Conclusion regarding the peer review of the pesticide risk assessment of the active substance

trifluralin

finalized: 14 March 2005

(version of 13 April 2005 with minor editorial changes)

SUMMARY

Trifluralin is one of the 52 substances of the second stage covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Greece being the designated rapporteur Member State submitted the DAR on trifluralin in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 11 July 2003. Following a quality check on the DAR, the peer review was initiated on 24 July 2003 by dispatching the DAR for consultation of the Member States and the notifier, the European Union Trifluralin Taskforce comprising of Agan Chemical Manufacturers Ltd. and Dintec Agroquímica Produtos Químicos Lda. at the time of finalisation of the conclusion. Subsequently, the comments received were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting on 15 January 2004. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in April, May and June 2004.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 10 February 2005 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide as proposed by the notifier which comprises spraying to bare soil to control grass and broad-leaved weeds in oilseed rape, sunflowers, cotton and winter cereals at application rate up 1.2 kg trifluralin per hectare. The representative formulated product for the evaluation was “EF-1521” ("Treflan"), an emulsifiable concentrate (EC), registered under different trade names in Europe. In case of oilseed rape, sunflowers, cotton, incorporation into soil takes place after the application. Trifluralin can be used only as pre-emergence herbicide.

[1] OJ No L 53, 29.02.2000, p. 25
[2] OJ No L 224, 21.08.2002, p. 25

Adequate methods are available to monitor all compounds given in the respective residue definition.

Trifluralin is extensively and rapidly metabolised and absorbed. It has a low acute toxicity, but has sensitising properties (proposed classification: R43). Trifluralin induced neoplastic changes and carcinogenic effects were seen in rats such as Leydig cell tumours, thyroid tumours and renal carcinoma (proposed classification: R40). A no observed adverse effect level (NOAEL) could not be established but the lowest observed adverse effect level (LOAEL) of 30 mg/kg bw/day in the rat was assigned as the most relevant effect level. There were no direct effects on reproductive performance or fertility.
The acceptable daily intake (ADI) is 0.015 mg/kg bw/day based on the LOAEL in the rat carcinogenicity study with a margin of safety between LOAEL and ADI of 2000.
The acceptable operator exposure level (AOEL) is 0.026 mg/kg bw/day and no acute reference dose (ARfD) was allocated. The estimated operator exposure was below the AOEL only if personal protective equipment (PPE) is worn both during mixing/loading and during application.

The metabolism of trifluralin in cereals is extensive and does not yield metabolites of toxicological concern. No residues of trifluralin were quantified in any of the cereal grain or straw samples from field trials conducted according the critical good agricultural practise (GAP) in Northern Europe. Further information is needed to conclude on the residue situation in cereals for Southern European uses.
For oilseed crops the present studies do not fully address consumer exposure via seeds. Therefore a further metabolism study is required for oilseeds to support uses on these crops. Subsequently the applicability of the submitted residue trials in oilseed crops has to be reviewed.
Due to the above mentioned requirements a final conclusion on the livestock dietary burden and on the possibly occurrence of residues in food of animal origin cannot be drawn at this stage.
The chronic dietary exposure assessment for consumers based on the currently available information in line with the Northern European GAP on cereals leads to estimated intakes less than 4% of the proposed ADI for the consumer subgroups of infants and young children. However, this assessment needs to be reviewed upon receipt of the outstanding data. An ARfD was not allocated, thus there is no acute risk for consumers arising from trifluralin residues in food.

In aerobic conditions degradation of trifluralin in soil did not lead to any major metabolite. Under flooded anaerobic conditions a major metabolite TR-4[3] is formed. Furthermore, metabolite TR-14[4] was formed at amounts above 5 % at the end of the study in all three anaerobic soils tested. Due to its potential degradation under aerobic conditions, TR-4 may be addressed by Member States where anaerobic conditions are envisaged to be relevant. Whereas not discussed in particular during the Peer Review, it is EFSA's opinion that the same conclusion may be reached for metabolite TR-14.

[3] α, α, α-trifluoro-5-nitro-N^4, N^4-dipropyl-toluene-3, 4-diamine 3-nitro-N^2-dipropyl-5-(trifluoromethyl)-1, 2-benzenediamine
[4] 7-amino-2-ethyl-1-propyl-5-(trifluromethyl)-bendimidazole

Under aerobic laboratory conditions trifluralin is medium to highly persistent with half-lives between 81 to 356 d at 22 °C. The degradation under anaerobic conditions was faster than under aerobic conditions. Data indicate that trifluralin is strongly adsorbed to soil and could be classified as immobile. Trifluralin is hydrolytically stable under environmental relevant conditions. Aqueous photolysis may contribute to the environmental degradation of trifluralin producing TR-6[5] and TR-15[6] metabolites. Trifluralin is not readily biodegradable. During the Peer Review, it was agreed that worst case DT_{50} = 13 d should be employed for the risk assessment performed in the context of Annex I inclusion and that a DT_{50} = 2 d could be used to refine risk assessment when appropriate. Due to the potential contribution of photolysis to the dissipation of trifluralin in water, the fate and behaviour in the environment expert meeting confirmed the need of a water sediment study conducted in the presence of light that could be used by MS to refine the risk assessment performed in the context of Annex I inclusion. Neither trifluralin nor its anaerobic metabolite TR-4 are expected to contaminate ground water at levels above 0.1 µg / L under the proposed conditions of use.
Trifluralin was designated as a "priority substance" under the Water Framework Directive[7] but has not been identified as a "priority hazardous substance". However, trifluralin has been added to the OSPAR (Convention for the Protection of the Marine Environment of the North-East Atlantic) List of Chemicals for Priority action in 2002 because it is considered to be a PBT substance fulfilling the criteria for Persistence, Bioaccumulation and Toxicity.
Because of its high volatility the occurrence of trifluralin in air and transport trough air is possible. However, photochemical half life in air is estimated to be short.

The risk to insectivorous and fish-eating birds and mammals, bees, ground dwelling arthropods, soil micro- organisms, including earthworms is low with respect to trifluralin and the metabolites as far as investigated.
High risks were identified for aquatic organisms, in particular the chronic risk to fish, which require consideration of appropriate risk mitigation measures. Using the initial predicted environmental concentrations (PEC's) together with the no observed effect level (NOEC) of 0.3 µg/L leads to a toxicity exposure ratio (TER)-value of 0.38 when a bufferzone of 15 metres is taken into account which is below the Annex VI trigger value of 10 (without detailed calculations, a bufferzone of 50 m should lead to a TER-value of approximately 1). Further data to address this risk is needed and the risk assessment can only be concluded when the outstanding data is evaluated.
The EPCO expert meeting (section ecotoxicology, June 2004) considered the risk to earthworm eating birds and mammals as low, based on the TER value reflecting the soil accumulation plateau. EFSA would like to highlight that the risk to earthworm eating birds and mammals should be considered further at MS-level when the product is applied after this plateau value is reached. EFSA proposes that a new litterbag study should be made available in which the tested dose rate reflects the concentration in the soil after a single application when the accumulation plateau has been reached as

[5] α, α, α-trifluoro-5-nitrotoluene-3,4-diamine 3-nitro-5-(trifluromethyl)-1,2-benzenediamine
[6] 2-ethyl-7-nitro-5-(trifluoromethyl) benzimidazole
[7] OJ No L 327, 22.12.2000, p.1

the study which is available at present was performed at a lower dose rate. This data requirement has not been discussed in an EPCO expert meeting

The risk to non-target plants could not be calculated with the appropriate endpoint (median emergence rate (ER50) value) as this value is not reported in the DAR. Based on a conservative no observed effect concentration (NOEC), the risk to non-target plants can be certainly regarded as low if a bufferzone of 5 metres is taken into account.

Regulation (EC) No 850/2004[8] of the European Parliament and of the Council on persistent organic pollutants and amending Directive 79/117/EEC[9] entered into force when the Peer Review of trifluralin was in an advanced stage. For this reason, EFSA's conclusion does not specifically assess trifluralin against the criteria set in the paragraph 1 of Annex D of the Stockholm Convention[10]. However, available information assessed during the Peer Review and provided in this conclusion should allow the Commission and the Member States to conduct the assessment of trifluralin with respect to Regulation (EC) No 850/2004. As this conclusion only considers a limited range of representative uses, other information may need to be considered by the Commission and the Member States when assessing trifluralin with respect to Regulation (EC) No 850/2004.

Key words: trifluralin, peer review, risk assessment, pesticide, herbicide

[8] OJ No L 158, 30.04.2004, p. 21
[9] OJ No L 33, 08.02.1979, p. 36
[10] http://www.pops.int/default.htm

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Trifluralin is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Greece as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Greece submitted the report of its initial evaluation of the dossier on trifluralin, hereafter referred to as the draft assessment report, to the EFSA on 11 July 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 24 July 2003 to the Member States and the main notifier the European Union Trifluralin Taskforce as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 15 January 2004 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier was attending this meeting.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the Pesticide Safety Directorate, United Kingdom. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 10 February 2005 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 8(7) of the amended Regulation (EC) No 451/2000, this conclusion summarises the results of the peer review on the active substance and the representative formulation

evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-1 of 04 February 2004)
- the consultation report

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 3-1 of 04 March 2005)

Given the importance of the draft assessment report including its addendum (compiled version of February 2005 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Trifluralin is the ISO common name for α,α,α-trifluoro-2,6-dinitro-*N,N*-dipropyl-*p*-toluidine (IUPAC).

Trifluralin, belonging to the class of dinitroaniline herbicides, can be used for the control of grass and broad-leaved weeds with or without incorporation into soil after application. Trifluralin is taken up via roots and shoots and inhibits cell division.

The representative formulated product for the evaluation was "EF-1521" ("Treflan"), an emulsifiable concentrate (EC), registered under different trade names in Europe.

The representative uses evaluated comprise spraying to bare soil to control grass and broad-leaved weeds in oilseed rape, sunflowers, cotton and winter cereals at application rate up 1.2 kg trifluralin per hectare. In case of oilseed rape, sunflowers, cotton, incorporation into soil takes place after the application. Trifluralin can be used only as pre-emergence herbicide.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of trifluralin as manufactured should not be less than 950 g/kg, which is higher than the minimum purity given in the FAO specification 183/TC/S (1988) of 930 g/kg. The higher

value relates to the submitted results of current batch analysis and not to any toxicological concern to increase the minimum purity. The technical material contains N-nitroso-di-*n*-propylamine, which has to be regarded as relevant impurity. The maximum content in the technical material should not be higher than 1 mg/kg (FAO 183/TC/S).
The content of trifluralin in the representative formulation is 480 g/L (pure). The maximum content of N-nitroso-di-*n*-propylamine may not be higher than the content found in the technical material (FAO 183/TC/S).
The assessment of the data package revealed no particular area of concern beside the maximum content of *N*-nitroso-di-*n*-propylamine and the emulsion stability in the two year shelf life study in respect of the identity, physical, chemical and technical properties of trifluralin or the respective formulation.
The recently finalised shelf life study was evaluated and described by the RMS in addendum 4 to Volume 3 (October 2004). The assessment was peer reviewed and confirmed by the experts of the EPCO expert meeting (section phys-chem properties/analytical methods, June 2004) in written form.

Adequate analytical methods are available for the determination of trifluralin in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material and the relevant impurity in the formulation.

Analytical methods for the determination of residues of trifluralin are available for commodities with high fat content (e.g. oil seed rape), cereals, soil, water (incl. drinking and surface water) and air.
An analytical method for food of animal origin is currently not required due to the fact that no residue definition can be proposed at the moment (see 3.2).

2. Mammalian toxicology

2.1 Absorption, distribution, excretion and metabolism (Toxicokinetics)

Triflurarin is rapidly and nearly completed absorbed, 82% within 48 hours. The excretion is also rapid, > 90% at 168 hours mainly *via* bile, otherwise *via* faeces, regardless of dose level. It is widely distributed and the highest concentration was found in adrenals, fat, kidneys, liver, skin and blood. There was no evidence of accumulation. Triflurarin is extensively metabolised and the major route is conjugation (75% of the urine residues), reduction of nitro-groups, N-dealkylation, hydroxylation and cyclisation reactions. There were numerous minor metabolites evident, four metabolites identified in the faeces.
A data requirement was stated in the DAR regarding the plant metabolites TR-22 and TR-28 of the assessment of relevance of the metabolites in groundwater and that *in vitro* tests and acute test should be performed. However, at the expert meeting on Residues (11-12 May 2004) it was concluded that the proposed use in oilseed giving rise to this requirement was not supported by appropriate crop metabolism data. Thus, the toxicological significance of these metabolites was not needed to be

considered. This message was forwarded to the expert meeting on Toxicology (May 2004) and it was agreed that the data requirement was no longer relevant.

2.2 ACUTE TOXICITY

The oral and dermal toxicity is low i.e. oral LD_{50} > 5000 mg/kg bw/day and dermal LD_{50} > 2000 mg/kg bw/day. The toxicity during inhalation in rats is also low, LC50 > 1.252 mg/l air. The rapporteur Member State concludes that trifluralin was only shown to be mild and reversible irritant in the skin and eye irritation studies.

Triflurarin was found to have sensitizing properties (Magnuson and Kligman test) and should therefore be labelled as such. The following symbol; risk phrase is proposed on the basis of the outcome of the acute studies: **Xi; R43 "May cause sensitisation by skin contact"** is proposed on basis of the outcome in the acute studies.

2.3 SHORT TERM TOXICITY

The short term effects of trifluralin were studied in a 28-day study in rat, two 90-day studies in rat (one in pregnant rat), and a 1-year dog study, one 21-day inhalation study in rat and one 28-day dermal study in the rabbit. No 90-day dog study was available. However, at the expert meeting (May 2004) it was agreed that the 1-year dog study was adequate for the risk assessment and that a 90-day dog study would not be required.

The main effects observed were a decrease in body weight gain, increased alpha-1 globulin and albumin concentration (rat), anaemia (dog) and increased liver weight (rat and dog).

The relevant oral NOAEL is 2.4 mg/kg bw/day, based on abnormal stool, increased liver weight, and some minor changes in chemistry observed at 40 mg/kg bw/day in the 1-year dog study.

Following dermal exposure of trifluralin in the rabbit local irritation and secondary haematological and histopathological effects but no systemic effects were observed at the tested dose, 1000 mg/kg bw/day (limit test). **The relevant dermal NOAEL is 1000 mg/kg bw/day.**

There were no treatment related effects observed in male or female rats during inhalation exposure of trifluralin. **The relevant inhalation NOAEL is > 0.09 mg/ kg bw/day (i.e. 22.5 µg/L).**

2.4 GENOTOXICITY

In the DAR, 11 *in vitro* studies and five *in vivo* studies have been evaluated and presented. There was evidence of aneuploidy induction from an *in vitro* chromosome aberration study, positive effects in a comet tail test, as well as weak positive effects in an *in vivo* micronucleus study. In order to clarify these effects, the need of performing of a new micronucleus study was requested by the rapporteur Member State. This was stated as a data requirement in level 4 of the DAR "An *in vivo* bone marrow micronucleus assay in mice with kinetochore or centromeric staining in order to ascertain the nature of the micronuclei induced". The new study was performed and submitted by the notifier and the rapporteur Member State has evaluated and presented it in the Addendum. No increase in the incidence of micronuclei formation or the aneuploidy was recorded, when it was administered as a single dose to male and female mice. Hence, trifluralin is considered negative for clastogenic and aneugenic potential in the present study.

