EFSA to issue a scientific opinion as to whether the placing on the market of GT73 oilseed rape, for import and processing, is likely to cause any adverse effects on human health and the environment in the context of Directive 2001/18/EC. The EFSA GMO Panel considered the information made available by the applicant as sufficient to assess the safety of GT73 oilseed rape and to address all the specific questions raised by the Member States related to risk assessment. Therefore additional experimental studies are not deemed necessary.

GT73 oilseed rape has been developed for tolerance to glyphosate herbicide by the introduction of a glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthase gene (*epsps*) from *Agrobacterium* sp., and a glyphosate-degrading glyphosate oxidoreductase gene (*gox*) from *Ochrobacter anthropi*. The GMO Panel has considered information provided on (1) the molecular inserts within the transgenic event, (2) the chemical composition of the GM and non-GM oilseed rape, (3) the safety of the proteins expressed and (4) the potential for risks associated with any changes to the toxicological, allergenic or nutritional properties of GT73 oilseed rape. Having considered the evidence, the GMO Panel is of the opinion that GT73 oilseed rape is as safe as conventional oilseed rape for humans and animals, and, in the context of its proposed use, the environment.

DOCUMENTATION PROVIDED TO EFSA

1. Notes to Ms. Husu-Kallio (DG SANCO) from Catherine Day (DG ENVIRONMENT) concerning a request to the European Food Safety Authority for a scientific opinion on the notification C/NL/98/11 for the placing on the market of GT73 Roundup Ready oilseed rape, for import and processing, under Part C of Directive 2001/18/EC from Monsanto (annex 2 of note dated 12 September 2003, with ref. C4 KT (2003)/441457: advance copy; note dated 10 October 2003, with ref. C4 KT D(03)/441563)
2. Letter to Mr. Podger, dated 23 October 2003 with ref. SANCO.D5/MW D(2003) 450135, from Ms. Husu-Kallio and following correspondence with EFSA (ref. HK/sm (2003) 2, 7 November 2003; HK/sm (2003) 490, 17 December 2003).
3. Initial comments from the Member States with regard to Notification GT73 Roundup Ready oilseed rape (Directive 2001/18/EC)
4. Meeting record between the competent authorities, applicant and Commission, on 28 April 2003, where the objections were discussed
5. Objections from Member States with regard to Notification C/NL/98/11 (GT73 oilseed rape under Directive 2001/18)
6. Submission from Monsanto Services International (28 October 2003) to EFSA concerning the scientific review by EFSA of the Application for consent to place on the market Roundup Ready® oilseed rape derived from line GT73 (C/NL/98/11) containing

    a. Notification letter for Roundup Ready® oilseed rape derived from line GT73 (C/NL/98/11)
    b. Directive 90/220/EEC application dossier for Roundup Ready® oilseed rape derived from line GT73; also confidential appendices
    c. Supplementary information to Directive 90/220/EEC application dossier; also confidential part
    d. Supplementary information according to Directive 2001/18/EC
    e. Non-confidential summary of the application dossier (SNIF)
    f. Initial assessment report by the Dutch lead competent authority
    g. Notifier's response to Member State questions issued during the 60-day Member State consultation period (non-confidential part; also confidential appendices)

7. Additional information from Monsanto to the Member States following the responses to Member State objections submitted on July 3rd 2003 (November 13th 2003; submitted through the Dutch Competent Authority and DG Environment on 26 November 2003).
8. Updated initial assessment report by the Dutch Competent Authority (submitted through DG Environment on 12 January 2004)
9. Letters from EFSA to applicant with request for clarification/additional information (ref. SR/ (2004) 002, 7 January 2004; SR/ (2004) 084, 23 January 2004).
10. Correspondence between EFSA and DG Environment regarding the request for additional information and the scope of the application (ref. HK/(2004) 051 of 19 January 2004; HM/SM/sf/D(04) 440091 of 21 January 2004).
11. Additional information from Monsanto to the GMO Panel following a request from EFSA for additional information (submitted through the Dutch Competent Authority; ref. C/NL/11.18 on 15 and 22 January 2004).

