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

benfluralin.

Finalised: 3 March 2008

SUMMARY

Benfluralin is one of the 79 substances of the third stage Part A of the review program covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission 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.

Belgium being the designated rapporteur Member State submitted the DAR on benfluralin in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 16 February 2006. The peer review was initiated on 1 June 2006 by dispatching the DAR for consultation of the Member States and the sole applicant Dow AgroScience. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed on during a written procedure in May - June 2007. 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 October 2007.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in February 2008 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 a herbicide on lettuce and chicory (salad and root production) full details of the GAP can be found in the attached end points.
The representative formulated product for the evaluation was "Bonalan", an emulsifiable concentrate (EC).

Adequate methods are available to monitor benfluralin in plants, soil water and air. However for water and plants the residue definition has not been concluded on and further data may be required.

[1] OJ No L 224, 21.08.2002, p. 25, as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

For products of animal origin it is currently not clear if a residue definition is required and therefore further methods may be required in the future. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that at least some limited quality control measurements of the plant protection product are possible. There are still some outstanding issues related to a relevant impurity, R65 classification, emulsion stability, efficiency of the tank cleaning procedure and testing at different pH for various parameters.

In mammalian metabolism studies, benfluralin showed a rapid but incomplete oral absorption, rapid excretion, mainly via faeces, and no potential for accumulation.
Benfluralin has a low acute toxicity, but showed irritating and sensitizing properties, which require classification with R36/38 – irritating to eyes and skin – and R43 – may cause sensitisation by skin contact. Main target organs in short term and long term studies were the liver and kidneys. Classification with R40 – limited evidence of a carcinogenic effect – is proposed, based on neoplastic changes observed in the liver of rats and mice and thyroid tumours in rats upon long term exposure. Benfluralin showed no potential for genotoxicity or neurotoxicity. No effects on fertility or on reproductive parameters were observed as well as any adverse effects on development or teratogenicity.
The acceptable daily intake (ADI) is set at 0.005 mg/kg bw/day considering an assessment factor of 100; the acceptable operator exposure level (AOEL) is 0.05 mg/kg bw/day set using an assessment factor of 100 with a correction of 30 % for oral absorption (overall assessment factor of 333); no acute reference dose (ARfD) is allocated.
The estimated operator exposure is below the AOEL if personal protective equipment (PPE) as gloves is used, at least during the mixing and loading operations. No risk is anticipated for workers or bystanders derived from benfluralin applications.

The plant metabolism of benfluralin was investigated in lettuce (category leafy crops), alfalfa and peanuts (pulses/ oilseed crop category). The Meeting of experts considered that the detailed information on the undertaken preliminary work on the metabolites characterisation/ identification should be submitted in order to conclude on the validity of these studies. No metabolism study was submitted to support a use in root and tuber crops. The experts in residues have concluded that further data is necessary to finalise the residue definition for primary and rotational crops, the livestock exposure assessment and eventually the consumer risk assessment. At the current stage, a residue definition and MRLs can only provisionally be proposed, but need to be reconsidered upon receipt of the necessary data. Based on the presumption that the only relevant residues for consumer exposure is parent benfluralin in primary crops, the estimated chronic intake would be less than 1% of the ADI of benfluralin for the considered consumer groups.
The consumer risk assessment will have to be revised when the outstanding data and information was evaluated.

Available data demonstrate that under aerobic conditions the degradation of benfluralin in soil did not lead to any major (> 10% of the applied radioactivity (AR)) metabolite, although the minor non transient metabolite B12 was formed in amounts > 5% AR at two consecutive sampling points. Benfluralin is moderate to medium persistent in soil under aerobic conditions with half-lives ranging from 20 to 86 days. No reliable DT_{50} values for metabolite B12 are available. Field dissipation studies were conducted in northern Europe only and resulted in moderate half-lives of 34 to 73 days for benfluralin.

Two major metabolites B36 (max. 23.2% AR at day 1) and U6#1 (max. 25.0% AR at day 2) were formed under anaerobic conditions. The peer review concluded that, if applied for intended uses, no further assessment was necessary for these metabolites.

