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Austria	Ministry of Health, Family and Youth	D, 02 Information on the sequences actually inserted or deleted	The notifier presents data to support that a single insertion of transgenic DNA is present in GT73 oilseed rape based on comparison with the non-modified oilseed rape variety Westar. However additional data to corroborate the conclusion should be submitted, since the analysis by Southern Blot is based on the identification of hybridising fragments in a high-molecular weight range (outside the range of the molecular weight markers as indicated on the blots). Such high-molecular weight fragments are difficult to differentiate and the data submitted cannot be regarded as being "distinctive" as concluded by the notifier. Additionally the positive control used in the experiment documented in Fig. 6 (technical dossier p.45) was used in excess quantities and is composed of low molecular fragments only in contrast to the high-molecular weight fragments identified for GM oilseed rape GT73. The analysis furthermore is not complemented by an evaluation of the sensitivity of the detection system to assess the minimal length of partial insertions detectable in the experiments. The same weakness of the assessment applies to the analysis of vector backbone sequences present or absent in GM oilseed rape GT73. Regarding the issue of sensitivity of experiments the submitted data apparently indicate that conditions of lower sensitivity were chosen. Fig. 5 (technical dossier p. 44) depicts the probes used for Southern Blot analysis of individual inserted elements and shows that the probes used to detect goxv247 and cp4epsps-elements present in the GT73 insert extend into the E-9 terminator sequence. The results of the analysis using these probes however indicate that only the goxv247 and cp4epsps-elements are detected. This suggests that the stringency of detection system used was set in a way that only full length elements are detected. That raises the question whether the sensitivity of the analysis was high enough to detect any partial insertions of transgenic sequences. However according to EFSA guidance the molecular characterisation should be designed to identify any partial inserts present in a specific GM plant. The notifier is requested to submit additional data of complementing experiments, which are properly designed, of	The GMO Panel agrees that the Southern analyses were not of very high quality. However, a fragment ca. 6% of the full length of the insert was clearly visible. Also clearly visible was the spiked plasmid DNA that corresponded to 0.5 gene copy per genome. The Panel therefore concludes that the sensitivity of the Southern analyses was sufficient. Overall, the dataset gave no indication of insertions other than the one reported by the applicant. The GMO Panel points out that the risk assessment of a GM product is based on several considerations and that molecular characterization is only one part of the risk assessment process.

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			high technical quality and address the mentioned ambiguities. Specifically with regard to detection of potential partial insertions of transgenic elements further data should be submitted, together with a demonstration of the sensitivity of the used methods.	
Austria	Ministry of Health, Family and Youth	D, 03 Information on the expression of the insert	For the assessment of expression of goxv247 and cp4epsps in GM oilseed rape GT73 data from field trials at Canadian locations (from 1992 and 1993) as well as data from European locations (from 1994, 1995 and 1995/96 growing seasons) were submitted. However, only seed material was analysed in all trials. Only in the trials conducted in Canada 1992 and Europe 1995 as well as for a GT73 winter oilseed variety 1995/96 leaf material was analysed for expression of transgenic components as the only other plant tissue in GM oilseed rape GT73. Furthermore different varieties were used for the mentioned trials and the designs of the trials were not comparable (e.g. number of locations, replications, etc.). For some of the trials (Canada 1993 and Europe 1994 and 1995) data were submitted for GM oilseed rape GT73 treated and not-treated with Glyphosate. However for the Canadian trials 1992 and for the European winter-oilseed rape trial 1995/96 only results for GM oilseed rape GT73, which was not-treated with Glyphosate were submitted. Regarding developmental expression of transgenic components only data for mature seed are available for all indicted trials. The analysis of leaf tissue from Canadian (1992) and European trials (1995 and 1995/96) lacks detail to assess at which growth stage the samples had been taken (specifically for European trials 1995 and 1995/96). Therefore the analysis of developmental expression falls short of an adequate assessment. The notifier is therefore requested to submit additional data for a comprehensive assessment of expression of transgenic components in GM oilseed rape GT73. Specifically supplementary data to assess developmental expression and expression in different tissues need to be supplied. Furthermore the notifier shall submit specific information on the varieties used for the assessment, e.g. based on a breeding history of GM oilseed rape GT73, to identify which	The scope of the application includes food and food ingredients, as well as feed materials, feed additives and food additives produced from oilseed rape GT73. The application excludes cultivation. For this reason, expression data on the two proteins in mature seeds are considered sufficient by the GMO Panel. Two novel proteins are expressed in GT73: GOXv247 and CP4 EPSPS. There is no evidence that either of these proteins has toxic or allergenic properties. Most studies were carried out using GT73 (heterozygous or homozygous for the glyphosate tolerance trait) and Westar parent. In one season in Europe, GT73 crossed with two winter oilseed rape varieties (Libero, Composite Hybrid) was analysed; the crossing was well justified. The different genetic backgrounds did not appear to affect the expression levels. Glyphosate treatment did not influence the expression levels of the two proteins. Altogether, expression data for the two proteins were provided from five growing seasons in a number of locations in Canada and Europe. The GMO Panel considers this sufficient for evaluation purposes.