It is summarised in the List of Endpoints as follows **"Weak clastogenic and aneugenic effects in a limited number of *in vivo* and *in vitro* studies, not confirmed in the most reliable, recent, *in vivo* GLP study (micronucleus study with kinetochore staining)".**

2.5 LONG TERM TOXICITY

Several long term toxicity studies were performed in the rat, mouse and dog. However, a large number of these were rejected by the rapporteur Member State and defined as unacceptable due to a large number of limitations. Four studies in the rat of which only one is acceptable, two studies in the mouse of which only one is acceptable and three studies of which none are acceptable but one could be used for supplemental information.

The main effects observed in the Fisher 344 rat study were neoplastic changes i.e. liver hepatic cell adenoma and liver hepatocellular carcinoma that were observed in males from the lowest dose level and from the mid dose level, respectively. Histopathological changes were observed in the kidney. The carcinogenic effects seen were Leydig cell tumours, thyroid tumours and renal carcinoma observed in rats. However, the mechanism of tumour formation was not identified.

Thus, since no NOAEL could be established in the in the two-year study in the Fisher 344 rats the LOAEL of 30 mg/kg bw/day was agreed on to be used as most relevant effect level (Emerson 1980a). This study is used for the allocation of ADI, see 2.10.

The following symbol; risk phrase is proposed on the basis of the results in the long term and cancer studies: **Xn; R40 "Limited evidence of a carcinogenic effect"**.

2.6 REPRODUCTIVE TOXICITY

Four studies were submitted in the dossier on rat and one in the dog in order to determine the reproductive effects of trifluralin (one-, two- and four-generation studies). Two studies were not acceptable according to the rapporteur Member State, these (four generation in the rat and the dog study) were of very old date (1966) and thus there were many deficiencies and deviations according to test guideline. A summary of the two-generation rat study is also presented in the Addendum.

There were no direct effects on reproductive performance or fertility observed. Whether trifluralin was a possible endocrine disrupter was discussed at the expert meeting (May 2004). The meeting agreed that there were no clear evidence only limited evidence for endocrine effects, recorded at high dose levels and being hard to distinguish from systemic toxicity.

The relevant NOAEL for reproduction was set to 4.5-5.8 mg/kg bw/day in the rat based on haematological changes, decreased maternal body weight during gestation and decreased offspring growth and survival, respectively at 40.7-50.8 mg/kg bw/day (Rubin *et al*., 1987).

The reproduction NOAEL to be used within ecotoxicological risk assessments was set to 148 mg/kg bw/day which was the top dose in a two generation study in the rat (Hoyt, 1986).

In order to examine teratogenic or developmental effects of trifluralin four studies in rat and rabbit were submitted in the dossier and two (one rat and one rabbit) were not accepted according to the rapporteur Member State, since it was of very old date (1966) and thus there were many deficiencies

and deviation according to test guideline. One dog study was submitted in the dossier but was not considered acceptable according to same statement as above.
From these studies it is concluded that trifluralin did not induce teratogenic or fetotoxic effects at non-maternally toxic doses.
The relevant developmental NOAEL is 50 mg/kg bw/day in the rabbit based on decreased foetal weight and postimplantation losses at 120 mg/kg bw/day (Rubin *et al*., 1986) and **the relevant maternal NOAEL is 50 mg/kg bw/day in the rabbit** based on reduced body weight and food consumption at 120 mg/kg bw/day (Rubin *et al*., 1986).

2.7 NEUROTOXICITY

No studies performed.

2.8 FURTHER STUDIES

Urinalysis studies in rats were performed and evaluated in the DAR. An increase in hyaline droplet formation in the renal tubular epithelium was seen at 200 ppm and the NOAEL is 50 ppm i.e. 2.6 mg/kg bw/day (Usher 1985). This study is used for the allocation of AOEL, see 2.10.

Supplemental studies in the rat regarding the mechanism of nephrotoxicity of trifluralin have been evaluated. Trifluralin induced changes in the kidney (mild renal tubular epithelial degeneration) and urine which may suggest a mechanism for induction of proliferative urinary tract lesions observed in the two-year studies.

2.9 MEDICAL DATA

Reports from plant employees exposed for trifluralin and trifluralin containing products describe effects such as redness, rash, hives, vesicular change, bullae and pruritis. Epidemiological studies revealed that there was no correlation between increased cancer incidence rate, reproductive effects or asthma following exposure to trifluralin.

2.10 ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

ADI
Initially in the DAR the rapporteur Member State proposed an ADI of 0.024 mg/kg bw/day based on the NOAEL of 2.4 mg/kg bw/day in the 1-year dog study. The rapporteur Member State also made a second proposal of ADI to use the LOAEL of 30 mg/kg bw/day in the rat cancer study. Since the ADI then would be based on a LOAEL value instead of a NOAEL value the rapporteur Member State used a margin of safety between LOAEL and ADI of 1000 and an ADI of 0.03 mg/kg bw/day was set at that time.
The ADI value was discussed at the expert meeting (May 2004) and it was agreed that it should be based upon the LOAEL in the rat cancer study (Emmerson 1980a). However, the expert meeting agreed that margin of safety between LOAEL and ADI should be increased to 2000 instead

of 1000 since the ADI would be set on a LOAEL value and that at this dose level tumour formation was evident.

The resulting ADI is thus 30 mg/kg bw/day/2000 i.e. 0.015 mg/kg bw/day.

AOEL

The AOEL is based on the NOAEL of 2.6 mg/kg bw/day in the 90-day mechanistic study in rats (Usher 1985) with a safety factor of 100 and no correction for oral absorption required.

The AOEL is 0.026 mg/kg bw/day.

ARfD

The allocation of ARfD was discussed at the expert meeting (May 2004), considering the overall database as well as the results of the rabbit developmental study, and the meeting concluded that the effects were not of concern for acute toxicity. It was agreed that an ARfD was not required for trifluralin.

No ARfD allocated.

2.11 DERMAL ABSORPTION

Only one study was submitted in the dossier and it is performed on the Rhesus Monkey. Based on the results from this study the rapporteur Member State suggested in the DAR that the dermal absorption should be equal to 1% for both undiluted and diluted formulation.

The study, from a scientific point of view, was discussed at the expert meeting (May 2004). The meeting concluded that there were some major limitations such as a small number of animals in the group only 2 and that not all material was accounted for. Therefore, the meeting agreed to use 10% (for both concentrate as well as diluted solution) as a default value instead.

2.12 EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product TREFLAN (code EF-1521) is an emulsifiable concentrate (EC) containing 480 g trifluralin/L. According to the intended uses submitted by the notifier the applied doses are in the range of 0.48 to 1.2 g a.i./kg while the application volume ranges from 150 to 600 L. The plant protection product is applied using tractor mounted boom sprayer with hydraulic nozzles and water is the intended dilutent/carrier.

In the DAR the dermal absorption of 1% was used for both concentrate and diluted formulation. However, this value was changed to a default value of 10% for both concentrate and diluted formulation, see point 2.11 above. Thus, the operator risk assessment was revised (see Addendum).

The risk of exposure for operator and bystander *via* inhalation of the vapour was discussed at the expert meeting (May 2004). The issue of whether there was a need for the notifier to submit further data on volatility of trifluralin in the spraying solution was also examined. The meeting agreed that the potential for inhalation exposure was low and that no concerns had been identified in the 21-day

rata inhalation study. The meeting concluded that no further consideration of inhalation exposure was required for operators and bystanders.

Operator exposure

The estimated operator exposure is below the AOEL of 0.026 mg/kg bw/day for proposed uses of TRFLAN EC (according to German model) only if PPE are used both during mixing and loading (i.e. gloves) as well as during application (i.e. coverall), see table below.

Estimated exposure, % of AOEL, according to calculations with the German model.

Application rate	No PPE	With PPE: gloves (M/L)	With PPE: gloves (M/L) and coverall (Appl.)
1.2 kg a.i./ha	1469	562	62
0.48 kg a.i./ha	588	223	23

M/L= mixing and loading, Appl.= application

Worker exposure

Trifluralin is a pre-emergence herbicide applied directly to soil. Thus, the scenario of re-entry of workers is not applicable and a worker re-entry risk assessment is not considered necessary.

Bystander exposure

Bystanders may be exposed briefly and to relatively low quantities of spray as compared to an operator. No calculations were presented in the DAR. However, since the AOEL is exceeded to a great extent for operators when no PPE is used some kind of clarification would increase transparency. From calculations, provided by EFSA (November, 2004) after the peer review process and thus not peer-reviewed at this stage, it is evident that the estimated exposure of bystanders is below the AOEL, see Addendum.

3 Residues

3.1 NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1 Primary crops

Studies were presented in cotton, soybean and mustard dealing with either translocation or metabolism following pre-planting incorporation of radiolabelled trifluralin to soil at rates comparable to the intended GAP. Radioactivity was translocated to the aerial parts of the plants and the expiration of ^{14}C-carbon dioxide indicated that trifluralin was metabolised. Although not necessarily attributed to trifluralin, the concentration of residues in the seeds of these crops increased with time. Metabolites having a similar lipophilic nature as trifluralin may be accumulating in seeds of oilseed crops. Because no attempts have been made to investigate the nature of the residue in the seeds although significant levels of total radioactivity were analysed, the oilseeds studies were

regarded as inadequate to conclude on a residue definition for oilseed and a new oilseed metabolism study is necessary to support oilseed uses.
Additionally the metabolism of trifluralin was studied in maize following post-emergence spray application. Trifluralin was rapidly metabolized as it was only detected in maize forage within the first four weeks after treatment. Resulting from an extensive metabolism the radioactive residue consisted of a complex mixture of compounds. Only few metabolites were identified due to their occurrence at very low levels. Further on a large part of the radioactivity was bound to natural plant constituents (lignin and cellulose). Limited translocation of radioactivity to the cobs and grain was observed. Due to the low levels of radioactivity (0.02 mg/kg) in the grain at harvest identification was not possible. In addition, no radioactive residues were found in the oil or flour processed from the grain of treated plants. Therefore the expert meeting on residues regarded acceptable to establish the residue definition for risk assessment and monitoring purposes as parent trifluralin. Due to the limitation to cereals only a residue definition for plants in general can not be proposed.

The magnitude of trifluralin residues in grain and straw was determined in a total of 6 cereal field residue trials (2 in barley and 4 in wheat) conducted over two growing seasons in Northern European regions consistent with critical GAP. All residues were analyzed using validated methods. Trifluralin was the only residue determined. Grain and straw residues were determined at a limit of quantification (LOQ) of 0.01 mg/kg in all trials. At harvest (> 87 days after application) no residues were found in any of the cereal grain or straw samples. In addition, a large number of trials generated in the 1960s and 1970s in Canada and the USA were submitted. It was decided by the expert meeting on residues that a comparability and acceptability assessment of these trials needed to be made to consider their relevance to the Southern European GAP, which is currently not supported by available data.
Also a range of residue trials in oilseed crops were submitted. With regard to the determined residue the applicability of these trials needs to be reconsidered when a residue definition for oilseed crops has been established.

3.1.2 Succeeding and rotational crops

In the field trifluralin degrades slowly (See point 4.1.2) Therefore three crop rotation studies with radiolabelled trifluralin were presented in order to address the potential incorporation of soil residues into succeeding and rotational crops. A variety of crops was planted in treated soil aged for 30 days up to 395 days. Total radioactive residues were less than 0.08 mg/kg in crop parts relevant for human consumption from trials in line with conditions expected from representative GAPs. Analyses of these residues indicated that they were comprised of multiple components, none of them exceeding 0.01 mg/kg. Except in turnip roots parent trifluralin was generally not detected in any of the other rotational crops. Exceptionally, in one maize grain sample obtained from a trial following a soil application twice the intended rate a residue of 0.03 mg/kg trifluralin was found.
However, residues in crops grown in rotation in commercial practice are expected to be negligible. Therefore, no concern about exposure to trifluralin residues incorporated into these crops by uptake from soil is raised.

3.2 NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

It is noted that with regard to its logPow trifluralin is characterised as fat-soluble. Moreover it cannot be excluded that metabolites with a similar lipophilic nature may occur in susceptible plant parts of crops used for animal feeding (e.g. seeds of oilseed crops). Due to the lack of data supporting the uses on oilseed crops a final conclusion on the livestock dietary burden can not be drawn at this stage. However, in terms of the representative use on cereals no quantifiable trifluralin residues were found in cereal grains and straw at the time of harvest and significant levels of trifluralin residues are not expected to occur in potential feeding crops grown in rotation with cereals. Thus metabolism and feeding studies in livestock are not necessary to support the use on cereals as long as cereal green forage is not used in animal diet. (See point 3.1.1) Therefore no residue definition or MRLs for food of animal origin is currently proposed. This would need to be reviewed for other uses than cereals relevant for animal nutrition, inter alia oilseed crops.

3.3. CONSUMER RISK ASSESSMENT

The chronic dietary exposure assessment for consumers is based on the information obtained from Northern European residue trials in cereals and on consumption data from the WHO/GEMS Food European diet, on consumption data of UK consumers and on the German diet of a 4-6 year old girl. The dietary estimates include contributions from the raw agricultural commodities (cereal) and processed fractions (e.g. flour, pasta, baked goods etc.) In the calculations the proposed MRL by Member States of 0.05* mg/kg is used. The three different models employed show a contribution to the ADI of 0.015 mg/kg bw less than 2 % for adults and less than 4% for children and infants.
An ARfD was not allocated for trifluralin (See point 2.10), thus trifluralin residues on food do not pose an acute risk to consumers.

3.4. PROPOSED MRLS

It is noted that currently no sufficient data is available to support an MRL proposal for cereals for Southern European uses. Thus the proposed MRL only regards uses on cereals in Northern Europe.
Originally it was proposed by the RMS to set the maximum residue level (MRL) in cereals (wheat, barley, oat, rye, triticale) to the limit of quantification (LOQ) of the analytical method of 0.01 mg/kg, resulting in an MRL of 0.01* mg/kg. However, in the evaluation meeting Member States proposed to raise the MRL to an LOQ of 0.05 mg/kg to allow a cost effective monitoring as the dietary exposure assessment doesn't indicate any of the considered consumer subgroups to be at risk by applying a LOQ of 0.05 mg/kg.

Trifluralin is approved in non-EU countries; however no Codex MRLs have been established or proposed yet and need to be considered.

4 Environmental fate and behaviour

4.1 FATE AND BEHAVIOUR IN SOIL

4.1.1 Route of degradation in soil

Information of trifluralin metabolism in soil under dark aerobic conditions at 22 °C is provided by one study where three different soils are used. The soils covered a range of pH values (4.9-7.0), clay contents (8.8 % - 36.4 %) and organic matter contents (2.6 - 5.1 %). Volatiles were only trapped and analysed for one soil.

In aerobic conditions degradation of trifluralin in soil did not lead to any major metabolites but several minor metabolites were formed by oxidative dealkylation of N-propyl, reduction of nitro groups with cyclation and dimerization to form azoxy-benzene compounds. The level of unextractable residues was between 23.3 % and 43.1 % AR after 120 d and reached between 33.5 % and 54.1 % after one year. Most of the non extractable residue was in the humin fraction. As measured in one of the soils, CO_2 evolved was 8.4 % AR at 120 d and 18 % AR after one year.
An analogous study under flooded anaerobic conditions shows the formation of a major metabolite **TR-4** (α, α, α-trifluoro-5-nitro-N^4, N^4-dipropyl-toluene-3, 4-diamine 3-nitro-N^2-dipropyl-5-(trifluoromethyl)-1, 2-benzenediamine, maximum 13.2 % AR after 60 days). Metabolite **TR-14** (7-amino-2-ethyl-1-propyl-5-(trifluromethyl)-bendimidazole) was formed at amounts above 5 % at the end of the study in all three soils tested (maximum 8.3 % AR after 60 d). Relevance of TR4 for the proposed representative uses and need for further assessment was discussed in the fate and behaviour in the environment expert meeting (EPCO 2, April 2004). Whereas it was not possible to exclude the relevance of anaerobic conditions for the representative uses it was judged, based on molecular structure, that this metabolite would be degraded under aerobic conditions. However, MS may need to address further the fate and behaviour and ecotoxicology of this metabolite for specific environmental conditions. Relevance of the other anaerobic metabolite TR-14 was not discussed during the peer review, however since levels found are lower than for TR-4 and that under aerobic conditions may be expected to follow a degradation route analogous to other aerobic metabolites the same conclusion reached for metabolite TR-4 is applicable to metabolite TR-14.
According the soil photolysis study, photolysis is not expected to be a significant degradation route of trifluralin in the environment and no major photolysis products were identified.