Soil photolysis is not expected to be a significant route of degradation in the environment.

Data indicate that benfluralin is strongly adsorbed to soil and could be classified as immobile. No reliable data on adsorption properties of metabolite B12 are available.

Benfluralin is hydrolytically stable under environmental conditions. Aqueous photolysis may contribute to the environmental degradation of benfluralin producing the major metabolites des-alkyl benfluralin diamine (max 11.5% AR), propyl benzimidazole (max. 16.4% AR), methyl benzimidazole (max 11.5% AR), ethyl propyl benzimidazole (max 19.5% AR). Because of the rapid photodegradation of benfluralin in water, a data gap was identified by the fate experts to address the potential surface water contamination of the photolysis metabolites.

Parent benfluralin is not expected to contaminate ground water at levels above 0.1 µg/L under the proposed conditions of use. The meeting of Member State experts identified a data gap with respect to metabolite B12 for the necessary information (including experimentally derived Koc values and degradation rates) to produce revised FOCUS groundwater assessment.

The water/sediment study, the aerobic soil metabolism study and Henry's Law constant indicated the high volatility of benfluralin. However, the calculated photochemical oxidative degradation half-life of benfluralin in air is rapid (<6 hrs) and therefore significant amounts of benfluralin are not expected to be present in air.

Benfluralin is applied pre-sowing or pre-planting by broadcast spray followed by incorporation in soil to control weeds. Hence no leafy crops or weeds are present in the field after the application. Benfluralin is not systemic and the uptake of plants is limited. A potential high risk was identified for earthworm eating-birds and mammals. The suggested refinements were not accepted in the expert meeting and a data gap was identified for a new refined long-term risk assessment for earthworm eating birds and mammals. The risk to algae and higher aquatic plants was assessed as low. A 20m non-spray buffer zone was included in the PECsw values used in the aquatic risk assessment for the water bodies stream and ditch. The TERs for fish were above the trigger of 100 in all drainage scenarios (D3, D4, D6) and in the run-off scenarios R1 and R4 but were below the trigger in the run-off scenarios R2 and R3. No full FOCUS scenario resulted in TERs above the trigger of 100 for aquatic invertebrates. Only the TERs for the part scenarios D4 (pond) and R1 (pond) exceeded the trigger of 100. The chronic TER values for fish and daphnia were calculated with 50 d twa-PECsw

instead of initial PECsw. The experts agreed that time weighted average PECsw values can be used in the TER calculations for endpoints based on growth effects (fish early life stage study) but the rapid dissipation from the water phase has to be considered and the time period should not be longer than 5 times the DT_{50} (in this case 7days). The chronic endpoint for daphnids is based on reproduction and therefore should be compared to initial PECsw concentrations. A data gap was identified in the expert meeting for the applicant to provide a new chronic aquatic risk assessment taking into account the suggestions of the expert meeting and to refine further the acute risk to invertebrates. No final conclusion can be drawn on the risk to aquatic organisms from the photolysis metabolites at this stage and should be addressed in the new aquatic risk assessment in line with the data gap identified in the section on fate and behaviour. The risk assessment for soil non-target arthropods resulted in a TER of 4.8 based on an initial PEC soil of 1.14 mg benfluralin/kg from the worst case application in lettuce. Since the TER value is close to the trigger of 5 and based on initial PECs it was agreed in the expert meeting that the risk to soil non-target arthropods is sufficiently addressed for most environmental conditions but Member States could ask for further risk refinement if benfluralin is expected to degrade slowly under their local environmental conditions.

The risk to bees, earthworms, non-target arthropods, soil micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low.

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

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, as amended by Commission Regulation (EC) No 1095/2007 regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Benfluralin is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating Belgium as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Belgium submitted the report of its initial evaluation of the dossier on benfluralin, hereafter referred to as the draft assessment report, to the EFSA on 16 February 2006. 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 11(2) of the Regulation (EC) No 1490/2002 the revised version of the draft assessment report was distributed for consultation on 1 June 2006 to the Member States and the main applicant Dow AgroScience as identified by the rapporteur Member State. Originally, Makhteshim Agan had also notified for this substance but finally did not submit an application.