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			GM oilseed rape GT73 lines were used in the conducted trials.	
Austria	Ministry of Health, Family and Youth	D, 03 Information on the expression of the insert	Expression of potential fusion proteins The notifier submitted information that 13 potential fusion proteins were identified by bioinformatics analysis at the junction regions of transgenic insert sequences and flanking genomic sequences (including a 22 bp sequence of unknown origin). The notifier should address, whether all the FAO/WHO criteria for bioinformatics have been implemented in the analysis of the potential fusion proteins for possible allergenic effects. Furthermore the analysis is not supported by any experimental data. Therefore the notifier is requested to submit additional experimental evidence that the identified potential fusion proteins are not transcribed and translated into proteins in GM oilseed rape GT73.	On the request of the GMO Panel the applicant provided an updated bioinformatic search for putative open reading frames spanning the GT73 insert – genomic junction (both 5' and 3') which may be created as a result of the genetic modification, in order to assess the potential for production of novel chimeric proteins with homology to known toxins, allergens or other bioactive peptides. The data do not indicate any safety concerns from the potential production of new toxins. No putative peptide met or exceeded the Codex Alimentarius Commission threshold for potential allergenicity of 35% identity over 80 amino acids, or of at least eight consecutive identical amino acids. The bioinformatic analyses thus confirmed the original analysis carried out by the applicant.

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Austria	Ministry of Health, Family and Youth	D, 05 Genetic stability of the insert and phenotypic stability of the GM plant	The notifier is requested to explain how the data included in the technical dossier on genetic stability as well as phenotypic stability were established (see technical dossier p.82-84). Specifically for the analysis of genetic stability the notifier is requested to indicate the history of the used lines of GM oilseed rape GT73 based on a breeding history. Furthermore the notifier shall explain which number of individual plants have been analysed by Southern Blot as well as PCR analysis to conclude genetic stability (according to technical dossier p. 82-83, Kolacz and Higgins 1995, Taylor et al 1997a). The notifier shall additionally explain differences between data submitted in the technical dossier and in Kolacz and Higgins 1995, since apparently different sets of probes were used for the analyses. Regarding the phenotypic analysis of 3rd generation offspring plants the notifier is requested to address ambiguities of the submitted description. First of all the dossier information indicates that the assessment is based upon data of a trial conducted 1994 in Belgium (referring to Brants 1995). However the data presented in Table 13 (tech. dossier p.84) are apparently taken from a report by J. Patel (Pioneer Hi Bred Int.) annexed to the report by Brant (1995), which analysed F3 offspring of several GM oilseed rape varieties supplied by Monsanto at field trials in Canada. With regard to these data the notifier is requested to additionally explain whether the GM oilseed rape variety (17209-121-1), which is analysed in detail according to the report, is corresponding to GM oilseed rape GT73 or to another GM oilseed rape variety developed by Monsanto. On the other hand data of the trial conducted in Belgium (Brants 1995) for was not analysed further in the technical dossier. The notifier shall specifically address these data in relation to the conclusions drawn. The notifier is therefore requested to present a comprehensible assessment of the genetic and phenotypic stability, and specifically to submit additional information addressing the mentioned questions.	Evidence for both genetic and phenotypic stability was provided in the original application across several generations of propagation, during breeding in different genetic backgrounds, and under different environmental conditions both in Canada and in Europe. The stability of the herbicide tolerance trait is ensured by a seed quality and stewardship program put in place by the applicant to maintain the performance of the product.

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Austria	Ministry of Health, Family and Youth	D, 07.01 Comparative assessment	The field trials in Canada showed higher contents of alkyl glucosinolates in the GT73 as compared to the parental line Westar (Nickson & Taylor 1994). It is stated that all values were below the commercial threshold. Further more lower glucosinolate levels were found in France as compared to the other two European field trials, but this fact was not discussed e.g. in relation to site or weather conditions. Therefore clarification is needed. In the European field trials performed at 3 locations (France, Belgium, UK), ranges and mean values as an average of the means of samples from each of 3 sites for GT73-A (untreated), GT73-B (treated) and Westar were presented. Thus any detailed comparisons relating to site conditions are not possible due to the lack of original data which can not be regarded as appropriate: These solely comparisons of ranges of compounds are apt to level any individual changes. But it was still notable, that the protein contents in seeds were generally higher in Canada as compared to Europe: It is stated by Taylor (1995) with regard to the European field trials: "The values for ranges of % protein (in defatted meal) in GT73 are 36.0-40.5% and 37.1-40.2% for GT73-A (untreated) and GT73-B (treated), respectively, which are consistent with the range of results for Westar (37.8 - 41.0%) from this study". In the Canadian field trials 1992 and 1993 the mean values as well as the value ranges were higher (Table 14, Techn. Dossier, page 87): In 1993 the Canadian ranges were 39,6-44,8% for untreated GT73 and 40,2-44,7% for treated GT73. It is suggested that these observations should be clarified by the notifier. Therefore the conclusion that "the composition analyses support the conclusion that GT73 grown in the European field trials is equivalent to GT73 and Westar grown in Canada" is a very rough estimate based on the wide compound ranges at all possible for the variant not suitable for a comprehensive risk assessment.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the comparative assessment that could change its previous conclusion. With regard to the glucosinolate levels in Roundup Ready canola GT73, a follow-up study (1998-2001) of Canadian cooperative extension trials reports that the levels of glucosinolates in GM varieties (glyphosate- and glufosinate-resistant varieties) actually were on average below those of conventional varieties, which probably is more influenced by the presence of weed seeds in the harvested crop seed than the genetic modification itself. (J.K. Daun, 2004, Journal of Agricultural Science 142, 273-280; abstract at http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=266025). According to the guidance developed by EFSA and Codex alimentarius, the initial focus of the comparative assessment should be on the comparison between the GMO and its control. In section 3.2.2 of the previous opinion on GT73 (2004), the compositional analysis is summarized as follows: "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,