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

Degradation rate of trifluralin at 22 °C under aerobic and anaerobic conditions is investigated in the same studies used to establish the trifluralin metabolism and in another study under aerobic conditions with two additional soils. Half-lives were obtained by fitting degradation curve to first order kinetics. Under aerobic laboratory conditions trifluralin is medium to highly persistent with half-lives between 81 to 356 d at 22 °C. The degradation under anaerobic conditions was faster than under aerobic conditions with first order half-life between 23 to 54 d.

Field dissipation studies are available in EU (Germany and United Kingdom) and USA (Georgia, Illinois and California). Trifluralin shows to be highly persistent in the EU sites and moderately persistent in the USA sites. Overall mean half life in field is 170 d confirming the concern for the highly persistence of this compound already shown by the laboratory studies.
A field accumulation study is available in a UK site for five years. Under the study conditions, trifluralin residues in soil did not increase after each annual application. However, since field dissipation studies show quite variable results, potential for accumulation has been estimated by calculation with the worst case field DT_{50} of 375 d and given in the end points list.
PEC soil presented in the DAR were calculated taking into account different DT_{50} (mean field, 80th percentile field and worst case). However, only PEC soil calculated using worst case DT_{50} (375 d) are used in the risk assessment for Annex I inclusion and shown in the list of end points. Initial PEC soil are also provided for anaerobic metabolite TR-4.

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

A batch adsorption / desorption study in four soils is available for trifluralin. Data indicate that trifluralin is strongly adsorbed to soil (Koc = 6414 – 13600 mL / g) and may be classified as immobile. For anaerobic metabolite TR-4 a Koc = 13600 mL / g was estimated, using the "pckocwin v.1.66 (EPA)" program, indicating also low mobility potential for this metabolite.
Two aged residue column leaching studies with a total of three experiments are available. Amounts between 0.4 to 2.54 % AR are found in the leachate. However, this radioactivity may not be attributed to the parent and was not further identified. More data on leaching potential of metabolite TR-4 was initially requested by the RMS in the DAR pending decision on its relevance. According conclusions of the fate and behaviour in the environment expert meeting no further data for this metabolite are necessary to finalise the assessment made in the context of Annex I inclusion.

4.2 FATE AND BEHAVIOUR IN WATER

4.2.1 Surface water and sediment

Trifluralin is hydrolytically stable in sterile aqueous buffers between pH 3 and pH 9 at 52 ^{o}C with an extrapolated half life above one year at 20 ^{o}C.
Aqueous photolysis may contribute to the environmental degradation of trifluralin ($DT_{50\ irr.}$ = 7 h *vs.* DT_{50dark} = 480 h). Aqueous photolysis is enhanced in natural water (DT_{50} = 1.1 h). Photodegradation of trifluralin led to the formation of two major photoproducts **TR-6** (α, α, α-trifluoro-5-nitrotoluene-3,4-diamine 3-nitro-5-(triflurомethyl)-1,2-benzenediamine, maximum 50.4 % AR at the end of the study after 48.5 h continuous irradiation) and **TR-15** (2-ethyl-7-nitro-5-(trifluoromethyl) benzimidazole, maximum 31.5 % AR at the end of the study after 48.5 h continuous irradiation). Initial PECsw have been calculated for these metabolites based on the maximum amounts observed in the photolysis study. These values have been used for the risk assessment. No further data on these metabolites was deemed necessary by the fate and behaviour in the environment expert meeting to conclude the risk assessment.

Trifluralin is not readily biodegradable.

Two water / sediment studies were available in the original dossier and summarized in the DAR (July 2003). First study was performed in two water sediment systems. Half life of trifluralin in the whole system was 4.9- 5.9 d. Half life for trifluralin in the water phase was estimated to be 13 d based in the worst case system (sandy loam). Volatilization was the major dissipation route identified for trifluralin (50 – 73 % AR) specially produced during the first part of the study where heavy aeration was done. Second study was performed in one water sediment system. In this study trifluralin was applied to the sediment. Water phase was not analyzed in this system since radioactivity was below 10 % AR in all samples. Major metabolite TR-4 (max 16 % after 16 d) was identified in the sediment phase. Non identified substances reached a level of 27 % at the end of the study. Volatilization reached levels of 5 – 7 % AR.

RMS required a third study with direct application of the substance to the sediment, in order to minimize evaporation, to obtain degradation data on the major sediment metabolite TR-4 and to identify non-characterized substances.

MS decided in the Evaluation meeting (January 2003) that the DT_{50} to be used on the PECsw calculation for the risk assessment should be discussed in an experts meeting (Open point 4.3).

A new water sediment study was submitted by the notifier and summarized by the RMS in an addendum (see final addendum, addendum 2). Two water sediment systems were studied where the test substance was applied to the sediment. Three major metabolites were found in the sediment TR-4 (max. 27 % AR after 7d), **TR-7** (α, α, α trifloro-N^4,N^4-dipropyltoluene-3,4,5 triamine, max. 14.2 % AR after 33d) and TR-14 (max. 29.5 % after 54 d). Non identified compounds (up to 23 % AR) were shown to be the sum of multiple peaks of minor components. Non extractable residues grow up to a maximum of 77 % AR and are associated with the humin fraction. No volatiles were observed in this study. Dissipation half lifes in the water phase in these systems are one and two days based on the only three data points (0 – 3 d) where trifluralin was observed in the aqueous phase.

The selection of the most appropriate DT_{50} to be used for PECsw water calculation and aquatic risk assessment was discussed in two EPCO experts meetings (section fate and behaviour, April 2004 and June 2004). Experts took into account the different factors contributing to the dissipation of trifluralin from the water phase (e.g. volatilization, photolysis, adsorption to sediment). They also took into account the different experimental settings used in the studies reported (e.g. application to water or to sediment). It was agreed that worst case DT_{50} = 13 d (from first study, Yon, 1993) should be employed for the risk assessment in the context of Annex I inclusion and that a DT_{50} = 2 d (from third study, Cook, W.L., Meitl, T.J.) could be used to refine risk assessment when appropriate. The DT_{50} = 6 h used in the original DAR for ecotoxicological aquatic risk assessment was found not reliable by the experts meetings. This shorter half life was claimed to be derived from the low amount of substance found in the water phase at the first sampling point in day 0 with respect to the theoretical application rate in the first water sediment study (Yon, 1993; Ref K40) under the Dutch guideline study design. As already shown in the DAR this part of the study suffers of some drawbacks (e.g. volatilization has been artificially and unrealistically enhanced by fast aeration).

In a letter to the evaluation meeting of November 2004 the RMS proposes to reconsider dissipation in water column supporting a DT_{50} under six hours. However, no new data were offered for

consideration. The evaluation meeting supported EFSA in collecting the values agreed during the peer review in its conclusions. RMS expressed his wish that the particular position in opposition of these values to be quoted in the EFSA conclusions. [11]

PECsed are calculated for trifluralin metabolites TR-4 and initial PECsed are also calculated for metabolites TR-7 and TR-14.

Due to the potential contribution of photolysis to the dissipation of trifluralin in water, the fate and behaviour in the environment expert meeting confirmed the need of a water sediment study conducted in the presence of light that could be used by MS to refine the risk assessment performed in the context of Annex I inclusion.

4.2.2. Potential for ground water contamination of the active substance their metabolites, degradation or reaction products

PECgw of trifluralin and anaerobic metabolite TR-4 were estimated using FOCUS PELMO 1.1.1 for the nine EU scenarios and the representative uses. In the lack of a reliable DT_{50} for TR-4 a worst case of DT_{50} = 1800 d (ten times DT_{50} of trifluralin) was used in the simulation. Calculated concentration in ground water for both compounds was negligible in all nine scenarios.

Monitoring data in EU, Switzerland and Norway were reviewed. Within this data set, trifluralin occurrence in ground water is rare and extremely rare at levels above 0.1 µg / L that were attributed isolated pollution incidents. Trifluralin was more frequently found in surface waters with maximum concentration between 0.2 µg / L and 0.7 µg / L. In the countries where trifluralin is found in surface waters, positive samples range between 4 % and 16.4 % of analyzed samples but only a maximum of 3.2 % of samples were above 0.1 µg / L. Trifluralin was designated as a "priority substance" under the water framework Directive but has not been identified as a "priority hazardous substance"[12]. However, trifluralin has been added to the OSPAR (Convention for the Protection of the Marine Environment of the North-East Atlantic) List of Chemicals for Priority action in 2002.[13]

4.3 FATE AND BEHAVIOUR IN AIR

Because of its high volatility [vapour pressure= 9.5 x 10^{-3} Pa (25 °C) and Henry's Constant Law= 10.2 Pa m^3 mol^{-1} at 20°C] the occurrence of trifluralin in air and transport trough air is possible. This was confirmed by the study conducted to assess the volatilisation of trifluralin from the soil surface. However, photochemical half life in air, estimated with SAR method (Atkinson), was of 5.3 h.

PEC air were not calculated since they are not used in the assessment and no method at EU level is agreed for such calculation.

[11] A. Ioannou, **Trifluralin / Position of the RMS on the fate and behaviour section (Dissipation of Trifluralin from the water column.** Hellenic Ministry if Rural Development and Food. General Directorate of Plant Produce Directorate of Plant Protection Department of Pesticides. File No. 121175. Athens 3/11/2004.

[12] OJ No L 327, 22.12.2000, p. 1

[13] Trifluralin, Hazardous substances series. OSPAR Commission, 2004 (ISBN 1-904426-37-9).

5 Ecotoxicology

5.1 RISK TO TERRESTRIAL VERTEBRATES

The risk to birds and mammals is calculated according to the Guidance Document on Birds and Mammals (SANCO/4145/2000). The risk was calculated for an insectivorous bird and an insectivorous mammal. This risk assessment is based on the residue values for large insects. It was considered that these residue values were more appropriate as the product will be applied to bare soil and hence only ground dwelling species are exposed. This risk assessment was revised by the RMS in addendum 3 of June 2004. It was considered not necessary to assess the risk for herbivorous birds and mammals as the product will be applied to bare soil (trifluralin is a pre-emergence herbicide).

All calculated first tier TER values for insectivorous birds and mammals do not breach the appropriate Annex VI trigger value and hence the acute, short and long term risk to insectivorous birds and the acute and long term risk to insectivorous mammals can be considered as low for the representative uses.

Also the risk from secondary poisoning was assessed as the log Pow exceeds 3. This risk assessment was revised in the addendum 3 of June 2004.
The risk to fish eating birds and mammals can be regarded as low (Annex VI trigger not breached).
The Annex VI trigger value is breached for earthworm eating birds (TER=2.8) and mammals (TER=3.12) if the risk is calculated with the PEC(twa, 4 weeks) value which takes into account the accumulation plateau (which is reached after 14 years). The risk to earthworm eating birds and mammals was discussed in the EPCO expert meeting (section ecotoxicology, June 2004). The experts considered this as an extreme worst case situation. The Annex VI trigger value of 5 is respected if the risk is calculated based on the plateau PEC, i.e. the background contamination after 14 years, leading to a TER value of 5.27 for earthworm eating birds and 5.96 for earthworm eating mammals. The experts considered the risk to earthworm eating birds and mammals low based on this calculation. EFSA would like to highlight that, the risk to earthworm eating birds and mammals should be considered further at MS-level when the product is applied after the plateau value is reached.

5.2 RISK TO AQUATIC ORGANISMS

Selenastrum capricornutum is the most sensitive aquatic organism on an acute time-scale and fathead minnow is the most sensitive species on a chronic time-scale when tested with trifluralin and the lead formulation. Due to the difference in Annex VI trigger value, the risk assessment is driven by the endpoints for fish both on an acute as long term time-scale.
The resulting acute TER-value at 1 m from a field (7.9) is below and hence breaches the Annex VI trigger value of 100 so the risk should be considered as high. The rapporteur Member State calculated the risk taking into account buffer zones. This resulted in a TER-value of 110 indicating a low acute risk to fish if a bufferzone of 15 meters is taken into account.
The choice of a relevant endpoint for the long-term risk to fish was extensively discussed during the EPCO expert meeting (section ecotoxicology, June 2004). Trifluralin induces vertebral lesions in several fish species, and in some instances this effects is induced after short term exposure (24 hours

for brown trout). The meeting agreed that the risk assessment should be based in initial PEC and on the NOEC of 0.3 µg/L (based on the observed vertebral lesions in the study with fathead minnow) together with an uncertainty factor of 10 to conduct the risk assessment. This would lead to a TER value of 0.38 when a buffer zone of 15 m is taken into account (without detailed calculations, a bufferzone of 50 m should lead to a TER-value of approximately 1). Consequently the risk for aquatic organisms should be regarded as high. Therefore the risk should be further refined either by higher tier studies or by a refinement of the exposure assessment.
The meeting agreed that the use of time weighted average PECsw values is a possible approach (i.e. a refinement of the exposure assessment) but in that case more information is needed on the critical exposure period (time to onset of effects) in order to choose the most relevant time weighted average PECsw value. Therefore, the expert meeting set the following data requirement: notifier to submit exposure studies with different exposure times using the fathead minnow as the most sensitive fish species. As an alternative microcosm tests with a more realistic exposure regime may be run.

Trifluralin and the metabolites TR-4, TR-7 and TR-14 can be found in concentrations above 10% of the AR in the sediment. Therefore the risk to sediment dwelling organisms needs to be addressed. This risk assessment is available in the addendum 3 of June 2004. The effects of the a.s. and the metabolite TR-4 were tested on sediment dwelling organisms. The resulting TER values do not breach the Annex VI trigger value and hence the risk from the a.s. and the metabolite TR-4 can be regarded as low. No studies with the metabolites TR-7 and TR-14 on sediment dwelling organisms are available. The RMS regarded the risk from these metabolites as addressed based on the similarity with the parent compound. This was not accepted by the EPCO expert meeting (section ecotoxicology, June 2004) because if metabolites have different functional groups than the parent than they may act differently. Although the QSAR approach is usually not relevant for major metabolites it was decided that in this case this tool could be used as data from other metabolites are available. If the part of the molecule relevant for the pesticide activity has been removed and the QSAR calculations with both metabolites show, confirmed by the project leader of the PSD-project or another independent organization or authority, a lower toxicity than the active than no further testing is required. Alternatively studies with sediment dwelling organisms should be made available. In the evaluation meeting of November 2004 the RMS indicated that this data was already made available to them but was not evaluated.

Furthermore the metabolites TR-6 and TR-15 were tested. These metabolites are less toxic to aquatic organisms than the parent compound. Based on the resulting TER-values the risk from these metabolites can be considered as low (Annex VI trigger not breached).