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 during a written procedure in May – June 2007 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

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 experts' meetings in October 2007. 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 during a written procedure with the Member States in February 2008 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 11(4) of the Regulation (EC) No 1490/2002, 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 26 June 2006)

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. 2-1 of 16 February 2008).

Given the importance of the draft assessment report including its addendum (compiled version of January 2008 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.

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report (Volume 3, B1, B2, B4, B6, B8, B9, Volume 4) which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can be found in the original draft assessment report together with the peer review report, both of which are publicly available.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Benfluralin is the ISO common name for N-butyl-N-ethyl-α,α,α-trifluoro-2,6-dinitro-p-toluidine (IUPAC).

Benfluralin belongs to the class of dinitroanaline herbicides such as pendimethalin or trifluralin. Benfluralin is a selective soil herbicide which is absorbed by the roots. It affects seed germination and prevents weed growth by inhibition of root and shoot development.

The representative formulated product for the evaluation was "Bonalan", an emulsifiable concentrate (EC).

The evaluated representative uses are as a pre-emergence herbicide on lettuce and chicory (salad and root production) full details of the GAP can be found in the attached end points.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of benfluralin as manufactured should not be less than 960 g/kg. At the moment no FAO specification exists.

The technical material contains ethyl-butyl-nitrosamine, which has to be regarded as a relevant impurity. The maximum content in the technical material should not be higher than 0.1 mg/kg. However there is a question over the maximum content of this impurity because in a submitted storage study the nitrosamine content found showed that the technical material used was out of specification for this relevant impurity. Therefore a data gap has been identified for the company to address this.

The content of benfluralin in the representative formulation is 180 g/L (pure).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of benfluralin or the respective formulation. However there are several data gaps that have been identified as follows:
Storage stability data where the relevant impurity is analysed before and after storage.
Emulsion stability before and after storage at the lowest in use concentration.
Method of analysis for the relevant impurity in the plant protection product.
Address why the UV spectrum were different depending on the pH.

A storage study was previously provided where the relevant impurity was only analysed after storage and therefore the above data gap was identified. Also a method of analysis was provided for the relevant impurity in the formulation but it did not have a low enough LOQ.

In the meeting of experts there was a long discussion on R65 classification “Harmful: may cause lung damage if swallowed” some experts considered that there was sufficient data to classify but others felt that a further viscosity study at 40 ºC was needed and therefore no conclusion was reached. This classification labelling issue will have to be dealt with at Member State level. In addition to this the meeting of experts agreed that there was insufficient information/data on the efficiency of the tank cleaning procedure and it was agreed that this should also be dealt with at Member State level.

The main data regarding the identity of benfluralin and its physical and chemical properties are given in appendix 1.

In the main, sufficient test methods and data relating to physical, chemical and technical properties and analytical methods are available to ensure that at least limited quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor benfluralin in plants (high water content crops only), soil water and air. However for water and plants the residue definition has not been concluded on and further data may be required. For products of animal origin it is currently not clear if a residue definition is required and therefore further methods may be required in the future

The methodology used for food of plant origin is GC-ECD with a LOQ of 0.01 mg/kg, the confirmatory method was GC-MS. A multi-residue method like the Dutch MM1 or the German S19 is not applicable due to the nature of the residues. For soil the method is GC-ECD with a LOQ of 0.01 mg/kg the confirmatory method was GC-MS. Water and air are analysed by a specific GC-MS method with an LOQ of 0.05 µg/L for water and 0.15 µg/m^3.

Also a method for body fluids and tissues is not required because benfluralin is not classified as toxic or highly toxic.

2. Mammalian toxicology

Benfluralin was discussed at the PRAPeR Expert's Meeting on mammalian toxicology (PRAPeR 34) in October 2007.