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				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." As can be inferred from the quote above, the EFSA GMO Panel has previously considered the comparison between GT73 and its direct control throughout multiple seasons and across different environments.

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Austria	Ministry of Health, Family and Youth	D, 07.04 Agronomic traits	Agronomic Traits and Substantial Equivalence (Annex 5; Annex 6) Nickson & Taylor (1994) conclude in their summary, that "the environment will benefit from the use of an environmentally friendly herbicide." This statement implies first, that glyphosate is an environmentally friendly herbicide and second, that no glyphosate tolerant weeds will evolve, necessitating the additional use of other, possibly less environmentally friendly herbicides. Both statements are based on assumptions, since the negative effects of glyphosate are well documented and up to 10 glyphosate tolerant weeds have already been discovered (Pechlarner, R., Pfister, P., Pipp, E., Rott, E. (2003): Threats to freshwater ecosystems from glyphosate-based herbicide applications on land. Angewandte Gewässerökologie GesmbH, Innsbruck, TIROL, AUSTRIA VanGessel M.J., 2001: Rapid Publication. Glyphosate-resistant horseweed from Delaware, Weed Science 49: 703-705 Heap I.M. 2000: The occurrence of herbicide-resistant weeds worldwide. Pesticide Science 51, 235-243; Hin C.J.A. et al, 2001: Agronomic and environmental impacts of the commercial cultivation of glyphosate tolerant soybean in the USA. CLM Centre for Agriculture and Environment, Utrecht.).	Issues related to plant-protection products are regulated by Directive 91/414/EEC and fall outside the remit of the GMO Panel.

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Austria	Ministry of Health, Family and Youth	D, 07.08 Toxicology	Toxicity studies The toxicity tests (simulated digestion, acute oral toxicity) were done with the E. coli expressed transproteins. Such studies provide only limited evidence for safety. Acute toxicity in mice Two acute toxicity studies were performed (CP4 EPSPS and GOXv274) but no details on the guideline used were found. OECD guideline 407 known as repeated oral toxicity study should be preferred to any other. Test period of these studies was only 7 days. No differences were seen in body weight, cumulative body weight or food consumption but still uncertainty exists because no haematology, clinical biochemistry and no microscopic investigation were performed as suggested by OECD guidelines. Therefore clarification and further investigations by the notifier are regarded as necessary. Testing of the whole GM food/feed The first rat study (Naylor 1994b) as well as the trout-study have to be excluded from risk assessment due to the fact that the diets were contaminated/mixed(?) with OSR GT200. Appreciated was the fact, that both, heat treated and not heat treated meal was applied in the rat study. In the second rat study (Naylor 1995) only processed meal was fed. Despite this fact liver weights differed between groups. It is of special interest to investigate the meal without heat treatment as transproteins are heat labil. Further, this is an indicator for carrying out a more appropriate study design for toxicological approach and a 90 day rodent toxicity study including microscopic evaluation is therefore highly recommended. The third study (Naylor 1996) was set up with a different study design where one GM variety was compared with several non-GM varieties and a rat chow as negative control. No differences in body weight, cumulative weight gain, terminal body weights or feed consumption or any organ weights were seen. It is a fact that the more varieties used, the higher is the variability and the lower the likelihood of statistically significant differences. Only near isogenic control groups should be included in the test design.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the toxicology assessment that could change its previous conclusion. With regard to acute toxicity studies in rodents, these are used to establish LD50 values and usually no additional parameters are analyzed besides the ones mentioned (e.g. the clinical/histo-pathological parameters are usually measured in longer-term studies). The previous opinion also describes the outcomes of additional studies provided for the assessment potential toxicity of the purified newly expressed proteins that have been evaluated by the EFSA GMO Panel, including bioinformatics and *in vitro* resistance to protein-degrading enzymes (such as pepsin; see previous opinion published in 2004 for details). According to EFSA's and Codex alimentarius' guidance on the safety assessment of foods (and feed) derived from genetically modified plants, testing of the whole product only has to be performed on a case-by-case basis, both for safety testing (e.g. oral 90-days rodent study) and for nutritional value testing (e.g. fish feeding studies). In the EFSA GMO Panel's evaluation (dated 15 June 2009) of Austria's scientific underpinning of the latter's safeguard clause on oilseed rape event GT73, it is concluded that "Because the compositional analysis of oilseed rape GT73 gave no indications of any changes, no further in vitro or in vivo toxicological testing was deemed necessary." In its previous opinion on oilseed rape event GT73 (dated 2004), the EFSA GMO Panel indeed took note of the reported contamination of oilseed meal tested in various feeding studies (e.g. in rat, rainbow trout, and quail). As mentioned in the