Studies on bio-accumulation in fish are available as the logPow exceeds 3 and the DT_{50} in water exceeds 10. The steady state bioconcentration factor is found to be 5674 which exceeds the Annex VI trigger value of 100 for not readily biodegradable products.
In the list of endpoints available at the EPCO expert meeting (section ecotoxicology, June 2004) it is stated that the CT50 for bioaccumulation is 6 hours. In a summary of all chronic toxicity studies,

which was made available by the RMS during the expert meeting, other and longer depuration half-lifes were mentioned under remarks as the main aim of these studies was to look at chronic effects. The experts concluded that the risk for bioaccumulation was addressed and hence the risk for bioaccumulation can be regarded as low based on the very fast depuration. After this meeting EFSA noticed that the CT50 of 6 hours was erroneous. The RMS communicated to EFSA that the correct value is 4.7 days. This was verified by EFSA in the study by Graper and Rainey (1988), on which the BCF is based, and it is indeed stated in this study report that the depuration half-life equals 4.7 days. As this implies that the experts in the meeting may have based their decision on the wrong CT50 value in the list of endpoints at that time, the risk for bio-accumulation is further worked out by EFSA below in this conclusion.

This BCF-value and the fact that the depuration is less than 95% after 14 days triggers a fish full life cycle study which is available with the sheephead minnow. The resulting NOEC from this study is 1.3 µg/L (based on fecundity, no vertebral lesions observed) which is higher than the NOEC which is chosen for the long term risk assessment. As mentioned above a high long term risk to aquatic organisms was identified for which a data requirement is still open. Therefore, EFSA proposes that Member States may reconsider the risk for bioaccumulation when this long term assessment is revised, on receipt of the above mentioned data requirement. Residues in fish were found during the available field monitoring study.

The secondary poisoning for birds and mammals was assessed (see 5.1) and the risk to fish eating birds and mammals can be regarded as low (Annex VI trigger not breached).

An assessment of the biomagnification in aquatic food chains is not considered necessary as the DT90 for water and sediment is below 100 d.

5.3 RISK TO BEES

Acute contact and oral toxicity studies both with trifluralin and the lead formulation are available. The resulting HQ values do not breach the appropriate Annex VI trigger value indicating a low risk to bees.

5.4 RISK TO OTHER ARTHROPOD SPECIES

Toxicity to non-target arthropods was high in laboratory studies on the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. Therefore extended laboratory studies with both indicator species were performed in which the effect on mortality was less than the 50% Escort II trigger value but the effect on fecundity exceeded this trigger for both species. Effects on fecundity at 60 g as/ha (drift rate= 33.24 g as/ha) are below the trigger indicating a low risk for arthropods off-field.

Besides studies with the two indicator species, 4 acceptable studies with other species are presented of which 2 are ground dwelling species (*Poecilus cupreus* and *Aleochara bilineata*) and 2 are foliage dwelling (*Chrysoperla carnea* and *Phygadeuon trichops*). For none of these species effects were noted above the Escort II trigger value and hence the risk in-field for these species can be regarded as low. Ground dwelling species are considered the most relevant in-field for this representative use as the product will be applied to bare soil.

5.5 RISK TO EARTHWORMS

Studies on the acute toxicity to earthworms from trifluralin, the lead formulation and the metabolite TR-4 are available. The endpoints were corrected for the high logPow. The TER-values resulting from the endpoints derived from these studies do not breach the Annex VI trigger value indicating a low acute risk to earthworms for the representative uses.

Due to its high DT_{90} ($DT_{90field}$ > 365 days) long term exposure is expected. A study on the effects on reproduction is available. The long term risk assessment for earthworms was revised. This was during the EPCO expert meeting (section ecotoxicology, March 2004) expert meeting not yet available in an addendum but it was made available later by the RMS (addendum 3 of June 2004). The resulting NOEC was refined taking into account actual test values (application rate and surface of the test unit, dry soil weight in the test unit) as the first tier long term TER value breached the Annex VI trigger value. This refined endpoint resulted in a TER-value of 4.44 which is slightly below the Annex VI trigger value of 5. It was agreed by the EPCO expert meeting that the long term risk to earthworms could be regarded as low in this case given the worst case assumptions associated with the risk assessment (e.g. max soil PEC taking into account 14 years of accumulation and NOEC being at the top dose tested).

5.6 RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

Given the persistency in soil ($DT_{90field}$ > 365 days) a litterbag study was conducted for this substance. For the 0.025 mm mesh bags no statistically significant effects were seen after six months when compared with the control. For the 0.5 mm mesh bags statistically significant effects were seen after six months when compared with the control as the organic breakdown was increased in the treatment group. This was not regarded as an adverse effect.

It was noted by EFSA that the application rate in this study equals a single application and not a single application including the accumulated concentration in the soil according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). Therefore, EFSA proposes that a new litterbag study should be made available in which the tested dose rate reflects the concentration in the soil after a single application when the accumulation plateau has been reached. The need for this study was not discussed in an EPCO expert meeting.

5.7 RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of a 480 EC formulation and the soil metabolite TR-4 were tested on soil microbial respiration and nitrogen transformation. No deviations of more than 25 % after 60 days were observed (i.e. no breaching of the Annex VI trigger value) and hence the risk to soil non-target micro-organisms is considered to be low. The tested concentrations cover the max. PECs taking into account accumulation.

5.8 RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

Studies on the effects of trifluralin on non-target terrestrial plants are available. The RMS assesses the risk in the DAR by comparing the NOEC expressed in drift rate with the Ganzelmeier drift rate at 1 m

without calculating a TER-value. The RMS concludes that the risk to non-target plants is low and concludes that risk mitigation measures are not necessary. But this approach does not take into account a safety factor.
Based on a NOEC of 35 g as/ha for cereals, the TER-values result in 1.05 at 1 m and 5.12 at 5 m. According to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) the TER of the most sensitive species should be compared to a trigger of 5 if at least 6 species have been tested. But this TER is than based on an ER50 and not on a more conservative NOEC value. Therefore, the risk to non-target terrestrial plants can certainly be considered as low if a no spray buffer zone of 5 m is taking into account as it is based on this conservative NOEC value (see addendum made by EFSA).
Also a study on the post-emergence is available. Here cucumber is the most sensitive species with an ER25 (again no ER50 reported) of 748 g as/ha which results in a TER value of 22.5 at 1 m (see addendum 2 made by EFSA). The difference in sensitivity between the pre-emergence and post-emergence study can be explained by the fact that trifluralin is a pre-emergence herbicide.
The risk to non-target plants was not discussed in an EPCO expert meeting.

5.9 RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No effects were seen at the highest concentration tested (100 mg/L). The risk for biological methods of sewage treatment is considered to be low.

6 Residue definitions

Soil

Definitions for risk assessment: Trifluralin, TR-4, TR-14.
Definitions for monitoring: Trifluralin.

Water

Ground water

Definitions for risk assessment: Trifluralin, TR-4, TR-14.
Definitions for monitoring: Trifluralin.

Surface water

Definitions for risk assessment: Trifluralin, TR-6, TR-15.
Definitions for monitoring: Trifluralin.

Sediment

Definition for the risk assessment: Trifluralin, TR-7[14] and TR-14.

[14] α, α, α trifloro-N^4,N^4-dipropyltoluene-3,4,5 triamine

Air

Definitions for risk assessment: Trifluralin.

Definitions for monitoring: Trifluralin.

Food of plant origin

Definitions for risk assessment: Trifluralin (cereals only)

Definitions for monitoring: Trifluralin (cereals only)

Food of animal origin

Definitions for risk assessment: not necessary/not proposed

Definitions for monitoring: not necessary/not proposed

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Trifluralin	Medium to highly persistent ($DT_{50\ lab}$ = 81 to 356 d at 22 °C)	See points 5.5, 5.6 and 5.7.
TR-4 (the EPCO expert meeting agreed that no further assessment was necessary for EU evaluation)	Anaerobic metabolite. No DT_{50} available, assessed to be degradable under aerobic conditions based on chemical structure. Worst case DT_{50} = 1800 d used for FOCUS gw	Acute risk to earthworms is considered to be low (trigger not breached). The risk to soil non-target micro-organisms is considered to be low.
TR-14 (EFSA concludes that no further assessment is necessary for EU evaluation)	Anaerobic metabolite. No DT_{50} available, assessed to be degradable under aerobic conditions based on chemical structure.	No data with soil organisms available.

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses	Pesticidal activity	Toxicological activity	Ecotoxicological activity
Trifluralin	Immobile	No	Yes, to be assessed by Member States	Yes, assessed in the DAR	Yes, assessed in the DAR

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses	Pesticidal activity	Toxicological activity	Ecotoxicological activity
TR-4 (anaerobic) (the EPCO expert meeting agreed that no further assessment was necessary for EU evaluation)	Immobile (SAR estimation)	No	-	-	Acute risk to earthworms is considered to be low (trigger not breached). Also the risk to sediment dwelling organisms and soil non-target micro-organisms is considered to be low (trigger not breached).
TR-14 (anaerobic) (the EPCO expert meeting agreed that no further assessment was necessary for EU evaluation)	No data	Not assessed	-	-	

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Trifluralin (water and sediment)	See point 5.2.
TR-6 (photolysis metabolite, water phase only)	The risk to aquatic organisms is considered low (trigger not breached) based on an acute toxicity study with fish, an acute toxicity study with *Daphnia magna* and a toxicity study with algae.
TR-15 (photolysis metabolite, water phase only)	The risk to aquatic organisms is considered low (trigger not breached) based on an acute toxicity study with fish, an acute toxicity study with *Daphnia magna* and a toxicity study with algae.

Compound (name and/or code)	Ecotoxicology
TR-4 (sediment only)	The risk to sediment dwelling organisms is considered to be low (trigger not breached).
TR-7 (sediment only)	See data requirement
TR-14 (sediment only)	See data requirement

Air

Compound (name and/or code)	Toxicology
Trifluralin	See points 2.1-9

LIST OF STUDIES TO BE GENERATED OR STILL ONGOING

- The notifier should submit further data on the toxicity of the metabolites TR-7 and TR-14 to sediment dwelling organisms using the PSD-model or from another independent organization or authority based on the QSAR approach from Allister or alternatively studies with sediment dwelling organisms (relevant for all representative uses evaluated; data already made available to the RMS but not evaluated yet; refer to point 5.2)
- A further metabolism study is required for oilseed crops, and oilseed uses are not currently supported by available metabolism data. (relevant for the representative uses in oilseed rape, sunflower, cotton; submission date proposed by the notifier: March 2006; refer to point 3.1.1)
- Further information on conduct and comparability of North American residue trials in cereals is required to support Southern European uses. (relevant for the representative uses in cereals; submission date proposed by the notifier: December 2005; refer to point 3.1.1)
- For situations where anaerobic conditions are expected to be relevant potential ground water contamination by metabolite TR-14 may need to be assessed (not essential to finalize the risk assessment at EU level, refer to point 4.1).
- A water sediment study conducted in the presence of light that could be used by MS to refine the risk assessment performed in the context of Annex I inclusion (not essential to finalize the risk assessment at EU level, refer to point 4.2).
- It is noted by EFSA that throughout the section on ecotoxicology formulations were tested which differ from the lead formulation. Therefore, their composition should be made available to the RMS in order to assess their comparability to the lead formulation (relevant for all representative uses evaluated; no submission date yet proposed by the notifier; refer to point 5).
- In the aquatic risk assessment the initial PEC's together with the NOEC of 0.3 µg/L are used. If the notifier disagrees on this, additional studies with different exposure regimes to identify the most critical exposure period should be conducted : Notifier to submit exposure studies with different exposure times using the fathead minnow as most sensitive species or alternatively another higher tier study (maybe mesocosms studies) can be conducted; (relevant for all representative uses evaluated; submission date proposed by the notifier: July 2005; refer to point 5.2)
- A new litterbag study should be made available in which the tested dose rate reflects the concentration in the soil after a single application when the accumulation plateau has been reached. This data requirement is proposed by EFSA and has not been discussed in an EPCO expert meeting (relevant for all representative uses evaluated; no submission date yet proposed by the notifier; refer to point 5.6)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide as proposed by the notifier which comprises spraying to bare soil to control grass and broad-leaved weeds in oilseed rape, sunflowers, cotton and winter cereals at application rate up 1.2 kg trifluralin

per hectare. The representative formulated product for the evaluation was "EF-1521" ("Treflan"), an emulsifiable concentrate (EC), registered under different trade names in Europe. In case of oilseed rape, sunflowers, cotton, incorporation into soil takes place after the application. Trifluralin can be used only as pre-emergence herbicide.

Analytical methods for the determination of residues of trifluralin are available for commodities with high fat content (e.g. oil seed rape), cereals, soil, water (incl. drinking and surface water) and air.
An analytical method for food of animal origin is currently not required due to the fact that no residue definition can be proposed at the moment.
Trifluralin is extensively and rapidly metabolised. Within 48 hours, 82% is absorbed and more than 90% is excreted within 168 h mainly *via* bile. It has a low acute toxicity, but displayed sensitising properties and should be labelled with **Xi; R43 "May cause sensitisation by skin contact"**. The relevant oral NOAEL in the short term studies was 2.4 mg/kg bw/day in the 1-year dog, based on increased liver weight and some minor changes in the chemistry. The dermal and inhalation toxicity after subchronic exposure was low.
Regarding genotoxic properties of trifluralin it was concluded that trifluralin induces weak clastogenic and aneugenic effects in a number of *in vivo* and *in vitro* studies, but this was not confirmed in a more reliable and recently performed (2003) micronucleus test. Trifluralin induced neoplastic changes and carcinogenic effects such as Leydig cell tumours, thyroid tumours, urinary bladder tumors and renal carcinoma in the rat. Since no NOAEL could be established the LOAEL of 30 mg/kg bw/day in the rat is assigned as the most relevant effect level. The following risk phrase is proposed **Xn; R40 "Limited evidence of a carcinogenic effect"**.
There were no direct effects on reproductive performance or fertility observed and the relevant NOAEL for reproduction was set to 4.5-5.8 mg/kg bw/day in the rat based on haematological changes, decreased maternal body weight during gestation and decreased offspring growth and survival, respectively. Trifluralin did not induce teratogenic or fetotoxic effects at non-maternally toxic doses and the developmental and maternal NOAEL is 50 mg/kg bw/day in the rabbit based on decreased foetal weight, postimplantation losses and reduced body weight, food consumption, respectively.
The proposed ADI is 0.015 mg/kg bw/day based on the LOAEL in the rat cancer study with a margin of safety between LOAEL and ADI of 2000 since the ADI is based on a LOAEL value instead of a NOAEL value and that at this dose level tumour formation was evident.
The proposed AOEL is 0.026 mg/kg bw/day based on the NOAEL in the 90-day mechanistic study in rats using a safety factor of 100. No correction for oral absorption required.
No ARfD allocated.
The outcome of the risk assessment for the plant protection product TREFLAN (code EF-1521) an emulsifiable concentrate (EC) containing 480 g trifluralin/L showed that the estimated operator **exposure levels (according to German model) were below the AOEL only if PPE are used both during mixing/loading (gloves) and application (i.e. coverall),** Calculated exposure levels for bystanders were also below the established AOEL. The value of dermal absorption is 10% for

concentrate and diluted formulation. There was no need for estimating the worker exposure since trifluralin is a pre-emergence herbicide applied directly to soil.

The metabolism of trifluralin in cereals is extensive and does not yield metabolites of toxicological concern. No residues of trifluralin were quantified in any of the cereal grain or straw samples from field trials conducted according the critical GAP in Northern Europe. Further information is needed to conclude on the residue situation in cereals for Southern European uses.
For oilseed crops the present studies do not fully address consumer exposure via seeds. Therefore a further metabolism study is required for oilseeds to support uses on these crops. Subsequently the applicability of the submitted residue trials in oilseed crops has to be reviewed.
Due to the above mentioned requirements a final conclusion on the livestock dietary burden and on the possible occurrence of residues in food of animal origin can not be drawn at this stage.
The chronic dietary exposure assessment for consumers based on the currently available information in line with the Northern European GAP on cereals leads to estimated intakes less than 4 % of the proposed ADI for the consumer subgroups of infants and young children. However, this assessment needs to be reviewed upon receipt of the outstanding data. An ARfD was not allocated, thus there is no acute risk for consumers arising from trifluralin residues in food.