Proposed technical specification of the active substance was considered to be sufficiently covered by the toxicological batches. The maximum acceptable level of the impurity ethyl-butyl-nitrosamine in the technical specification was considered to be at the LOQ in order to be kept at a minimum level.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

Oral absorption was considered by the rapporteur Member State to represent 30 % of the administered dose, based on urinary excretion, residual carcass/tissue levels after 7 days, and biliary excretion observed at 24 hours. This value was discussed by the experts considering that it was obtained from the dose level of 100 mg/kg bw, which is quite high compared to the NOAEL value used for AOEL setting (17 mg/kg bw/day). It was recognised that this value is a worst case and might represent a conservative approach. The value was confirmed by the meeting.

The plasmatic levels were proportional to the administered dose, being maximal at 5-10 hours or up to 24 hours after low (100 mg/kg bw) or high dose (500 mg/kg bw) respectively. Overall, highest residues levels were found in liver and kidneys seven days after administration, and also, mostly for females, in blood and fat. There was no potential for accumulation. The elimination half-live was about 55 to 62 hours for the low and high dose respectively. Excretion occurred predominantly via faeces (73 % in faeces and 17 % in urine after 168 hours), biliary excretion was a minor pathway (6-12 %), and most of the radioactivity, 77 and 90 % of the dose, had been excreted after 48 hours for the high and low dose respectively.

Parent was the most prominent compound recovered in faeces; two non-polar metabolites were also identified, B36[2] and B37[3], as reduced compounds of benfluralin. In urine, the major metabolite resulted from di-dealkylation of parent (B3[4]), which was further metabolised to about 100 polar metabolite fractions.

2.2. ACUTE TOXICITY

Acute oral toxicity of benfluralin is low. No dermal toxicity was observed up to 5000 mg/kg bw, but irritation occurred during the 14-day observation period. Due to the physico-chemical properties of the compound, no satisfactory respirable dust aerosol could be generated. According to two skin irritation tests in rabbits, the mean irritation scores were below the trigger for classification, however considering the marked skin lesions observed in two 21-day repeated dose dermal toxicity studies in rabbits, classification as "irritant", symbol Xi, and risk phrase **R38** "**irritating to skin**" is proposed. Benfluralin was found to be also an eye irritant and a skin sensitizer according to both a Buehler and a Maximisation tests, so both risk phrases **R36 "irritating to eyes"** and **R43 "may cause sensitisation by skin contact"** are also required.

2.3. SHORT TERM TOXICITY

Oral short term effects of benfluralin were examined in several 90-day studies (four in rats, one in mouse, and two in dogs) and one 1-year study in dogs. Older studies were considered only as additional information. Two 21-day dermal toxicity studies in rabbits were also presented.

In rats, the target organs were the blood, liver and kidneys, as suggested by slight reversible anaemia, higher organ weights, clinical chemistry and histopathological changes as centrilobular hepatocytes hypertrophy and nephrosis. Main effects in mice were limited to the liver. Dog's studies presented increased platelet counts, alkaline phosphatase (AP) activity, liver weights and haemosiderin deposits in liver or spleen. The relevance of these effects with particular incidence on the increased spleen pigmentation was discussed by the experts; as this finding was not associated with changes in blood cells, in histopathological or biochemical observations, it was concluded that no adverse effects could be detected at 25 mg/kg bw/day. **The relevant oral NOAEL was set at the dose level of 17 mg/kg bw/day** from the 90-day rat study, based on liver and kidney changes at 74 mg/kg bw/day.

Following dermal exposure during 21 days in the rabbit, local irritation and secondary haematological and histopathological effects were noted in a dose related pattern from the lowest dose on (100 mg/kg bw/day). **Overall systemic dermal NOAEL was set at 500 mg/kg bw/day**, based on liver effects (hepatocellular necrosis at the top dose of 1000 mg/kg bw/day) whose adversity could not be ruled out.