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				previous opinion, the outcomes of these feeding studies were therefore not taken into consideration by the EFSA GMO Panel In section 4.2.3 of its previous opinion on oilseed rape event GT73, the EFSA GMO Panel thus summarizes and evaluates the data on animal feeding studies as follows: "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 glyphosatetolerant 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.

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				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

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				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.

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				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,

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				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."
Austria	Ministry of Health, Family and Youth	D, 07.10 Nutritional assessment of GM food/feed	Nutritional assessment of GM food/feed Studies were following the guidelines and did include animals in growing and finishing period. But to the bioavailability of nutrients was paid little attention and only feed intake, body weight and general performance as well as feed efficiency were investigated. Further tests are suggested to be carried out.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the feed safety and nutritional assessment that could change its previous conclusion. According to EFSA's and Codex alimentarius' guidance on the safety assessment of foods (and feed) derived from genetically modified plants, testing of the whole product only has to be performed on a case-by-case basis, both for safety testing (e.g. oral 90-days rodent study) and for nutritional value testing (e.g. fish feeding studies). In the EFSA GMO Panel's evaluation (dated 15 June 2009) of Austria's scientific underpinning of the latter's safeguard clause on oilseed rape event GT73, it is concluded that "Because the compositional analysis of oilseed rape GT73 gave no indications of any changes, no further in

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				vitro or in vivo toxicological testing was deemed necessary." In its previous opinion on oilseed rape event GT73 (dated 2004), the EFSA GMO Panel indeed took note of the reported contamination of oilseed meal tested in various feeding studies (e.g. for rat, rainbow trout, and quail). As mentioned in this previous opinion, the outcomes of these feeding studies were therefore not concluded on by the EFSA GMO Panel In section 4.2.3 of its previous opinion on oilseed rape event GT73, the EFSA GMO Panel thus summarizes and evaluates the data on animal feeding studies as follows: "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 glyphosatetolerant or control oilseed rape meal. Rats fed oilseed rape meal had higher liver to body weight ratio than rats

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				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

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				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

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				(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

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				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."
Belgium	Belgian Biosafety Advisory Council	D, 07.01 Comparative assessment	The glucosinolate content of single meal samples from GT73 and Westar was measured. The value for alkyl glucosinolates was 10.5 µmole/g defatted meal (butenyl, pentenyl, hydroxybutenyl and hydroxypentenyl glucosinolates) and 4.7 µmole/g defatted meal for GT73 and Westar, respectively. The approximately two-fold difference in alkyl glucosinolates is possibly a result of differential loss upon processing. Q: Aren't the processed in exactly the same way?	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the comparative assessment that could change its previous conclusion. With regard to the glucosinolate levels in Roundup Ready canola GT73, a follow-up study (1998-2001) of Canadian cooperative extension trials reports that the levels of glucosinolates in GM varieties (glyphosate- and glufosinate-resistant varieties) actually were on average below those of conventional varieties, which probably is more influenced by the presence of weed seeds than the genetic modification itself. (J.K. Daun, 2004, Journal of Agricultural Science 142, 273-280; abstract at

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				http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=266025). Besides the pilot-processed toasted meal fractions that Belgium refers to, the glucosinolate content of defatted meal obtained at a laboratory-scale was tested for the compositional analysis of oilseed rape GT73 and its comparators harvested during various field trials in multiple seasons. Section 3.2.2 of the EFSA GMO Panel's previous opinion on the glucosinolate levels measured during compositional analysis GT73 summarizes and evaluates this as follows: "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

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				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

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				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."
Belgium	Belgian Biosafety Advisory Council	D, 07.03 Selection of compounds for analysis	It is recognised in the dossier that tannins, saponins and sinapine are substances that may restrict the use of oil seed rape meal in animal foodstuffs (part II, page 12). Thus it is surprising that no values for tannins and saponins are reported. However, based on the animal feeding studies reported it is expected that the meal of rapeseed GT73 poses no extra problem compared to regular rapeseed meal. Nutritional properties of non-modified canola meal have been published (Animal Feed Resources Information System). Anonymous. Animal Feed Resources Information System. Canola meal, Rapeseed meal, 00-Rapeseed, 0-Rapeseed http://www.fao.org/ag/Aga/AGAP/FRG/afris/Data/724.htm	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information that could change its previous conclusion. Thank you for the interesting reference to the FAO document. It may be useful to note here that OECD develops consensus documents on key compositional parameters that can be used in the comparative assessment of new varieties of crops. The OECD consensus document on low-erucic-acid rapeseed mentions tannins, saponine, and sinapine as other constituents "that may be considered" besides glucosinolates, which are described as key toxicants (see http://www.olis.oecd.org/olis/2001doc.nsf/LinkTo/NT0000098E/$FILE/JT00118009.PDF). These consensus documents are also referred to by EFSA guidance as reference for the compositional analysis (see section 7.3. of the EFSA guidance for safety data required for applications for food/feed derived from GM crops).