In aerobic conditions degradation of trifluralin in soil did not lead to any major metabolites but several minor metabolites were formed by oxidative dealkylation of N-propyl, reduction of nitro groups with cyclation and dimerization to form azoxy-benzene compounds. The level of unextractable residues was between 23.3 % and 43.1 % AR after 120 d and reached between 33.5 % and 54.1 % after one year. As measured in one soil, CO_2 evolved was 8.4 % AR at 120 d and 18 % AR after one year.
Under flooded anaerobic conditions a major metabolite TR-4 is formed. Furthermore, metabolite TR-14 was formed at amounts above 5 % at the end of the study in all three anaerobic soils tested. The EPCO experts meeting (section fate and behaviour) agreed that according to the molecular structure it may be expected that this metabolite undergoes degradation under aerobic conditions and that therefore, relevance of metabolite TR4 may be addressed by Member States where anaerobic conditions are envisaged to be relevant. Whereas not discussed in particular during the Peer Review it is the EFSA opinion that the same conclusion may be reached for metabolite TR14.
Under aerobic laboratory conditions trifluralin is medium to highly persistent with half-lives between 81 to 356 d at 22 ^{o}C. The degradation under anaerobic conditions was faster than under aerobic conditions.
Overall mean half life in field is 170 d confirming the concern for the highly persistence of this compound already shown by the laboratory studies. Potential for accumulation has been estimated by calculation with the worst case field DT_{50}. PEC soil calculated using worst case DT_{50} are employed in the risk assessment for Annex I inclusion and shown in the list of end points.
Data indicate that trifluralin is strongly adsorbed to soil and could be classified as immobile. For anaerobic metabolite TR-4 Koc was estimated, using the "pckocwin v.1.66 (EPA)" program, indicating also low mobility potential for this metabolite.

Trifluralin is hydrolytically stable in sterile aqueous buffers between pH 3 and pH 9 at 52 °C with an extrapolated half life above one year at 20 °C. Aqueous photolysis may contribute to the environmental degradation of trifluralin and it is enhanced in natural water. Photodegradation of trifluralin led to the formation of two major photoproducts TR-6 and TR-15. Initial PECsw have been calculated for these metabolites based on the maximum amounts observed in the photolysis study. No further data was deemed necessary to conclude the risk assessment for these metabolites.
Trifluralin is not readily biodegradable.
The selection of the most appropriate DT_{50} to be used for PECsw water calculation and aquatic risk assessment was discussed in two EPCO experts meetings (section fate and behaviour, April 2004 and June 2004). It was agreed that worst case DT_{50} = 13 d (from first study, Yon, 1993) should be employed for the risk assessment performed in the context of Annex I inclusion and that a DT_{50} = 2 d (from third study, Cook, W.L., Meitl T.J.) could be used to refine risk assessment when appropriate. PECsed are calculated for trifluralin metabolites TR-4 and initial PECsed are also calculated for metabolites TR-7 and TR-14.
Due to the potential contribution of photolysis to the dissipation of trifluralin in water, the EPCO expert meeting (section fate and behaviour) confirmed the need of a water sediment study conducted in the presence of light that could be used by MS to refine the risk assessment performed in the context of Annex I inclusion (data requirement 4.4).
PECgw of trifluralin and anaerobic metabolite TR-4 were estimated using FOCUS PELMO 1.1.1 for the nine EU scenarios and the representative uses. Calculated concentration in groundwater for both compounds was negligible in all nine scenarios.

Trifluralin was designated as a “priority substance” under the water framework Directive but has not been identified as a “priority hazardous substance”. However, trifluralin has been added to the OSPAR (Convention for the Protection of the Marine Environment of the North-East Atlantic) List of Chemicals for Priority action in 2002 because it is considered to be a PBT substance.
Because of its high volatility the occurrence of trifluralin in air and transport trough air is possible. However, photochemical half life in air is estimated to be short.
PECair were not calculated since they are not used in the assessment and no method at EU level is agreed for such calculation.

The risk to insectivorous and fish-eating birds and mammals, bees, ground dwelling arthropods, soil micro-organisms, including earthworms is low with respect to trifluralin and the metabolites as far as investigated.
High risks were identified for aquatic organisms, in particular the risk to fish, which require consideration of appropriate risk mitigation measures. Using the intial PEC’s together with the NOEC of 0.3 µg/L leads to a TER-value of 0.38 when a bufferzone of 15 metres is taken into account which is below the Annex VI trigger value of 10 (without detailed calculations, a bufferzone of 50 m should lead to a TER-value of approximately 1). Further data to address this risk is needed and the risk assessment can only be concluded when the outstanding data is evaluated.
EFSA proposes that Member States should reconsider the risk for bioaccumulation.

The EPCO expert meeting (section ecotoxicology, June 2004) considered the risk to earthworm eating birds and mammals as low based on the TER value reflecting the soil accumulation plateau. EFSA would like to highlight that, the risk to earthworm eating birds and mammals should be considered further at MS-level when the product is applied after this plateau value is reached
EFSA proposes that a new litterbag study should be made available in which the tested dose rate reflects the concentration in the soil after a single application when the accumulation plateau has been reached as the study which is available at present was performed at a lower dose rate. This data requirement has not been discussed in an EPCO expert meeting
The risk to non-target plants could not be calculated with the appropriate endpoint (an ER50-value) as this value is not reported in the DAR. Based on a conservative NOEC, the risk to non-target plants can be certainly regarded as low if a bufferzone of 5 metres is taken into account.

Regulation (EC) No 850/2004[15] of the European Parliament and of the Council on persistant organic pollutants and amending Directive 79/117/EEC entered into force when the Peer Review of trifluralin was in an advanced stage. For this reason, EFSA's conclusion does not specifically assess trifluralin against the criteria set in the paragraph 1 of Annex D of the Stockholm convention.
However, available information assessed during the Peer Review and provided in this conclusion should allow the Commission and the Member States to conduct the assessment of trifluralin with respect to Regulation (EC) No 850/2004.
EFSA acknowledges that the assessment presented in this conclusion only considers a limited range of representative uses on the basis of the information provided by the notifier in the application dossier and the Member States during the Peer Review. Therefore, other information may need to be considered by the Commission and the Member States when assessing trifluralin with respect to Regulation (EC) No 850/2004.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- The two year shelf life study indicates that permanent agitation of the tank mixture during the spraying is appropriate to exclude any problems regarding the emulsion stability.
- The estimated operator exposure was below the AOEL only if PPE is used during mixing and loading as well as coverall during application (refer to point 2.12).
- The residue definition should be restricted to the representative uses in cereals. If for future uses residue levels (and/or metabolite) become significant, this would need to be reviewed (refer to point 3.1.1).
- A withholding period for cereal green forage of at least 4 weeks after application is recommended. Forage data demonstrated that trifluralin was present within the first four weeks in maize forage samples, partially at significant levels (refer to points 3.1.1 and 3.2). For the use on oilseeds a withholding period for forage has to be considered upon receipt and evaluation of the outstanding data.

[15] OJ No L 158, 30.04.2004, p. 21

- Appropriate risk mitigation measures are required with regard to the acute risk for aquatic organisms in particular the chronic risk to fish (refer to point 5.2).
- Appropriate risk mitigation measures (e.g. a 5 meter no spray bufferzone) are required with regard to the risk for non target terrestrial plants (refer to point 5.8).
- EFSA would like to highlight that, the risk to earthworm eating birds and mammals should be considered further at MS-level when the product is applied after the plateau value is reached (refer to point 5.1).

Critical areas of concern

- The risk to aquatic organisms is high, in particular to the risk to fish. Using the initial PEC's together with the NOEC of 0.3 µg/L leads to a TER-value of 0.38 when a bufferzone of 15 metres is taken into account which is below the trigger value of 10 (without detailed calculations, a bufferzone of 50 m should lead to a TER-value of approximately 1).

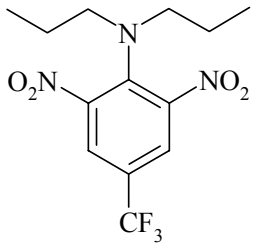
APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Trifluralin
Function (e.g. fungicide)	Herbicide
Rapporteur Member State	Greece

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	α,α,α-trifluoro-2,6-dinitro-*N*,*N*-dipropyl-*p*-toluidine
Chemical name (CA) ‡	2,6-dinitro-*N*,*N*-dipropyl-4-(trifluoromethyl) benzenamine
CIPAC No ‡	183
CAS No ‡	1582-09-8
EEC No (EINECS or ELINCS) ‡	EINECS: 216-428-8 ELINCS: not applicable
FAO Specification ‡ (including year of publication)	AGP: CP/235 (1988); 183/TC/S 950 g/kg (±20 g) *N*-nitroso-di-*n*-propylamine: max. 1 mg/kg)
Minimum purity of the active substance as manufactured ‡ (g/kg)	950 g/kg, for both companies of the EUTTF
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Dow AgroSciences: *N*-nitrosamines: max.0.4 mg/kg Makhteshim Agan: *N*-nitroso-di-*n*-propylamine: max.0.5 mg/kg
Molecular formula ‡	$C_{13}H_{16}F_3N_3O_4$
Molecular mass ‡	335.28
Structural formula ‡	

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	47.2 ± 0.1 °C (pure 99.4%)
Boiling point (state purity) ‡	Not determinable due to decomposition
Temperature of decomposition	202 ± 1 °C (pure 99.4%)
Appearance (state purity) ‡	pure a.s. (99.4%): bright orange crystalline solid, with odour vaguely of mothballs tech. a.s. (96.2%): bright orange crystalline solid, with faint aniline odour
Relative density (state purity) ‡	D_4^{22} = 1.36 (tech.: 96.8%)
Surface tension	at 24.5 C: 71.4 mN/m (saturated solution) 72.1 mN/m (half-saturated solution) (tech. 96.8%)
Vapour pressure ‡ (in Pa, state temperature)	9.5×10^{-3} Pa at 25 °C (pure 100%)
Henry's law constant (Pa m^3 mol^{-1}) ‡	10.2 $Pa \cdot m^3 \cdot mol^{-1}$ at 20 °C (pure 100%)
Solubility in water ‡ (g/Lor mg/L, state temperature)	At 20 °C (pure 100%): In distilled water: 0.194 mg/L pH 5: 0.184 mg/L pH 7: 0.221 mg/L pH 9: 0.189 mg/L
Solubility in organic solvents ‡ (in g/L or mg/L, state temperature)	>250 g/kg in hexane, toluene, chloroform, methylene chloride, acetone, ethyl acetate and acetonitrile, at 20 °C. 142.0 g/L in methanol at 18 °C.
Partition co-efficient (log $P_{O/W}$) ‡ (state pH and temperature)	log $P_{o/w}$ = 5.27 at 20 °C (pure 100%) pH ranged 7.73-8.86 (pH of aqueous phase after partition)
Hydrolytic stability (DT_{50}) ‡ (state pH and temperature)	Less than 10% degradation at pH 4, 7 and 9 after 5 days at 50 °C, therefore the extrapolated half-life (at 25 °C) is estimated >1 year (96.8% tech.)
Dissociation constant ‡	Not determinable since trifluralin does not contain ionizable functional groups.
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	In neutral medium (CH_3OH): λmax (nm) — ε ($M^{-1} \times cm^{-1}$) 209.0 — 19.4×10^3 272.2 (or 273) — 8.46×10^3 (or 7.69×10^3) 385 — 2.44×10^3
Photostability (DT_{50}) ‡ (aqueous, sunlight, state pH)	pH 7: DT_{50} = 7 hours (xenon lamp)
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	0.0112

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Flammability ‡	Non-flammable
Explosive properties ‡	Non-explosive

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

List of representative uses evaluated*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Oilseed rape	Northern and Southern Zones	EF-1521	F	Grass and broad-leaved weeds	EC	480 g/L	BI	Pre Pre A/S	1	NA	0.08-0.8	150-600	0.48-1.2	NA	Low rate in light soils, high rate in heavy soils The dose should not exceed the 1.2 kg a.s./ha
Sunflower	Northern and Southern Zones	EF-1521	F	Grass and broad-leaved weeds	EC	480 g/L	BI	Pre Pre S	1	NA	0.08-0.8	150-600	0.48-1.2	NA	
Cotton	Southern Zone	EF-1521	F	Grass and broad-leaved weeds	EC	480 g/L	BI	Pre Pre S	1	NA	0.08-0.48	200-600	0.48-1.2	NA	
Winter Cereals	Northern Zone	EF-1521	F	Grass and broad-leaved weeds	EC	480 g/L	BS	Post Pre A	1	NA	0.096-0.74	150-600	0.576-1.2	NA	

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Winter Cereals	Southern Zone	EF-1521	F	Grass and broad-leaved weeds	EC	480 g/L	BS	Post Pre A	1	NA	0.096-0.74	150-600	0.576-1.2	NA	

BI = Broadcast spray to bare soil followed by incorporation into soil
BS = Broadcast spray to bare soil without incorporation
Pre Pre= Pre-sowing pre-emergence
Post Pre = Post sowing pre-emergence
A = Autumn , S= Spring, NA = Not applicable

Remarks:				
	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	Dow AgroSciences Certain amounts of trifluralin technical and dimethyl phthalate (IS) are dissolved in acetone and trifluralin content is determined by GC/FID. Makhteshim Agan Certain amounts of trifluralin technical product and dipropylphthalate (internal standard) are dissolved in acetonitrile. The solution is sonicated and filtered through a 0.45m filter. Analysis is made by GC/FID.
Impurities in technical as (principle of method)	DowAgroSciences Significant impurities Trifluralin technical is dissolved in acetone. Analysis is made by GC/FID using the external standard technique. N-nitrosamines The method is applied for the determination of the volatile nitrosamines NDMA, NDEA, NDPA, NDBA, NPIP, NPYR and NMOR. Certain amounts of trifluralin technical, sodium chloride, ascorbic acid, glycerine are dissolved in water. The mixture is boiled at 35oC under vacuum in a Claisen apparatus and the distillate is collected. The distillate is extracted by SPE (elution with dichloromethane). The determination of the volatile nitrosamines is performed by GC using thermo energy analyzer detector. Quantitation is made by the internal standard technique (N-nitroso-buthyl-propyl-amine). Makhteshim Agan Significant impurities Trifluralin technical is dissolved in acetonitrile. The solution is sonicated and filtrated through a 0.45µm filter. Analysis is made by GC/FID using the external standard technique. N-nitrosamines The method is applied for the determination of N-nitrosodipropylamine (NDPA). A certain amount of trifluralin technical and a certain amount of N-nitrosodiethylamine (NDEA) standard solution (internal standard) are dissolved in n-hexane. The solution is sonicated, cleaned-up through a Bio-Rad chromatographic column and filtered through a 45µm filter paper. Analysis is made by GC using a thermal energy analyzer detector.