[2] B36: Benfluralin diamine = N^2-butyl-N^2-ethyl-3-nitro-5-(trifluoromethyl)-benzene-1,2-diamine
[3] B37: N^2-butyl-N^2-ethyl-5-(trifluoromethyl)-1,2,3-benzenetriamine
[4] B3: 2,6-dinitro-4-(trifluoromethyl)- benzenediamine

2.4. GENOTOXICITY

Benfluralin was tested *in vitro* for point mutations in Ames tests with *S. typhimurium* and *E. coli*, for gene mutations in the TK locus of L5178Y TK+/- mouse lymphoma cells, for chromosomal aberrations in Chinese Hamster Ovary (CHO) cells and for unscheduled DNA synthesis in rat hepatocytes (UDS assay), and *in vivo*, for sister chromatid exchange in Chinese Hamster bone marrow and for micronucleus in a mouse bone marrow tests. No potential for genotoxicity or clastogenicity was found.

2.5. LONG TERM TOXICITY

Long term toxicity was studied in two chronic studies in rat, one in mouse and one 2-year study in dogs. The older study in rat was rejected by the rapporteur Member State and defined as unacceptable due to a large number of limitations; for the same reason, the dog study was shortly reported and was considered to provide additional information.

The liver, thyroid and kidneys were the target organs in the Fisher 344 rat, leading at higher dose levels (136 mg/kg bw/day and up) to neoplastic changes in the liver and thyroid. The experts discussed the relevance of the sciatic nerve degeneration observed at high doses and concluded that this finding was linked to aged rats in association with marked toxicity, so no further requirements are needed and benfluralin should not be considered neurotoxic.

A mechanistic study carried out with trifluralin, that was meant to explain a rat-specific mode of action leading to thyroid tumours, was not accepted by the experts because no full comparability between the effects observed upon trifluralin and benfluralin administration could be established, although both substances are chemically very similar. **The NOAEL in the two-year rat study was the dose level of 0.5 mg/kg bw/day** based on increased hepatocellular pigmentation and centrilobular hypertrophy, and increased incidence and severity of hyalin droplets in the kidneys at 5.4 mg/kg bw/day.

The target organ in mice was the liver, and the combined hepatocellular adenoma/carcinoma incidence was increased at the LOAEL level of 36 mg/kg bw/day. The NOAEL was discussed focusing on equivocal decreased body weight gain during the first year of the study that the rapporteur Member State considered as potentially adverse, however the meeting agreed to set **the NOAEL at this low dose level of 6.0 mg/kg bw/day**.

Based on rats' thyroid tumours and liver tumours observed in both rats and mice, a classification as category 3 carcinogen is proposed for benfluralin leading to the following symbol and risk phrase: **Xn; R40 "limited evidence of a carcinogenic effect"**.

2.6. REPRODUCTIVE TOXICITY

Two reproductive studies were performed, the older one (rat, 4-generation) was considered by the rapporteur Member State as additional information due to its poor quality.

Benfluralin did not affect the reproductive performance or fertility of rats treated up to the highest dose tested, however higher mortality and decreased body weight were observed in pups together with impaired maternal health status (decreased body weight, liver and kidney toxicity) at the

LOAEL of 53 mg/kg bw/day and up. **Both parental and offspring's NOAELs (systemic) were the dose level of 5.5 mg/kg bw/day**, while the reproductive NOAEL was the highest dose level of 278 mg/kg bw/day.

The effects of benfluralin on the development were examined in rat and rabbit; one older rabbit study was not considered acceptable and a dose range-finding test in rat was considered to give supplementary information, but there was one reliable study available for each species.
No treatment-related malformation and no adverse effect on development were observed in either species, so the developmental NOAEL was in both cases the highest dose tested (225 mg/kg bw/day in rabbits and 1000 mg/kg bw/day in rats). The lowest NOAEL for maternal toxicity was 50 mg/kg bw/day from the rabbit study based on decreased food consumption and body weight gain at 100 mg/kg bw/day.

2.7. NEUROTOXICITY

No studies are available; based on the toxicological profile of benfluralin presented in the dossier, no specific neurotoxicity study was considered necessary (see point 2.5 above).

2.8. FURTHER STUDIES

A mechanistical study on the potential effects of trifluralin on the thyroid gland was presented, but the extrapolation from trifluralin to benfluralin was not accepted by the experts (see point 2.5 above).