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Belgium	Belgian Biosafety Advisory Council	D, 07.08 Toxicology	Testing of the whole GM food/feed 42-day feeding study with broiler chickens (Stanisiewski et al., 2001; Stanisiewski et al., 2002; Taylor et al., 2004) Sixty two out of the 800 total birds died during the study. The distribution of the broilers that died from day 7 to study termination was random across treatments (deaths per treatments averaged 7.8% and ranged from 2% to 17% across all treatments). Most of the apparent causes of death were identified at necropsy and occur commonly in chickens (sudden death syndrome and ascites). The highest mortality occurred in the treatment group fed the parental control (17%), followed by the test line (13%). The mortality in this study was slightly higher than expected; the majority of deaths occurred in the males, which can be expected since males are heavier and grow faster than females. A possible explanation for the high mortality rate could be that canola meal was incorporated into diets at an upper extreme (25% wt/wt canola meal during the first 20 d and 20% wt/wt canola meal thereafter) relative to industry practice (12-15%). However, broilers in all treatment groups were in good health based on twice daily pen observations. The starting and final body weights of the chicks were normal and the average body weight gain/bird values were comparable between treatments. In both Stanisiewski et al., 2001 and Stanisiewski et al., 2002 only the CP4 EPSPS protein is mentioned. What about the GOXv247? In Taylor et al., 2004 both are mentioned.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the toxicology assessment that could change its previous conclusion.
Belgium	Belgian Biosafety Advisory Council	D, 07.08 Toxicology	Comment 1 For reasons of comparison the question has been raised to provide the data on the GOXv247 and CP4 EPSPS concentrations in leaf and seed in ng/mg Dry Weight. Comment 2:CP4 EPSPS: Acute Oral Toxicity Study in Mice (Naylor, 1993). In the study, the E. coli-purified CP4 EPSPS protein was administered as a single dose by gavage to groups of 10 male and 10 female CD-1 mice at dose levels up to 572 mg/kg. There were no treatment-related effects on survival, clinical observations, body weight gain, food consumption or gross pathology. Therefore, the No Observed Effect Level (NOEL) for CP4 EPSPS was considered to be equal to or greater than 572	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the toxicology assessment that could change its previous conclusion. Issues related to plant-protection products are regulated by Directive 91/414/EEC and fall outside the remit of the GMO Panel.

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			mg/kg, the highest dose tested. The CP4 EPSPS content in oil seed rape is about 5 till 10 times as low as the GOXv247 content. Why then is the highest used dose in acute toxicity testing about 5 times smaller for GOXv247 compared to CP4 EPSPS? Comment 3: Testing of new constituents other than proteins Although it is realised that the residue issue falls outside the scope of Regulation 1823/2003, I think that it is worthwhile to take a stand about the question whether components that are taken up by the plant without killing it due to the genetic modification, and their subsequent metabolites are to be considered as residues or rather as new constituents. Indeed, they could be accumulated in plant tissues and not be reduced by cleaning procedures. Accumulation of glyphosate and is major metabolite AMPA has been described in transgenic glyphosate-resistant soybean (Aregui et al., 2004). In the case of GT73 this may not be a problem. Major metabolites in the plant are the same as in the environment and it is claimed as a comment in the broiler feeding study that pesticide levels (which ones?) in GT73 were below the limit of detection (Part I, page 135). An "estimate of acceptable daily intakes for humans" has been made for glyphosate and AMPA (Joint Meeting of the FAO Panel of Experts on Pesticide residues in Food and the Environment and the WHO Core Assessment Group, 1997). Arregui MC, Leardon A, Sanchez D, Maitre MI, Scotta R, Enriquez S. Monitoring glyphosate residues in transgenic glyphosate-resistant soybean. Pest Manag Sci 2004: 163-166. Joint Meeting of the FAO Panel of Experts on Pesticide residues in Food and the Environment and the WHO Core Assessment Group, 1997. Pesticide residues in food – 1997. http://www.inchem.org/documents/jmpr/jmpmono/v097pr04.htm	Finally, 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.