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Plant protection product (principle of method)	An aliquot of the sample is diluted with an internal standard solution of dipropyl phthalate in ethyl acetate and analyzed by GC/FID. Quantitation is made by internal standard calculation using peak areas.
Impurities in the plant protection product (principle of method)	Determination of di-n-propylnitrosoamine in formulation EF-1521: An aliquot of the sample is spiked with an internal standard solution of di-iso-propylnitrosoamine (DiPNA) in 1-chlorobutane. A solid phase extraction technique is performed on an aliquot of sample that has been spiked with internal standard. An aliquot of the extract is analysed by GC/MS. Quantitation is performed at m/z 130 for both DiPNA and DnPNA. Qualitative confirmation is performed at m/z 70 for both DiPNA and DnPNA. External standard calculation using peak areas may also be performed.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Method GRM 01.29 (Ref. OR43) Substrates: cottonseed, wheat, barley Extraction: Samples are extracted with methanol. Clean up: The extracts are diluted with water and purified using a hydrophilic-lipophilic balanced SPE column. Analysis: Analysis is carried out by GC/NCI-MS. Determined analyte: trifluralin LOQ: 0.01 mg/kg Method ERC 94.13 (Ref. OR03) Substrates: oilseed rape (whole plant, straw, seed) Extraction: Samples are extracted with methanol. After addition of water the methanol extract is partitioned into hexane. Clean up: The hexane extract is purified using a Florisil SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.01 mg/kg for oilseed rape seed 0.2 mg/kg for oilseed rape whole plant and straw Method ERC 94.4 (Ref. OR02) Substrates: sunflower seed Extraction: Samples are extracted with methanol. After addition of water the methanol extract is partitioned into hexane.

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	Clean up: The hexane extract is purified using an aminopropyl SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.01 mg/kg
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No method submitted, but not required, since no MRLs have been proposed for products of animal origin.
Soil (principle of method and LOQ)	1) Method ERC-96.26 (Ref.: OR16) Substrate: sediment Extraction: Residues of trifluralin are extracted from sediment with an aqueous acetonitrile mixture. Clean up: The extract is purified using a C18 SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.01 mg/kg 2) Method ERC 92.41 (Ref.: OR05) Substrate: soil Extraction: Residues of trifluralin are extracted from sediment with an aqueous acetonitrile mixture. Clean up: The extract is purified using a C18 SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.01 mg/kg 3) Method AM-AA-CA-R116-AA-755 (Ref.: OR04) Substrate: soil Extraction: Residues of trifluralin are extracted from soil with an aqueous acetonitrile mixture. Clean up: The extract is purified using a C18 SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.022 mg/kg
Water (principle of method and LOQ)	Method GRM-01.34 (Ref.: OR51) Substrates: drinking water, surface water, ground water Extraction: Samples are extracted with isooctane. Analysis: Analysis is carried out by GC/NCI-MS. Determined analyte: trifluralin LOQ: 0.05 µg/L

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Air (principle of method and LOQ)	Method 295/152-D2149 (Ref.: OR55) Substrates: Air (ambient temperature and humidity and 35°C and >80% humidity) Extraction: The trifluralin residue is extracted from the XAD-4 resin air sampling tubes with hexane. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.72 µg/m^3
Body fluids and tissues (principle of method and LOQ)	No method submitted, but not required.

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	Not classified

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Rapid and nearly complete (82% at 48 hrs after single oral administration), plasma Cmax at 0.75-4 hrs after both single low and high oral dose administration
Distribution ‡	Widely distributed; highest concentration in adrenals, fat, kidneys, liver, skin and blood
Potential for accumulation ‡	No evidence of accumulation
Rate and extent of excretion ‡	Rapid and higher than 90% at 168 hrs, mainly *via* bile, otherwise *via* faeces, regardless of dose level
Metabolism in animals ‡	Extensively metabolized, mainly through conjugation (75% of the urine residue), reduction of nitro-groups, N-dealkylation, hydroxylation and cyclization reactions. Numerous minor urinary metabolites (<5% of the urine residue or <2% of the initial dose); four faecal identified metabolites (1-9% of the dose). No species difference
Toxicologically significant compounds ‡ (animals, plants and environment)	Parent compound and metabolites.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw
Rat LD_{50} dermal ‡	> 2000 mg/kg bw
Rat LC_{50} inhalation ‡	> 1.252 mg/L/ 4 hours head only exposure
Skin irritation ‡	Non-irritant
Eye irritation ‡	Non-irritant
Skin sensitization ‡ (test method used and result)	Sensitising (M&K) **R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Decreased body weight gain, increased alpha-1 globulin and albumin concentrations (rat), anaemia (dog), increased liver weight (rat, dog)
Lowest relevant oral NOAEL / NOEL ‡	2.4 mg/kg bw/day, 1-year dog study
Lowest relevant dermal NOAEL / NOEL ‡	1000 mg/kg bw/day, 21-day rabbit
Lowest relevant inhalation NOAEL / NOEL ‡	>0.09 mg/kg-bw/day (i.e. 22.5 µg/L), 21-day rat study (limit test)

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Genotoxicity ‡ (Annex IIA, point 5.4)

.....	Weak clastogenic and aneugenic effects in a limited number of in vivo and in vitro studies, not confirmed in the most reliable, recent, in vivo GLP study (micronucleus study with kinetochore staining)

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Body weight reduction, anemia, liver & kidney effects (mouse, rat). Tumor formation in kidney, thyroid, urinary bladder, Leydig cells (Fischer 344 rat).
Lowest relevant NOAEL / NOEL ‡	Not established LOAEL = 30 mg/kg bw/day, 2 year rat
Carcinogenicity ‡	Evidence of carcinogenic potential in Fischer 344 rat, (tumour formation in various tissues, i.e. kidney, urinary bladder, thyroid, Leydig cell). The mechanism of tumour formation is not identified. **R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Decreased maternal growth, anaemia, uterine atrophy and decreased offspring growth and survival from 40,7-50,8 mg/kg bw/day (rat)
Lowest relevant reproductive NOAEL/NOEL ‡	4.5-5.8 mg/kg bw/day Parental and offspring, rat
Developmental target / critical effect ‡	No teratogenic or fetotoxic effects were observed at non-maternally toxic doses (rat, rabbit)
Lowest relevant developmental NOAEL / NOEL ‡	50 mg/kg bw/day Maternal and developmental, rabbit

Neurotoxicity / Delayed neurotoxicity ‡ (Annex IIA, point 5.7)

.....	Not relevant

Other toxicological studies ‡ (Annex IIA, point 5.8)

Lowest relevant oral NOAEL / NOEL	2.6 mg/kg b.w./day (50 ppm), 90-day rat urinalysis mechanistic study
Target / critical effect	Increase in hyaline droplet formation in the renal cortical tubular epithelium and altered urinalysis.

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Medical data ‡ (Annex IIA, point 5.9)

.....	Effects of occupational exposure involve redness, rash, hives, vesicular change, bullae and pruritis. Epidemiological studies revealed that there was no evidence of correlation between increased cancer incidence rate or reproductive effects or asthma and exposure to trifluralin.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.015 mg/kg bw/day	LOAEL of 30 mg/kg bw/day rat carcinogenicity study	2000†
AOEL ‡	0.026 mg/kg bw/day	90-day rat mechanistic urinalysis study	100
ARfD ‡	Not relevant		

† The EPCO expert meeting in May 2004 (18002/EPCO/PSD/04) agreed to allocate a margin of safety to be allocated for trifluralin since the ADI is based on a LOAEL (based on tumour formation) instead of a NOAEL.

Dermal absorption (Annex IIIA, point 7.3)

.....	A default value of 10% is used for both the concentrate and the formulation TREFLAN EC (codeEF-1521).

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Acceptable exposure scenarios (including method of calculation)

Operator	The exposure levels to trifluralin are lower than the AOEL when gloves are worn during mixing/loading and application according to the German model for field application. The estimated operator exposure (German model), for the use of TREFLAN EC, was below the AOEL only if PPE are used. High application rate (1.2 kg a.i./ha) Without PPE: 1469% of AOEL PPE gloves (M/L): 562% of AOEL PPE gloves (M/L+A), coverall (A): 62% of AOEL Low application rate (0.48 kg a.i./ha) Without PPE: 588% of AOEL PPE gloves (M/L): 223% of AOEL PPE gloves (M/L+ A), coverall (A): 23% of AOEL
Workers	Re-entry is not applicable since it is a pre-emergence herbicide applied directly to the soil.
Bystanders	The exposure was below the AOEL.

M/L = Mixing and loading, Appl. = Application

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	Xn; Carc. Cat. 3; R40 Limited evidence of a carcinogenic effect Xi; R43 May cause sensitization by skin contact

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.4: Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	cereals (C) (maize)
Rotational crops	leafy crops (L) (cabbage), root vegetables (R) (sugar beet, turnip), cereals (C) (maize and wheat), pulses and oilseeds (P/O) (soybeans), fruits (F) (tomato)
Plant residue definition for monitoring	Trifluralin (parent compound) for cereals only
Plant residue definition for risk assessment	Trifluralin (parent compound) for cereals only
Conversion factor (monitoring to risk assessment)	None

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not applicable (N.A.)
Animal residue definition for monitoring	N.A.
Animal residue definition for risk assessment	N.A.
Conversion factor (monitoring to risk assessment)	N.A.
Metabolism in rat and ruminant similar (yes/no)	N.A.
Fat soluble residue: (yes/no)	Yes (log $P_{O/W}$ >4 at 25 °C)

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	In studies with radiolabelled trifluralin, total radioactive residues in a range of immature and mature rotational crops (leafy crops, root vegetables, cereals, pulses, fruits) planted 30 days or more after applications of trifluralin at rates approximately equal to the GAP rate were less than 0.15 mg trifluralin equivalents/kg. In all crops, the residue was multicomponent in nature and total residues were very low. In one study, trifluralin was found in one commodity only and at very low levels, 0.004 mg/kg. No component exceeded 0.01 mg/kg. In the second study trifluralin and its identifiable metabolites were not recorded. The results demonstrate that the metabolism in rotational crops is similar to those recommended for treatment with trifluralin. In field studies, residues of trifluralin in seed of maize (five sites) and wheat (three sites) planted in normal rotation after applications of trifluralin in two or three successive years were below the LOQ. In one other site, residues of 0.03 mg/kg were recorded in maize. Overall, the studies with radiolabelled trifluralin show that very little trifluralin or its metabolites are found and the field studies confirm these findings. Residues in crops

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	grown in rotation after cereals in commercial practice are expected to be below the LOQ. Any crop can be planted following harvest of a crop treated with trifluralin.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	For wheat straw there was no decline in residue levels following storage at 4ºC/ambient temperature for two months followed by storage at -15ºC to -25ºC for up to 16 months. For other commodities (sunflower seed, cotton seed, wheat grain) there was an initial decline in residue levels of 15 to 30% during storage for approximately one month at 4ºC/ambient temperature. However, there was no decline in residue levels following storage for a further one month at ambient temperature or following storage at -15ºC to -25ºC for up to 12 to 16 months. Trifluralin residues were stable in wheat grain and processed commodities stored frozen for up to eight months.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes/no	Poultry: yes/no	Pig: yes/no
Muscle	no	no	no
Liver	no	no	no
Kidney	no	no	no
Fat	no	no	no
Milk	no		
Eggs		no	

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Winter cereals Wheat Barley Oats Rye Triticale	N	4X0.01* 2X0.01*		0.01*	
	S	There are no residue trials for winter cereals in Southern Europe	Extrapolation from the trials conducted in USA and CAN may be possible subject to data requirement on comparability		

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.015 mg/k.g. b.w./day
TMDI (European Diet) (% ADI)	0.000167[1] mg/kg b.w./day (1.1% ADI)
NEDI (% ADI)	UK Model: adult: 0.000244[1] (1.6% ADI), child: 0.000417[1] (2.78% ADI), infant: 0.000531[1] (3.54% ADI) German model (girl 4-6 yrs): 0.00038[1] (2.5% ADI)
Factors included in NEDI	-
ARfD	Not proposed
Acute exposure (% ARfD)	Not applicable

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Not Applicable			

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Northern EU only	winter cereals (wheat, barley, oat, rye, triticale) 0.01*[2] mg/kg 0.05*[3] mg/kg

[2] Based on available data
[3] Proposal of MS to allow a cost effective monitoring

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	Measured: 8.4 % (after 120 days) & 18.5 % (after 364 days), (at 22 °C)
Non-extractable residues after 100 days ‡	Measured: 23.3 - 43.1 % (after 120 days) & 33.5 - 54.1 % (after 364 days), (at 22 °C)
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	None

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	Active substance (at 22 °C) : 25.5 - 57.0 % (30th day of flooded conditions) 12.3 - 35.6 % (60th day of flooded conditions) Volatile components: Less significant than under aerobic conditions Non-extractable residues: 23.2 - 42.4 % (30th day of flooded conditions) 35.3 - 60.1 % (60th day of flooded conditions) Major metabolites: TR-4: Range: ND - 11.6%, Max: 13.2% (60th day of flooded conditions)
Soil photolysis ‡	Active substance: 65.2 % after 29.8 days (irradiation) 80.2 % after 29.8 days (dark control) No major metabolites

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	Active substance: Solver function in a Microsoft Excel spreadsheet to find the best fit between the observed experimental data and the first order rate equation, as below: $C_t = C_0 \times e^{-k*t}$ Metabolite TR-4: Insufficient degradation data to calculate a DT_{50}/DT_{90}.

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Laboratory studies ‡ (range or median, with n value, with r^2 value)	DT_{50} (22°C, aerobic) Active substance: - SL: 154 days (r^2= 0.938) - L: 81 days (r^2= 0.956) - CL: 179 days (r^2= 0.948) - Speyer 2.1: 136 days (r^2= 0.930) - Speyer 2.2: 356 days (r^2= 0.973) Mean DT_{50} (22°C, aerobic): 181 days DT_{50} (20°C, aerobic) Active substance: Extrapolation from available data at 22°C using the mathematical formula $DT_{50\ (T1)} = DT_{50\ (T2)} * e^{[0.08*\ (T2-T1)]}$ (where T1=20 °C and T2=22°C). DT_{50} = 95 - 418 days Mean DT_{50} (20°C, aerobic): 212 days Metabolites: No major metabolites DT_{90lab} (22°C, aerobic): Active substance: - SL: 512 days (r^2= 0.938) - L: 270 days (r^2= 0.956) - CL: 593 days (r^2= 0.948) - Speyer 2.1: 452 days (r^2= 0.930) - Speyer 2.2: 1181 days (r^2= 0.973) Mean DT_{90} (22°C, aerobic): 602 days Metabolites: No major metabolites DT_{50} (10°C, aerobic) Active substance: Based on $DT_{50\ (20°C)}$ = 95 - 418 days & Q_{10} = 2.2, DT_{50} =209 to 920 days.