2.9. MEDICAL DATA

No adverse effects were revealed from health surveillance on manufacturing plant personnel carried out in the U.S production of benfluralin from 1972 to 1993 and in Europe production from 1994 to 2004. Twenty-five exposure incidents involving 71 persons were cited in a summary of exposure incidents to benfluralin from 1989 to 2003; relation to benfluralin exposure was often unclear due to mixed exposure with other pesticides; twenty-three cases included symptoms like skin rash, burn or irritation, or respiratory irritation. One case of allergic contact dermatitis was reported in the open literature.

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

ADI

The ADI for benfluralin was established at 0.005 mg/kg bw/day based on the NOAEL of 0.5 mg/kg bw/day from the 2-year, rat study and an assessment factor of 100.

AOEL

The rapporteur Member State proposed in the DAR an **AOEL of 0.05 mg/kg bw/day** based on the NOAEL of 17 mg/kg bw/day from the oral 90-day, rat study, a safety factor of 100 and a correction

factor for oral absorption of 30 % (overall assessment factor of 333). The meeting agreed with this approach.

ARfD

The rapporteur Member State did not propose to allocate an ARfD for benfluralin based on current Guidance document for setting the ARfD. Taking into account the entire toxicological profile of the substance, the meeting agreed not to set an ARfD.

No ARfD allocated.

2.11. DERMAL ABSORPTION

During the written procedure, the value of dermal absorption was debated and an addendum to volume 3, B.6, was produced by the rapporteur Member State, dated September 2007, in agreement with the new proposed values.

Two studies were submitted to extrapolate the dermal absorption value for benfluralin. Both studies were conducted with the representative formulation "Bonalan": one *in vivo* study in the rat and one *in vitro* comparative dermal absorption study using rat and human skin. The complete dermal depot was included to the fraction potentially absorbed to calculate the dermal absorption of benfluralin. The final estimated dermal absorption was 0.6 % when handling the concentrate formulation and 4.45 % (which was rounded to 4.5 % for exposure risk assessment) for the in-use field dilution.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Bonalan (code EF-1533) is an emulsifiable concentrate (EC) containing 180 g benfluralin/L.

Exposure data were recalculated by the rapporteur Member State in the addendum to vol.3, B.6 (September 2007), once the values for dermal absorption had changed (see point 2.11).

Operator exposure

Bonalan is intended to be used as a pre-emergence herbicide in lettuce, endive or chicory crops, applied with tractor-drawn hydraulic field sprayer; knapsack application was not concluded as it was withdrawn by the Applicant during the peer review process.

According to the representative uses, the maximum applied dose is 1.71 kg a.i./ha, corresponding to 9.5 L product/ha; an application volume of 200 L spray/ha was considered for the calculations.

For the UK POEM, a container size of 5 L (wide neck) was used; default value for work rate is 50 ha/day and for operator body weight is 60 kg; according to the German model, default value for work rate is 20 ha/day and for operator body weight is 70 kg.

According to the UK POEM model calculations, the exposure of operators is about the AOEL only if PPE (gloves during mixing/loading and application) are used. According to the German model, the exposure is about the AOEL when no PPE are worn; using PPE as gloves, coverall and boots, as required when handling substances classified as carcinogen, the exposure level drops well below the AOEL.

Estimated operator exposure presented as % of AOEL (0.05 mg/kg bw/day)

Tractor-mounted (field crop)	**No PPE**	**With PPE during M/L**	**With PPE during M/L & application**
UK POEM	573	543 (a)	101 (a)
German model	103	90 (a)	8 (b)

(a) PPE: gloves

(b) PPE: gloves (M/L & application), protective garment and sturdy footwear (application)

Worker exposure

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

Bystander exposure

For the calculation of the bystander exposure, according to Ganzelmeier (1995), the following assumptions were considered: worst-case application rate of 9.5 L product/ha, 0.13 % drift deposition for a 7.5 m distance, an exposed area of 0.4225 m^2/person and a body weight of 60 kg.

Adding the potential dermal and inhalation exposures, bystander exposure represents about 0.33 % of the AOEL.