REFERENCES

ACNFP, 1995. Report on oil from a genetically modified glyphosate-tolerant oilseed rape. Annual Report 1995, Appendix IV. Advisory Committee on Novel Foods and Processes, UK. http://www.foodstandards.gov.uk/multimedia/pdfs/acnfp_app_iii-vi95.pdf

Brown, P.B., Wilson, K.A., Jonker, Y., Nickson, T.E., 2003. Glyphosate tolerant canola meal is equivalent to the parental line in diets fed to rainbow trout. J. Agric. Food Chem., 51, 4268-4272.

CAC, 2003. Codex principles and guidelines on foods derived from biotechnology. Joint FAO/WHO Food Standards Programme, Food and Agriculture Organisation, Rome. ftp://ftp.fao.org/codex/standard/en/CodexTextsBiotechFoods.pdf

Crawley, M.J., Brown, S.L., Hails, R.S., Kohn, D.D., Rees, M., 2001. Transgenic crops in natural habitats. Nature, 409, 682-683.

EC, 1991. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. Official Journal of the European Communities, L230, 1-32. http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31991L0414&model=guichett

EC, 1997. Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal of the European Communities L43, 1-7. http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997R0258&model=guichett

EC, 1998. Summary of notifications received in 1997 by the Commission pursuant to Article 5 of European Parliament and Council Regulation (EC) No 258/97. Official Journal of the European Communities C 200, 16. http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/c_200/c_20019980626en00160016.pdf

EC, 1999. Commission Regulation (EC) No 2316/1999 of 22 October 1999 laying down detailed rules for the application of Council Regulation (EC) No 1251/1999 establishing a support system for producers of certain arable crops. Official Journal of the European Communities, L280, 43-65.
http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/l_280/l_28019991030en00430065.pdf

EC, 2001. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Official Journal of the European Communities, L106, 1-39.
http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf

EC, 2002. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ, L31, 1-24.
http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

EC, 2003. Guidance document for the risk assessment of genetically modified plants and derived food and feed, prepared by the Joint Working Group on Novel Foods and GMOs, 6-7 March 2003.
http://europa.eu.int/comm/food/fs/sc/ssc/out327_en.pdf

EFSA, 2003. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference CE/ES/00/01) for the placing on the market of herbicide-tolerant genetically modified maize NK603, for import and processing, under Part C of Directive 2001/18/EC from Monsanto. The EFSA Journal, 10, 1-13.
http://www.efsa.eu.int/pdf/gmo/opinion_gmo_03_final_en.pdf

Goodman, R.E., Silvanovich, A., Hileman, R.E., Bannon, G.A., Rice, E.A., Astwood, J.D., 2002. Bioinformatic methods for identifying known or potential allergens in the safety assessment of genetically modified crops. Comments on Toxicology, 8, 251-269.

Hileman, R.E., Silvanovich, A., Goodman, R.E., Rice, E.A., Holleschak, G., Astwood, J.D., Hefle, S.L., 2002. Bioinformatic methods for allergenicity assessment using a comprehensive allergen database. Int. Arch. Allergy Immunol., 128, 280-291.

Ivanciuc, O., Schein, C.H., Braun, W., 2002. Data mining of sequences and 3D structures of allergenic proteins. Bioinformatics, 18, 1358-1364.

Jain, S.M., 2001. Tissue culture-derived variation in crop improvement. Euphytica, 118, 153-166.

Klassen, A.J., Downey, R.K., Capcara, J.J., 1987. Westar summer rape. Can. J. Plant Sci., 67, 491-493.