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Belgium	Belgian Biosafety Advisory Council	D, 07.09 Allergenicity	Assessment of the allergenicity of the whole GM plant or crop. The applicant did not evaluate the potential allergenicity of oilseed rape GT73, mainly on the basis that oilseed rape is not an allergen source. However, rapeseed allergy has been recently described and 2S albumin has been demonstrated as being an allergen of oilseed rape (1, 2). The 2S albumins are seed pan-allergens. Of note, the determination of oilseed rape allergenicity in the aforementioned references relied on skin testing with crushed seeds, which is not a form consumed by humans. Therefore, it might be argued that oilseed rape being only used to make refined oils in human diet, and refined oils being claimed to be devoid of proteins, conversely to crude oils, this rules out the possibility of allergic reaction against oilseed rape allergens. However, traces of proteins in quantities enough to induce allergic reactions were found in refined peanut oil (3), which shows that it might be possible to react after ingestion of refined oil. Therefore, although there is probably no allergy risk in the overwhelming majority of allergic population, it might be relevant to determine the levels of 2S albumin, but also of vicillin (another known seed pan-allergen family) in oilseed rape GT73, as compared to a natural counterpart. This is relevant particularly because the introduction of the new traits might have influenced the expression levels of these allergens in the GMO plant.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the allergenicity assessment that could change its previous conclusion. There is no reason to assume that GT73 is more allergenic than conventional oilseed rape. In addition, oil seed rape is not considered a common food allergen. The estimated exposure levels of oilseed rape GT73 in both humans and animals were very low.

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France	MEIE - DGCCRF	General comments	Le colza GT73 a été évalué par l'Agence française de sécurité sanitaire des aliments (AFSSA) en 2003 et 2004 au titre de la directive 2001/18/CE pour une utilisation en alimentation animale. Après examen des données complémentaires fournies par le pétitionnaire relatives à la construction génétique et à son insertion dans le génome du colza, l'AFSSA avait conclu qu'il n'y avait aucun élément évocateur d'un risque pour la santé lié à l'utilisation de la lignée GT73 en alimentation animale. Dans la mesure où l'AFSSA a pris en compte dans ses avis précédemment rendus des exigences communes à une utilisation en alimentation animale ou humaine sans distinction, elle considère que les conclusions de l'évaluation effectuée dans le cadre de la directive 2001/18/CE sont transposables à la présente demande de renouvellement. Cette transmission ne préjuge pas de la position finale des autorités françaises sur cet OGM. **EN TRANSLATION** GT73 oilseed rape was assessed for suitability for use as animal feed by the French Food Safety Agency (AFSSA) in 2003 and 2004 pursuant to Directive 2001/18/EC. Having examined the additional data provided by the applicant on the genetic make up and its insertion into the oilseed rape genome, AFSSA then concluded that that there was nothing in the use of the GT73 line as animal feed which might constitute a risk to health. Insofar as AFSSA has taken into account the common requirements covering use as animal feed or human food without distinction in the opinions it has issued previously, it considers that the conclusions of the assessment conducted pursuant to Directive 2001/18/EC may be applied to this request for renewal. This communication does not prejudge the final position of the French authorities regarding this GMO.	The GMO Panel agrees with the conclusions from AFSSA on GM oilseed rape GT73.

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Italy	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	General comments	Granted that the event (GT73) is allowed with Decision 2005/635/CE, under Directive 2001/18/CE, for import and processing, including use in feed products with the exception of cultivation and uses as or in food (art. 3), the applicant requires the extent of authorization for production of food and derived feed. Among the technical guidelines contained in the relative annex, is provided a general surveillance plan , to implement the Art. 4 – monitoring –. Actually should be necessary that the applicant supplies informations about the general surveillance plan as is set by the decision, and works out an appropriate general surveillance plan for this notification.	The EFSA GMO Panel concluded that no data have emerged to indicate that oilseed rape GT73 is any less safe than its non-GM comparator and conventional varieties. In addition, no biologically relevant agronomic and compositional changes were identified in oilseed rape GT73. Therefore, in line with the Guidance Document (EFSA, 2006), the EFSA GMO Panel is of the opinion that post-market monitoring of the GM food/feed is not necessary. According to Commission Decision 2005/635/EC of 31 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of GM oilseed rape event GT73, the consent holder shall ensure that the monitoring plan, contained in the notification C/NL/98/11, to check for any adverse effects on human and animal health or the environment arising from handling or use of the product, is put in place and implemented and this, throughout the period of validity of the consent. European Commission Decision 2005/635/EC, article 4, specifies that the applicant shall carry out general surveillance for any unforeseen adverse effects on human and animal health, and the environment. (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:228:0011:0013:EN:PDF)