3. Residues

Benfluralin was discussed at the PRAPeR Expert's Meeting on residues (PRAPeR 35) in October 2007.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of benfluralin was investigated in lettuce (representative use), alfalfa and peanuts following a pre-planting application to the soil of ring-^{14}C-labelled benfluralin. No metabolism study was submitted to support the use in root and tuber crops (i.e. the representative use on chicory roots).

According to the results of the available studies, benfluralin was absent or only present at very low levels in the crops at harvest. Metabolism of benfluralin lead to the formation of several unknown metabolites and of natural products derived from incorporation of benfluralin degradation products.

In **lettuce**, 71 days after a soil treatment, only 1.3 % of the total radioactive residue (TRR) was identified as benfluralin. Additional 35.5% TRR consisted of a number of unidentified organo-soluble metabolites, individually not greater than 1-3% of the TRR. A further16.4 % TRR consisted of very polar water soluble compounds including conjugates, and 25.4% TRR were found of very polar character after solubilisation of the post-extraction solids by acid hydrolysis. The polar fractions were multi-component, and no attempt to further elucidate the structure of those compounds was made.

Eventually, 17.7% TRR were found to be incorporated into cell wall material, in particular into lignin, mainly as hexose and pentose sugars.

In two additional studies in **alfalfa** and **peanuts**, representative for the pulses/oilseed crop category, the picture was similar to the findings from the lettuce metabolism study. At 114 days and 132 days respectively after planting of the crops into treated soil benfluralin was not detected in alfalfa seeds and nutmeat of peanuts, while in peanut hulls benfluralin was present at very low levels only (0.75 % TRR). Characterisation of the radioactivity demonstrated the multi-component nature of both the polar and organo-soluble fractions, but no metabolites could be identified. Again, a substantial part of the total radioactivity was incorporated into plant constituents such as fatty acids (36% TRR in nutmeat), lignin (33% TRR in peanut hulls; 14% TRR in alfalfa seeds) and cellulose (10% TRR in peanut hulls; 2% TRR in alfalfa seeds).

It was agreed by the experts of PRAPeR 35 that though the identification rate in the studies was low, it was sufficiently demonstrated that soil-applied benfluralin is taken up into the aerial plant parts and over time (71 to 132 days) extensively metabolised into numerous compounds that are partially incorporated into the structure of natural plant constituents. The applicant stated that for identification attempts a large library of metabolite standards was used, but none of the extracted metabolites could be linked to any of the reference standards. The meeting of experts noted that the library of reference standards and detailed information about the undertaken identification work has not been submitted, but should be provided by the applicant to permit a conclusion regarding the validity of these studies. Until then the residue definition for risk assessment and monitoring proposed as benfluralin should be considered provisional for the uses in lettuce and chicory (Witloof, Belgian endive). Whether the residue definition is also appropriate for root crops can currently not be concluded. Though there is a notified use on chicory roots no primary metabolism study in the category of root and tuber crops was submitted. Therefore the use on chicory roots is currently not supported by suitable metabolism data. The experts of PRAPeR 35 set a data gap for a new metabolism study in primary root crops. This metabolism study might make it possible to propose a global residue definition for all primary and rotational plant commodities (refer also to 3.1.2 of this document).

Residue trials in lettuce, chicory (witloof) and industrial chicory were conducted in compliance with the representative critical use pattern. Benfluralin was the residue analysed for. In all trials benfluralin residues were below 0.01 mg/kg. The residue trial data are supported by a validated method of analysis for benfluralin and acceptable storage stability data.

Investigation of the effects of processing on the nature and the level of the residues of benfluralin was not required.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

In soil benfluralin was reported to have a DT_{90} of up to 385 days (laboratory) and up to 242 days (field), respectively. Therefore the investigation of residues in rotational crops has been a requirement.

An available confined study was not considered to fully address metabolism in rotational crops since the study does not comply with current guidance on a number of points. The study however indicated

that after a plant back interval of 12 month significant total residue levels were still found in edible crop parts, but they were not identified. The experts in the meeting PRAPeR 35 noted that, given the notified use is an application to soil, primary crop metabolism data covering three different crops that demonstrates a similar metabolic pattern could be used to address rotational crop metabolism, but currently only data on leafy crops and the pulses/oilseed crop category is available. The required root metabolism study to support the use on chicory roots (see 3.1.1) might make it possible to also conclude on the rotational crop metabolism. Whether or not further data on rotational crops is required depends therefore upon the outcome of a metabolism study on rooting crops.