Kleter, G.A., Peijnenburg, A.A.C.M., 2002. Screening of transgenic proteins expressed in transgenic food crops for the presence of short amino acid sequences identical to potential, IgE-binding linear epitopes of allergens. BMC Structural Biology, 2, 8.
http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=139984&action=stream&blobtype=pdf

Metcalfe, D.D., Astwood, J.D., Townsend, R., Sampson, H.A., Taylor, S.L., Fuchs, R.L., 1996. Assessment of the allergenic potential of foods derived from genetically engineered crop plants. Crit. Rev. Food. Sci. Nutr., 36(S), 165-186.

Monsalve, R.I., Gonzalez de la Pena, M.A., Lopez-Otin, C., Fiandor, A., Fernandez, C., Villalba, M., Rodriguez, R., 1997. Detection, isolation and complete amino acid sequence of an aeroallergenic protein from rapeseed flour. Clin. Exp. Allergy, 27, 833-841.

Nickson, T.E., Hammond, B., 2002. Chapter 7: Canola tolerant to Roundup herbicide. An assessment of its substantial equivalence to non-modified canola. Genetically Modified Crops. Assessing safety, 138-163.

OECD, 1997. Consensus document on the biology of *Brassica Napus* L. (oilseed rape). Series on harmonization of Regulatory Oversight in Biotechnology No. 7. Organisation for Economic Co-operation and Development, Paris.
http://www.oecd.org/dataoecd/28/22/27531440.pdf

OECD, 2001. Consensus document on key nutrients and key toxicants in low erucic acid rapeseed (canola). Series on the Safety of Novel Foods and Feeds No. 1, ENV/JM/MONO(2001)13. Organisation for Economic Co-operation and Development, Paris.
http://www.olis.oecd.org/olis/2001doc.nsf/43bb6130e5e86e5fc12569fa005d004c/19f31700dc91b614c1256b19003bd79d/$FILE/JT00118009.PDF

Palmer, M.V., Sang, J.P., Oram, R.N., Tran, D.A., Salisbury, P.A., 1988. Variation in seed glucosinolate concentrations of Indian mustard (*Brassica juncea* (L.) Czern. + Coss.). Aust. J. Exp. Agric. 28, 779-782.

SCP, 1998a. Opinion of the Scientific Committee on Plants regarding the genetically modified cotton, tolerant to glyphosate herbicide notified by the Monsanto Company (notification C/ES/97/01).
http://europa.eu.int/comm/food/fs/sc/scp/out17_en.html

SCP, 1998b. Opinion of Scientific Committee on Plants regarding submission for placing on the market of fodder beet tolerant to glyphosate notified by DLF-Trifolium, Monsanto and Danisco Seed (notification C/DK/97/01).
http://europa.eu.int/comm/food/fs/sc/scp/out16_en.html

Soeria-Atmadja, D., Zorzet, A., Gustafsson, M, Hammerling, U., 2004. Statistical evaluation of local alignment features for prediction of allergenicity using supervised classification algorithms. Int. Arch. Allergy Immunol., 133, 101-112.

Stanford, K., Aalhus, J.L., Dugan, M.E.R., Wallins, G.L., Sharma, R., McAllister, T.A., 2003. Effects of feeding transgenic canola on apparent digestibility, growth performance and carcass characteristics of lambs. Can. J. Anim. Sci., 83, 299-305.

Suh, C.-H., Park, H.-S., Nahm, D.-H., Kim, H.-Y., 1998. Oilseed rape allergy presented as occupational asthma in the grain industry. Clin. Exp. Allergy, 28, 1159-1163.

Taylor, M.L., Stanisiewski, E.P., Riordan, S.G., Nemeth, M.A., George, B., Hartnell, G.F., 2004. Comparison of broiler performance when fed diets containing Roundup Ready (event RT73), nontransgenic control, or commercial canola meal. Poultry Sci., 83 (in press).

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[4] Information on the declarations of interest can be found in the minutes of the 5th Plenary meeting of the GMO Panel: http://www.efsa.eu.int/pdf/minutes_gmo_05_final_en.pdf