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	DT_{50lab} (22°C, anaerobic): Active substance: - SL: 54 days (r^2= 0.990) - L: 23 days (r^2= 0.998) - CL: 35 days (r^2= 1.000) Mean DT_{50} (22°C, anaerobic): 37 days DT_{90} (22°C, anaerobic): Active substance: - SL: 181 days (r^2= 0.990) - L: 77 days (r^2= 0.998) - CL: 116 days (r^2= 1.000) Mean DT_{90} (22°C, anaerobic): 125 days DT_{50} (photolysis): Active substance: - SL: 44 days (irrad.) & 68 days (dark control) (r^2= 0.867) DT_{90} (photolysis): Active substance: - SL: 147 days & 225 days (dark control) (r^2= 0.867)
	degradation in the saturated zone ‡: no data
Field studies ‡ (state location, range or median with n value)	DT_{50} (field): Active substance: Germany: 183 days (r^2=0.971), 164 days (r^2=0.963), 200 days (r^2=0.857), 375 days (r^2=0.810) United Kingdom: 177 days (r^2=0.986), 177 days (r^2=0.926), 281 days (r^2=0.854), 255 days (r^2=0.941) USA: 35 days (r^2=0.667) *(Shellman-Georgia)*, 54 days (r^2=0.976) *(Mansfield-Illinois)*, 56 days (r^2=0.930) *(Fresno-California)*, 84 days (r^2=0.789) (Marion Junction-Alabama) Mean DT_{50}: 170 days

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	DT_{90} (field): Active substance: Germany: 609 days (r^2=0.971), 544 days (r^2=0.963), 664 days (r^2=0.857), 1246 days (r^2=0.810) United Kingdom: 589 days (r^2=0.986), 589 days (r^2=0.926), 935 days (r^2=0.854), 848 days (r^2=0.941) USA: 116 days (r^2=0.667) *(Shellman-Georgia)*, 178 days (r^2=0.976) *(Mansfield-Illinois)*, 186 days (r^2=0.930) *(Fresno-California)*, 278 days (r^2=0.789) *(Marion Junction-Alabama)* Mean DT_{90}: 565 days
Soil accumulation and plateau concentration ‡	Experiment: Accumulation study in UK: five annual applications with trifluralin (Treflan) at a rate of 1.2 kg a.s./ha. Under the study conditions, trifluralin residues in soil one year after each application did not increase over the course of the five-year study. Therefore, it is considered that trifluralin does not accumulate in soil following successive applications. The maximum trifluralin concentrations, with respect to the 0-10 and 0-30 cm horizon were 1.26 mg/kg (following 2nd application) and 0.49 mg/kg (following 2nd application) respectively. Estimation: 1) Application Rate = 1 x 1.2 kg a.s./ha per year 2) Simulation period: 20 years 3) DT_{50SOIL} = 375 days (maximum value) derived from field studies, no process other than degradation considered. 4) Accumulation plateau = 1.661 mg/kg (reached after 14 years) Results and Comments: According to the submitted experimental data, trifluralin does not accumulate in soil following successive applications. However, an accumulation plateau for trifluralin can be observed in the field where the DT_{50} values of trifluralin are quite high. Based on the degradation data submitted for trifluralin ($DT_{50(max)\ FIELD-SOIL}$= 375 days), the highest predicted accumulation plateau in the soil was estimated to be 1.661 mg/kg after 14 years successive applications (application pattern: 1 x 1.2 kg a.s./ha per year).
Soil residue studies	No data are provided. Not required.

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡

Active substance: Adsorption

Soil	pH	Org. C	K_F	K_{oc}	1/n
S	7.7	0.29	18.6	6414	0.962
SL	5.7	0.81	54.6	6741	0.974
L	6.5	1.04	88.3	8490	0.966
CL	6.9	1.16	156	13414	0.986
Mean:			79.4	8764.7	0.972

Metabolite TR-4: Adsorption

No experimental data are provided.

A Koc value of 13600 mL/g was estimated using the "pckocwin v1.66" program (part of the US EPA's Estimated Program Interface (EPI) suite, v3.10).

Active substance: Desorption

Soil	pH	Org. C	K_F	K_{oc}	1/n
S	7.7	0.29	22.4	7724	0.972
SL	5.7	0.81	63.9	7889	0.983
L	6.5	1.04	103	9904	0.965
CL	6.9	1.16	193	16638	0.999
Mean:			95.6	10538.8	0.980

K_d ‡

Active substance:

Adsorption: K_d = 20.9 - 209 ml/g

Desorption: K_d = 24.3 - 218 ml/g

pH dependence ‡
(yes / no) (if yes type of dependence)

No.

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Not conducted. Not required.
Aged residues leaching ‡	After ageing for 30 days, 89.59 - 91.89 % AR was located in the top 6 cm of the soil columns. The leachate contained 0.7 - 2.5 % AR and consisted of unresolved polar metabolites. The leachate did not contain trifluralin nor any of the minor metabolites TR-2, TR-13 or TR-28 which were present at the initiation of the leaching procedure.
Lysimeter/ field leaching studies ‡	Not conducted. Not required.

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	Trifluralin is evenly distributed in the top 5 cm soil horizon with a soil bulk density of 1.5 g/mL, 0% crop intercept to represent pre-sowing application, first order kinetic, DT_{50} = 170 days (mean value), 255 days (80^{th}-ile) and 375 days (maximum value) derived from field studies, no process other than degradation considered.
Application rate	1 x 1.2 kg a.s./ha

$PEC_{(s)}$ (mg/kg)		Single application Actual concentration DT_{50}=375 d	Single application Time weighted average concentration DT_{50}=375 d
Initial	0 d	1.600	1.600
Short term	1 d	1.597	1.599
	2 d	1.594	1.597
	4 d	1.588	1.594
Long term	7 d	1.579	1.590
	14 d	1.559	1.579
	21 d	1.539	1.569
	28 d	1.519	1.559
	42 d	1.480	1.539
	50 d	1.459	1.528
	100 d	1.330	1.461

Metabolites

Method of calculation	Trifluralin is evenly distributed in the top 5 cm soil horizon with a soil bulk density of 1.5 g/mL, 0% crop intercept to represent pre-sowing application, first order kinetic, DT_{50} = 375 days (maximum value) derived from field studies, no process other than degradation considered. Simulation period = 20 years
Application rate	1 x 1.2 kg a.s./ha per year

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

$PEC_{(s)}$ (mg/kg)	Single application Actual (DT_{50}: 375 d)	Single application Time weighted average (DT_{50}: 375 d)	Multiple application Actual	Multiple application Time weighted average
Initial	3.26	3.26		
Short term 24 h [1]	3.25	3.26		
2 d [1]	3.25	3.25		
4 d [1]	3.24	3.25		
Long term 7 d [1]	3.22	3.24		
28 d [1]	3.10	3.18		
50 d [1]	2.97	3.11		
100 d [1]	2.71	2.98		
	[1)] Days after the accumulation plateau reached on 14th application. (Accumulation plateau = 1.661 mg/kg (reached after 14 applications with 1 appln/year with 1.2 kg a.s./ha) (see relevant point: Soil accumulation and plateau concentration)			

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	pH 4: 5% in 5 days at 50°C pH 7: 0% in 5 days at 50°C pH 9: 0% in 5 days at 50°C
Photolytic degradation of active substance and relevant metabolites ‡	Sterile buffer solution: Trifluralin degraded with a DT_{50} of 7 hours in sterile aqueous buffer ($DT_{50\ (dark\ control)}$ = 480 hours). Two significant photolysis products are formed, i.e. TR-6 (maximum 50. 4 % AR) and TR-15 (maximum 31.5 % AR). Natural water: Trifluralin degraded rapidly with a DT_{50} of 1.1 hours ($DT_{50\ (dark\ control)}$ = 47.9 hours). This is likely due to biotic activity and photosensitising compounds found in natural water systems. The degradation profile of the exposed samples was not determined.
Readily biodegradable (yes/no)	No
Degradation in water/sediment - DT_{50} water ‡	1st study : application to the water phase 13 d (worst-case value)

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

- DT_{90} water ‡	not calculated
- DT_{50} whole system ‡	4.9 - 5.9 d (by using the solver function)
- DT_{90} whole system ‡	16.3 - 19.6 d (» » »)
Mineralization	Volatile loss: 53- 60% of A.R. (day 60-end of the study). This loss was not characterised
Non-extractable residues	26% of A.R. (day 60 - end of the study).
Distribution in water / sediment systems (active substance) ‡	3-11 % (at 6 hours, water phase) 76-89 % (at 6 hours, sediment)
Distribution in water / sediment systems (metabolites) ‡	Metabolite TR-4 : 4 - 9% (at day14, sediment), not detected in water phase Non- identified substances: 12 - 14% of A.R. (after 2 months, in sediment)

PEC (surface water) (Annex IIIA, point 9.2.3)

Parent

Method of calculation	a) DT_{50} values: 2 and 13 days (worst-case, data from the original water/sediment study) b) A water depth of 30 cm and c) Spray–drifts of 2.77, 0.57, 0.29 and 0.20% (buffer zones of 1, 5, 10 and 15 m).
Application rate	One application of 1.2 kg a.s./ha
Main routes of entry	Spray drift

Days After Treatment	PECsw (µg/L)							
	DT_{50} = 2 day							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
0	11.08	2.28	1.16	0.80	11.08	2.28	1.16	0.80
1	7.83	1.61	0.82	0.57	9.36	1.93	0.98	0.68
2	5.54	1.14	0.58	0.40	7.99	1.64	0.84	0.58
4	2.77	0.57	0.29	0.20	5.99	1.23	0.63	0.43
7	0.98	0.20	0.10	0.07	4.16	0.86	0.44	0.30
14	0.09	0.02	0.01	0.01	2.27	0.47	0.24	0.16
21	0.01	0.00	0.00	0.00	1.52	0.31	0.16	0.11
28	0.00	0.00	0.00	0.00	1.14	0.23	0.12	0.08
42	0.00	0.00	0.00	0.00	0.76	0.16	0.08	0.06

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Days After Treatment	PECsw (µg/L)							
	DT_{50} = 2 day							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
50	0.00	0.00	0.00	0.00	0.64	0.13	0.07	0.05
100	0.00	0.00	0.00	0.00	0.32	0.07	0.03	0.02

Days After Treatment	PECsw (µg/L)							
	DT_{50} = 13 day							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
0	11.08	2.28	1.16	0.80	11.08	2.28	1.16	0.80
1	10.51	2.16	1.10	0.76	10.79	2.22	1.13	0.78
2	9.96	2.05	1.04	0.72	10.51	2.16	1.10	0.76
4	8.95	1.84	0.94	0.65	9.98	2.05	1.05	0.72
7	7.63	1.57	0.80	0.55	9.25	1.90	0.97	0.67
14	5.25	1.08	0.55	0.38	7.81	1.61	0.82	0.56
21	3.62	0.74	0.38	0.26	6.67	1.37	0.70	0.48
28	2.49	0.51	0.26	0.18	5.75	1.18	0.60	0.42
42	1.18	0.24	0.12	0.09	4.42	0.91	0.46	0.32
50	0.77	0.16	0.08	0.06	3.87	0.80	0.40	0.28
100	0.05	0.01	0.00	0.00	2.07	0.43	0.22	0.15

Metabolite TR-6 and TR-15 (photoproducts)

Method of calculation	a) Maximum exposure levels (from photolysis study) of 50.4% AR for TR-6 and 31.5% AR for TR-15, b) a water depth of 30 cm and c) spray–drifts of 2.77; 0.57 and 0.29 % (buffer zones of 1; 5 and 10m) d) molecular weight adjustment (MW_{TR-6}/ $MW_{Trifluralin}$= 221.2/335.3, MW_{TR-15}/ $MW_{Trifluralin}$ = 259.2/335.3)
Application rate	One application of 1.2 kg a.s./ha
Main routes of entry	Spray drift

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Photoproduct	PECsw (µg/L) - Initial		
	Buffer zone		
	1 m	5 m	10 m
TR-6	3.68	0.76	0.39
TR-15	2.70	0.56	0.28

PEC (sediment)

Parent

Method of calculation	a) DT_{50} value of trifluralin in sediment = 18.5 days, b) Partition to sediment 100%, c) A sediment layer of 5 cm depth and sediment bulk density of 1.3 g/ml and d) Spray - drifts : 2.77, 0.57, 0.29 and 0.20% (buffer zones of 1, 5, 10 and 15m)
Application rate	One application of 1.2 kg a.s./ha

Days After Treatment	PECsediment (µg/kg)							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
0	51.14	10.52	5.35	3.69	51.14	10.52	5.35	3.69
1	49.26	10.14	5.16	3.56	50.19	10.33	5.26	3.62
2	47.45	9.76	4.97	3.43	49.27	10.14	5.16	3.56
4	44.02	9.06	4.61	3.18	47.49	9.77	4.97	3.43
7	39.34	8.10	4.12	2.84	44.98	9.26	4.71	3.25
14	30.27	6.23	3.17	2.19	39.79	8.19	4.17	2.87
Days After Treatment	PECsediment (µg/kg)							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
21	23.28	4.79	2.44	1.68	35.40	7.29	3.71	2.56
28	17.91	3.69	1.88	1.29	31.67	6.52	3.32	2.29
42	10.60	2.18	1.11	0.77	25.76	5.30	2.70	1.86
50	7.86	1.62	0.82	0.57	23.11	4.75	2.42	1.67
100	1.21	0.25	0.13	0.09	13.33	2.74	1.40	0.96

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (sediment) – Metabolite TR-4

Method of calculation	a) DT_{50} value of TR-4 in sediment = 24 days, b) Partition to sediment 100% (worst-case assumption) and 16% (at day 28 from the water/sediment study), c) A sediment layer of 5 cm depth and sediment bulk density of 1.3 g/ml and d) spray - drifts : 2.77, 0.57, 0.29 and 0.20% (buffer zones of 1, 5, 10 and 15 m), d) molecular weight adjustment (MW_{TR-4}/ $MW_{Trifluralin}$= 305.3/335.3)
Application rate	One application of 1.2 kg a.s./ha

Initial PEC (sediment)

Metabolite TR-4

Method of calculation	a) Partition to sediment 26.5% AR, b) A sediment layer of 5 cm depth and sediment bulk density of 0.8 g/ml and c) Spray - drift values: 2,77; 0.57 and 0.29 % (buffer zones of 1, 5 and 10 m) d) molecular weight adjustment (MW_{TR-4}/ $MW_{Trifluralin}$= 305.3/335.3)
Application rate	One application of 1.2 kg a.s./ha

Metabolite	PEC_{SED} (µg/kg) - Initial		
	Buffer zone		
	1 m	5 m	10 m
TR-4	20.05 (2.673 µg / L)	4.13	2.10

Initial PEC (sediment) - Metabolites TR-7 and TR-14

Method of calculation	a) Partition to sediment 14.2% AR for TR-7 and 29.5% for TR-14, b) A sediment layer of 5 cm depth and sediment bulk density of 0.8 g/ml and c) Spray - drift values: 2,77; 0.57 and 0.29 % (buffer zones of 1, 5 and 10 m) d) molecular weight adjustment (MW_{TR-7}/ $MW_{Trifluralin}$= 275.3/335.3 and MW_{TR-14}/ $MW_{Trifluralin}$= 271.2/335.3)
Application rate	One application of 1.2 kg a.s./ha

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolite	PEC_{SED} (µg/kg) - Initial		
	Buffer zone		
	1 m	5 m	10 m
TR-7	9.69	1.99	1.01
TR-14	19.83	4.08	2.08

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	1ST STUDY Active substance: FOCUS groundwater scenarios and the PEsticide Leaching MOdel (FOCUSPELMO 1.1.1). DT_{50}: 181 d (mean of 5 soils at 22°C), K_{oc}: 8765 ml/g (mean of 4 soils); 1/n: 0.972 (mean of 4 soils) 2ND STUDY Metabolite TR-4: Two FOCUS groundwater scenarios (PIACENZA & HAMBURG) and the PEsticide Leaching MOdel (FOCUSPELMO 3.3.2). DT_{50}: 1810 d (ten times more persistent than trifluralin in soil -DT_{50}: 181 d), K_{oc}: 13600 ml/g (estimated using the "pckocwin v1.66" program (part of the US EPA's Estimated Program Interface (EPI) suite, v3.10); 1/n: 0.972 (mean of 4 soils), bare soil. 3RD STUDY Active substance: Same as above. Metabolite TR-4: Same as above.
Application rate	1ST STUDY Active substance: 1 application per year to bare soil for a period of 20 years assuming: i) 1.2 kg as/ha (1 March), with soil incorporation to 5 cm. (Spring Application to Cotton), ii) 1.2 kg as/ha (1 March), with soil incorporation to 5 cm. (Spring Application to Sunflowers), iii) 1.2 kg as/ha (30 September), with soil incorporation to 5 cm. (Autumn Application to Oilseed Rape), iv) 1.2 kg as/ha (30 November), without soil incorporation. (Autumn Application to Winter Cereals).