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The Netherlands	Ministry of Agriculture, Nature and Food Quality and Ministry of Health	D, 03 Information on the expression of the insert | D, 07.09 Allergenicity	Although updated bioinformatics analyses have been provided for GOXv247 and CP4 EPSPS, an updated bioinformatics analysis has not been provided for the comparison of hypothetical peptide sequences encoded by the reading frames introduced or created by the insertion of the transgenic DNA in oilseed rape containing event GT73. The EFSA GMO Panel is advised to also consider these issues in its assessment of potential toxicity and allergenicity of GT73 oilseed rape. Previous data on sequence alignment of CP4 EPSPS with allergens indicate that at least one alignment (i.e. with herring worm allergen Ani s 3) would fulfill this criterion. Moreover, it appears that the alignment with Der f 2 has missed some additional identities because of the gap penalty. Therefore, besides an update of searches for short identical stretches (which have been provided), the comparisons with allergens should also include a sliding 80-amino-acid window with 35% identity threshold, as recommended by Codex.	In relation to this, a question has been raised to the applicant enquiring to provide an analysis using updated data from the most recent version of databases containing sequences of known toxic proteins. In addition and on the request of the GMO Panel the applicant also provided an updated bioinformatic search for putative open reading frames spanning the GT73 insert – genomic junction (both 5' and 3') which may be created as a result of the genetic modification, in order to assess the potential for production of novel chimeric proteins with homology to known toxins, allergens or other bioactive peptides. The data do not indicate any safety concerns from the potential production of new toxins. No putative peptide met or exceeded the Codex Alimentarius Commission threshold for potential allergenicity of 35% identity over 80 amino acids, or of at least eight consecutive identical amino acids. The bioinformatic analyses thus confirmed the original analysis carried out by the applicant.

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The Netherlands	Ministry of Agriculture, Nature and Food Quality and Ministry of Health	D, 07.01 Comparative assessment	In 2001, a consensus document of the OECD has been published, in which a number of key nutrients and anti-nutrients has been listed that are recommended to analyse for a comparative assessment of GM oilseed rape. For several analytes mentioned in this list, no statistical analysis has been provided for GT73 oilseed rape (several amino acids, fatty acids). Although in this case the data do not indicate compositional changes, normally statistical analyses should be provided. In addition, for some other nutrients, no data at all have been provided in the dossier (minerals). Without these additional data a proper evaluation of the compositional equivalence of GT73 is not possible, therefore such data should be provided. In addition, it is made obvious by the applicant that glucosinolate content in oilseed rape shows a great inter-individual variation. In addition, because of the crucial role of compositional data for risk assessment of food and feed safety and the central role of glucosinolate levels in the safety evaluation of GT73 oilseed rape, it should be stressed that it is important to provide new compositional data to prove that the glucosinolate content in the genetic modified oilseed rape is stable and below levels relevant for toxicological concern.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the comparative assessment that could change its previous conclusion. With regard to the glucosinolate levels in Roundup Ready canola GT73, a follow-up study (1998-2001) of Canadian cooperative extension trials reports that the levels of glucosinolates in GM varieties (glyphosate- and glufosinate-resistant varieties) actually were on average below those of conventional varieties, which probably is more influenced by the presence of weed seeds in the harvested crop seed than the genetic modification itself. (J.K. Daun, 2004, Journal of Agricultural Science 142, 273-280; abstract at http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=266025), With regard to proximate composition and amino acids, the chicken broiler feeding study published by Taylor et al lists the composition of seed used for that experiment, providing additional confirmation of an absence of any relevant effects on the composition of GT73 canola. (http://ps.fass.org/cgi/reprint/83/3/456.pdf)
The Netherlands	Ministry of Agriculture, Nature and Food Quality and Ministry of Health	D, 07.08 Toxicology	It cannot be concluded that E. coli- and plant-produced GOXv247 are equivalent with respect to glycosylation and molecular weight, due to a very bad quality of the reproduction of the provided blots in the dossier. This renders the data from the in vitro digestibility and in vivo acute oral toxicity studies of GOXv247 not useful for the evaluation of toxic properties of GOXv247. Moreover, in one of the 2 useful repeated dose toxicity studies in rats, an increase in liver weight of more than 10% was	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the toxicology assessment that could change its previous conclusion.

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			observed. This is an adverse effect. The fact that such an effect was not observed in the second study can be explained by the use of a lower dose level in the second study (10% instead of 15% (the limit of use in monogastric diets, OECD, 2001)). In addition, in the repeated dose toxicity studies, a maximum concentration of 15% oilseed rape meal was used, whereas up to 30% will be included in feed of ruminants. Effects on such dose levels on, for instance, liver effects are not known. Therefore, the dose levels used are too low to draw conclusions on the nutritional equivalence and safety for all food/feed uses.	
The Netherlands	Ministry of Agriculture, Nature and Food Quality and Ministry of Health	D, 07.08 Toxicology | D, 07.09 Allergenicity | D, 07.10 Nutritional assessment of GM food/feed	In the absence of actual data on mineral and glucosinolate levels in GT73 oilseed rape and its appropriate non-transgenic comparator, no additional data on probable liver toxicity, no bioinformatical update for the hypothetical peptides encoded by reading frames in the flanks, no additional data on the potential cross-reactivity of the transgenic GOX protein with allergenic tropomyosins, and no relevant nutritional study, a conclusion on food and feed safety of GT73 cannot be made.	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the toxicology assessment that could change its previous conclusion. On the request of the GMO Panel the applicant provided an updated bioinformatic search for putative open reading frames spanning the GT73 insert – genomic junction (both 5' and 3') which may be created as a result of the genetic modification, in order to assess the potential for production of novel chimeric proteins with homology to known toxins, allergens or other bioactive peptides. The data do not indicate any safety concerns from the potential production of new toxins. No putative peptide met or exceeded the Codex Alimentarius Commission threshold for potential allergenicity of 35% identity over 80 amino acids, or of at least eight consecutive identical amino acids. The bioinformatic analyses thus confirmed the original analysis carried out by the applicant. Cross-reactivity of Gox protein: Rape seed is not considered a common food allergen. In addition, even if an allergen is present in oil seed rape; it is very likely that the exposure to the protein would be very low or negligible. Moreover there is