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	2ND STUDY Metabolite TR-4: 1 application per year to bare soil for a period of 20 years assuming: i) 1.2 kg as/ha (1 March), with soil incorporation to 5 cm. (Spring Application to Sunflowers), ii) 1.2 kg as/ha (30 November), without soil incorporation. (Autumn Application to Winter Cereals). 3RD STUDY Active substance and Metabolite TR-4: 1 application per year to bare soil for a period of 20 years assuming: i) 1.2 kg as/ha (1 March), with soil incorporation to 5 cm. (Spring Application to Cotton), ii) 1.2 kg as/ha (1 March), with soil incorporation to 5 cm. (Spring Application to Sunflowers), iii) 1.2 kg as/ha (30 September), with soil incorporation to 5 cm. (Autumn Application to Oilseed Rape), iv) 1.2 kg as/ha (30 November), without soil incorporation. (Autumn Application to Winter Cereals).
$PEC_{(gw)}$	
Maximum concentration	FOR ALL THREE STUDIES: <0.001 µg/L for both trifluralin and TR-4.
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	FOR ALL THREE STUDIES: <0.001µg/L for both trifluralin and TR-4.

PEC(gw) - FOCUS modelling results

1st study

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			TR-4	---	---
FOCUS PELMO 1.1.1 / Oilseed Rape	CHATEAUDUN	<0.001	---	----	---
	HAMBURG	<0.001	---	---	---
	KREMSMUNSTER	<0.001	---	----	---
	OKEHAMPTON	<0.001	---	---	---
	PIACENZA	<0.001	---	----	---
	PORTO	<0.001	---	---	---

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			TR-4	---	---
FOCUS PELMO 1.1.1 / Sunflowers	PIACENZA	<0.001	---	----	---
	SEVILA	<0.001	---	---	---
FOCUS PELMO 1.1.1 / winter cereals	CHATEAUDUN	<0.001	---	----	---
	HAMBURG	<0.001	---	---	---
	JOKIOINEN	<0.001	---	---	---
	KREMSMUNSTER	<0.001	---	----	---
	OKEHAMPTON	<0.001	---	---	---
	PIACENZA	<0.001	---	----	---
	PORTO	<0.001	---	---	---
	SEVILA	<0.001	---	----	---
	THIVA	<0.001	---	---	---

2nd study

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			TR-4	---	---
FOCUS PELMO 3.3.2 / Sunflowers, winter cereals	PIACENZA	---	<0.001	----	---
	SEVILLA	---	<0.001		

3rd study

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			TR-4	---	---
FOCUS PELMO 3.3.2 / Cotton	SEVILLA	<0.001	<0.001	----	---
	THIVA	<0.001	<0.001	---	---
FOCUS PELMO 3.3.2 / oilseed rape	CHATEAUDUN	<0.001	<0.001	----	---
	HAMBURG	<0.001	<0.001	---	---
	KREMSMUNSTER	<0.001	<0.001	----	---
	OKEHAMPTON	<0.001	<0.001	---	---
	PIACENZA	<0.001	<0.001	----	---
	PORTO	<0.001	<0.001	---	---

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS PELMO 3.3.2 / Sunflowers	PIACENZA	<0.001	<0.001	---	---
	SEVILA	<0.001	<0.001	---	---
FOCUS PELMO 3.3.2 / winter cereals	CHATEAUDUN	<0.001	<0.001	---	---
	HAMBURG	<0.001	<0.001	---	---
	JOKIOINEN	<0.001	<0.001	---	---
	KREMSMUNSTER	<0.001	<0.001	---	---
	OKEHAMPTON	<0.001	<0.001	---	---
	PIACENZA	<0.001	<0.001	---	---
	PORTO	<0.001	<0.001	---	---
	SEVILA	<0.001	<0.001	---	---
	THIVA	<0.001	<0.001	---	---

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	No data. Not required.
Quantum yield of direct phototransformation	No data. Not required.
Photochemical oxidative degradation in air ‡	According to Atkinson's method the half-life of trifluralin in air was found to be 5.3 hours or 0.446 days (using [OH]= 1.5 x 10^6 radicals /cm^3 and assuming 12 h of sunlight per day).
Volatilization ‡	from plant surfaces: No data. Not required. from soil: Following spray application to the soil surface, losses of trifluralin due to evaporation were significantly higher and accounted for 41, 58 and 67% AR after 24 hours. When trifluralin is incorporated into the soil, volatilisation is minimal (1.1-1.4% AR after 24 hours).

PEC (air)

Method of calculation	Because of its high volatility [vapour Pressure= 9.5 x 10-3 Pa (25 °C) and Henry's Constant Law = 10.2 Pa m3 mol-1 at 20°C] the occurrence of trifluralin in air is possible. This was confirmed by the study conducted to assess the volatilisation of trifluralin from the soil surface. Therefore PECA calculation in air was required. However, the notifier cannot provide at the present time such calculations since no formal and agreed guidance at EU level is currently available.

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC$_{(a)}$

Maximum concentration	Such calculations cannot be provided at the present time since no formal and agreed guidance at EU level is currently available.

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil: Definition for risk assessment: Trifluralin, TR-4, TR-14. Definition for monitoring: Trifluralin. Water: Ground water: Definition for risk assessment: Trifluralin, TR-4, TR-14. Definition for monitoring: Trifluralin. Surface water: Definition for risk assessment: Trifluralin, TR-6, TR-15. Definition for monitoring: Trifluralin. Sediment: Definition for risk assessment: Trifluralin, TR-7, TR-14. Air : Definition for risk assessment and monitoring: Trifluralin

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data.
Surface water (indicate location and type of study)	Trifluralin was more frequently detected in surface waters, particularly in Belgium, France, Greece and the UK. The maximum concentrations reported from these countries were in the range 0.2-0.7 µg/L. Monitoring data on surface water in UK (report from the Department of the Environment) indicated that the maximum concentrations of trifluralin ranged from 0.5 to 0.6 µg/L while the mean values did not exceed 0.1 µg/L (1991-1993).
Ground water (indicate location and type of study)	Trifluralin occurrence in groundwater is rare.
Air (indicate location and type of study)	No data.

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	possibly a candidate for R53

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.6: Effects on non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals ‡	Technical: LD_{50} >5000 mg as/kg bw (rats) Formulated product: LD50 >919 mg as/kg bw (rats)
Long-term toxicity to mammals ‡	NOAEL =148 mg/kg bw/d (Rat 2 generation)
Acute toxicity to birds ‡	LD_{50} >2250 mg/kg bw (bobwhite quail)
Dietary toxicity to birds ‡	LC_{50} = 2974 mg as/kg diet (bobwhite quail) or 573,9 mg as/kg bw/d
Reproductive toxicity to birds ‡	NOEC = 1000 mg as/kg diet or = 102,85 mg as/kg bw/d

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
1.2	Oilseed rape, sunflower, cotton, winter cereals	Insectivorous bird	Acute	>129	10
		Insectivorous bird	Short-term	90	10
		Insectivorous bird	Long-term	16,1	5
		Earthworm eating bird	Acute	>59.9	10
		Earthworm eating bird	Short-term	15.28	10
		Earthworm eating bird	Long-term	5.27[1] 5.6[2]	5
		Fish eating bird	Acute	>283	10
		Fish eating bird	Short-term	72	10
		Fish eating bird	Long-term	13	5
		Insectivorous mammals	Acute	>87	10
		Insectivorous mammals	Long-term	38.38	5
		Earthworm eating mammals	Acute	>19.22	10
		Earthworm eating mammals	Long-term	5.96[1] 6.31[2]	5
		Fish eating mammals	Acute	>187	10
		Fish eating mammals	Long-term	30	5

[1] risk assessment based on the PEC initial value taking account soil accumulation over 14 years.
[2] risk assessment based on the PEC (twa, 3weeks) following 1 application (no accumulation);

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests				
Fish (*Oncorhynchus mykiss*)	Trifluralin	Acute	96h LC_{50}	0.088
Fish (*Oncorhynchus mykiss*)	EF-1521	Acute	96h LC_{50}	0.205
Fish (Fathead minnow)	Trifluralin	Chronic	35-day juvenile growth test NOEC	0.0003
Invertebrates *(D.magna)*	Trifluralin	Acute	48h EC_{50}	0.245
Invertebrates *(D.magna)*	EF-1521	Acute	48h EC_{50}	0.299
Invertebrates *(D.magna)*	Trifluralin	Chronic	21 days NOEC	0.0507
Algae(*Selenastrum capricornutum*)	Trifluralin	Chronic	96h EC_{50}	0.0122
Algae(*Selenastrum capricornutum*)	EF-1521	Chronic	96h EC_{50}	0.178
Aquatic plants (*Lemna gibba*)	Trifluralin	Chronic	14d EC_{50}	0.0435
Sediment organisms (*Chironomus riparius*)	Trifluralin	Chronic	28d NOEC	0.250 810 mg/kg
Fish (*Oncorhynchis mykiss*)	Metabolite TR-6	Acute	96h LC_{50}	1
Invertebrates (*Daphnia magna*)	Metabolite TR-6	Acute	48h EC_{50}	3.52
Algae (*Selenastrum capricornutum*)	Metabolite TR-6	Chronic	72 hours E_bC_{50} E_rC_{50}	 8.19 >5.56
Fish (*Oncorhynchus mykiss*)	Metabolite TR-15	Acute	96h LC_{50}	5.46
Invertebrates (*Daphnia magna*)	Metabolite TR-15	Acute	48h EC_{50}	9.36

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Algae (*Selenastrum capricornutum*)	Metabolite TR-15	Chronic	72 hours E_bC_{50} E_rC_{50}	 1.67 >9.15
Sediment organisms (*Chironomus riparius*)	Metabolite TR-4	Chronic	28d NOEC	0.3324

Microcosm or mesocosm tests
An extensive field monitoring study designed to investigate the ecological effects of trifluralin, primarily on fish (IIIA B.9.2.5/01) is available. In this study, water samples were collected from a 2.1-acre farm pond that received run-off from a 39-acre watershed treated with trifluralin for three years. 20 run-off events occurred during the last eight months of the study. The sediment concentrations in field run-off ranged from 0.2-32.2 g/L but the annual run-off loss of trifluralin from the watershed did not exceed 0.3% of the amount applied (17.7 kg). Analyses of filtered and unfiltered pond water from the treated site indicated that trifluralin remained below the detection limit of 0.3 µg/L throughout the study. Trifluralin concentrations in the pond sediment generally were ≤ 0.004 mg/kg and the estimated half-life in sediment was 5-6 days. The maximum concentration observed in pond sediment was 0.039 mg/kg. Throughout the study, considerable variations in trifluralin residues were seen amongst spp and amongst individual fish of the same spps. Trifluralin residues were predictable, however, using a bioconcentration model developed in a separate laboratory study (IIA B.9.2.3/02). The model provided reliable estimates of trifluralin concentrations in fish resulting from a wide range of exposure conditions associated with agricultural run-off. During the 14-month monitoring period 88 out of the 1277 fish collected at the treated site (6.9%) were diagnosed as having compression and/or deviation of the vertebral column, compared to 23 out of 606 fish sampled at the control site (3.8%). None of the fish diagnosed as having vertebral column lesions showed any gross external deformities. During the last eight months of the study, when substantial amounts of field run-off entered the pond, the mean lesion frequency generally increased three-fold compared to periods of low run-off, but analysis of data from the control site showed the same trend.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Application Rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
1.2	Oilseed rape, sunflower, cotton, winter cereals	Fish	Acute	1	7.9	100
				5	39	100
				15	110	100
		Invertebrate	Acute	1	22	100
				5	107	100
				15	306	100

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Application Rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
1.2	Oilseed rape, sunflower, cotton, winter cereals	Algae	Chronic	1	1.1	10
				5	5.4	10
				15	15	10
		Aquatic plants	Chronic	1	3.9	10
				5	19	10
		Sediment organisms	Chronic	1	23	10
		Fish	Chronic	1	0.03	10
				5	0.1	10
				15	0.38	10
		Invertebrate	Chronic	1	5	10
				5	22	10

Bioconcentration

Bioconcentration factor (BCF) ‡	BCF = 5674 mL/g
Annex VI Trigger:for the bioconcentration factor	100
Clearance time (CT_{50}) (CT_{90})	4.7 days 15 days
Level of residues (%) in organisms after the 14 day depuration phase	9.6%

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity ‡	LD_{50} technical > 100 µg as/bee LD_{50} formulation > 80 µg as/bee
Acute contact toxicity ‡	LD_{50} technical and formulation > 100 µg as/bee

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
1.2	Oilseed rape, sunflower, cotton, winter cereals	Oral	<15	<50
		Contact	<12	<50

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Field or semi-field tests No data submitted

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests ‡						
Typhlodromus pyri	Proto-nymphs	Treflan (EF-1521)	0.060 1.2	Mortality Fertility Mortality Fertility	10.5% 0.0% [a] 58.9% 26.3% [a]	50
Aphidius rhopalosiphi	Adult	Treflan (EF-1521)	0.060 1.2	Mortality Fertility Mortality Fertility	60.6% 86% [a] 84.8% N/A [b]	50
Chrysoperla carnea	Larvae	Treflan (EF-1521)	0.060 1.2 0.060 1.2	Mortality Fertility	0.0% 0.0% No effect	50
Phygadeuon trichops	Adult	Triflurex 48 EC	1.44	Parasitism	34.1% [c]	50
Poecilus cupreus	Adult	Triflurex 48 EC	1.44	Mortality Food consumption	6.6% 0.0% [d]	50
Aleochara bilineata	Adult	Triflurex 48 EC	1.44	Parasitism	-9% [c]	50
Extended Laboratory tests						
Typhlodromus pyri	Proto-nymphs	Treflan (EF-1521)	0.060 1.2	Mortality Fertility Mortality Fertility	7.5% 24.7% [a] 30% 64.9% [a]	50

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Aphidius rhopalosiphi	Adult	Treflan (EF-1521)	0.060 1.2	Mortality Fertility Mortality Fertility	0.0% 0.0% [a] 16.7% 68.7% [a]	50

[a] Fecundity effect measured
[b] Not assessed, no surviving females
[c] Parasitism effect measured
[d] Food consumption effect measured
- Indicates that the study design does not have a mortality end point

Field or semi-field tests
No data submitted

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡	Technical: LC_{50} >1000 mg as/kg LC_{50corr}* >500 Formulated: LC_{50} >480 mg as/kg LC_{50corr}* >240 Metabolite TR-4: LC50=186 mg/kg LC_{50corr}* 93
Reproductive toxicity ‡	Elancolan: NOEC≥ 28.98 mg as/kg $NOEC_{corr}$*≥ 14.49

* Corrected by a factor of 0.5 due to the high organic carbon content of OECD soil

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	End Points*	TER	Annex VI Trigger
1.2	Oilseed rape, sunflower, cotton, winter cereals	Acute (trifluralin) Acute (formulation) Acute (TR-4)	> 500 >240 93	>153 >74 484	10 10
		Chronic (trifluralin)	≥14.49	≥ 4.44**	5

* Corrected by a factor of 0.5 due to the high organic carbon content of OECD soil
** Based on initial soil residues after 14 years of accumulation + the immediate following application

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	Effects < 25% at 6.37 kg a.s./ha (8.50 mg a.s./kg) and at 10xPEC for the metabolite TR-4.
Carbon mineralization ‡	Effects < 25% at 6.37 kg a.s./ha (8.50 mg a.s./kg) and at 10xPEC for the metabolite TR-4

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	N; R50/53

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstracts
CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent degradation / dissipation
DT_{90}	period required for 90 percent degradation / dissipation
ε	decadic molar extinction coefficient
EC_{50}	effective concentration, median
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography or high pressure liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median

LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated Short Term Intake
NIR	Near-Infrared-(Spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
r^2	coefficient of determination
SPI	spraying
SRU	low volume spraying
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year