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				no reason to assume that GT73 is more allergenic than conventional oilseed rape. Nutritional study: As the extensive comparative compositional analysis of GT73 oilseed rape provides no indication for unintended effects of the genetic modification under consideration in this opinion, additional animal safety or nutritional studies are not required. With regard to the glucosinolate levels in Roundup Ready canola GT73, a follow-up study (1998-2001) of Canadian cooperative extension trials reports that the levels of glucosinolates in GM varieties (glyphosate- and glufosinate-resistant varieties) actually were on average below those of conventional varieties, which probably is more influenced by the presence of weed seeds in the harvested crop seed than the genetic modification itself. (J.K. Daun, 2004, Journal of Agricultural Science 142, 273-280; abstract at http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=266025), Various nutritional feeding studies in target animals as published in public literature, as well as provided with the dossier, are referred to the in the previous opinion. In addition, a swine feeding study in public literature provides further confirmation of previous findings on the nutritional equivalence of Roundup Ready canola to conventional canola (Caine et al., 2007, Growth performance, carcass characteristics and pork quality of pigs receiving diets containing meal from conventional or glyphosate-tolerant canola. Can. J. Anim. Sci. 87: 517–526). With regard to the observed changes in liver weights in the rat feeding studies, the EFSA GMO Panel has already commented on the issue in its previous opinion (section 4.2.3), as follows: "Rat Safety and wholesomeness of GT73 oilseed rape was

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				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 glyphosatetolerant 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

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				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."

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The Netherlands	Ministry of Agriculture, Nature and Food Quality and Ministry of Health	D, 07.09 Allergenicity	The EFSA opinion on GT73 also mentions the outcomes of a bioinformatics comparison of GOX with allergens (Kleter and Peijnenburg, 2002), in which GOX has been found to share an identical 6-amino-acid stretch (LAEEAD)_ with the shrimp allergen tropomyosin, which is also part of a larger peptide identified as IgE-antibody-binding epitope (FLAEEADRK). The EFSA opinion notes, however, that 6-amino-acid identities are likely to be false positives in many cases. In literature, also other IgE-epitopes in tropomyosins have been described that correspond to the epitope in shrimp tropomyosin, e.g. in the parasite Oncocherca volvulus tropomyosin allergen (AQLLAEEADRKYD; Jenkins et al., 1998) and in human tropomyosin auto-allergen (HIAEDADRK; Sakamaki et al, 2000). In addition, bioinformatics studies indicate that this peptide is part of a larger motif of allergenic tropomyosins (Marti et al., 2007). It is therefore recommended to request from the applicant additional data on the potential cross-reactivity of the transgenic GOX protein with allergenic tropomyosins and in particular with the IgE-binding peptide epitope contained by these tropomyosins showing similarity to the GOX peptide. Jenkins RE, et al. (1998) Tropomyosin implicated in host protective responses to microfilariae in onchocerciasis. Proc Natl Acad Sci USA 95: 7550-7555 Kleter GA, Peijnenburg AACM (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(1): 1-11. http://www.biomedcentral.com/1472-6807/2/8 Marti P, et al. (2007) Allergen motifs and the prediction of allergenicity. Immunol. Lett. 109: 47-55. doi:10.1016/j.imlet.2007.01.002 Sakamaki S, et al. (2000) Autoantibodies against the specific epitope of human tropomyosin(s) detected by a peptide based enzyme immunoassay in sera of patients with ulcerative colitis show antibody dependent cell mediated cytotoxicity against HLA-DPw9 transfected L cells. Gut 47: 236-241. doi:10.1136/gut.47.2.236	The information referred here to by the Member State was considered and the MS concern was already addressed by the EFSA GMO Panel in its previous scientific opinion. The Panel did not identify any new information regarding the allergenicity assessment that could change its previous conclusion. Cross-reactivity of Gox protein: Rape seed is not considered a common food allergen. In addition, even if an allergen is present in oil seed rape; it is very likely that the exposure to the protein would be very low or negligible. Moreover there is no reason to assume that GT73 is more allergenic than conventional oilseed rape.

EFSA, 2004. Opinion of the Scientific Panel on GM 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. The EFSA Journal (2004) 319, 1-27. http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1178620772413.htm