If the use on chicory roots were no longer a supported use and a root metabolism study won't be submitted, a new rotational crop metabolism study would be required. Based on the results of the required data on rotational crops consideration might have to be given to livestock intakes from rotational crops.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The metabolism of benfluralin was investigated in lactation goat and laying hen after repeated oral administration of radio-labelled benfluralin. The studies were summarised in the DAR and scientific comments have been received. However, the studies were not discussed by the meeting of experts in residues since, at the current stage, livestock studies would not be a requirement. Residues in the primary crops of the representative uses do not lead to significant intake by livestock (> 0.1 mg/kg diet) since lettuce and chicory is not normally used in animal diet.

If however upon finalisation of the assessment with regard to the rotational crops (see 3.1.2 above) there were indications of significant livestock exposure from rotated crops (> 0.1 mg/kg diet), animal metabolism studies would become relevant. At the moment it has to be left open if a residue definition might be necessary for food of animal origin.

It is noted that at the current stage the livestock metabolism studies should not be considered as peer reviewed.

3.3. CONSUMER RISK ASSESSMENT

The experts in residues (PRAPeR 35) have concluded that currently the consumer risk assessment **cannot be finalised**. The experts have identified that further data is necessary to conclude on a final residue definition for primary and rotational crops. Depending on the outcome rotational crop residue data and a re-evaluation of livestock exposure may be required.

At the current stage, a residue definition for risk assessment has only been provisionally proposed for the uses in lettuce and chicory (Witloof, Belgian endive), and it has not been concluded whether this residue definition is also appropriate for root crops. Moreover, it has to be left open if a residue definition might become necessary for food of animal origin.

In a preliminary assessment, based on the presumption that the only relevant residue for consumer exposure is parent benfluralin in primary crops (i.e. lettuce and chicory) at LOQ level (0.01 mg/kg), the RMS estimated the theoretical maximum daily intake (TMDI) to be less than 1% of the ADI of

benfluralin for the consumer groups of adults, toddlers and children. However, the consumer risk assessment will have to be revised when the outstanding data are available.

3.4. PROPOSED MRLS

At the current stage, a residue definition for monitoring has only been preliminarily proposed as benfluralin. Therefore, the MRLs proposed by the RMS at LOQ level (0.01 mg/kg) for benfluralin are provisional only.

4. Environmental fate and behaviour

Benfluralin was discussed at the PRAPeR experts' meeting for environmental fate and behaviour in October 2007 (PRAPeR 32), on the basis of the DAR, corrigendum (February 2007) and the addendum to Vol 3 (September 2007).

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Information of benfluralin metabolism in soil under dark aerobic conditions at 24ºC was provided by one study where a sandy loam (pH 7.1, organic carbon content 0.87%, clay content 13%) was used. Degradation of benfluralin in soil did not lead to any major (> 10% AR) metabolites, although the minor metabolite **B12**[5] was formed in amounts > 5% AR at two consecutive time points. Unextractable radioactivity increased to 42.3% AR after 125 days and mineralization accounted for 1.7% AR at day 125. Further analysis of the bound residue showed that most of the applied radioactivity was associated with the humin and fulvic acid fractions. Radioactivity found in the volatile traps after 125 days indicated that benfluralin volatilises to some extent (8.3% AR).

Under anaerobic laboratory conditions amounts of approximately 30% AR was evolved as volatile benfluralin within the first day of incubation. Degradation proceeded via reduction of the nitro group to form benfluralin diamine, **B36** (max. 23.2% AR at day 1), followed by cyclisation to form ethyl propyl benzimidazole, **U6#1**[6] (max. 25.0% AR at day 2). Several minor (<5% AR) metabolites were observed in the study. Mineralisation accounted for 1.3% AR at day 120 and bound residues for 50.2% AR at day 120.

Because of the intended use of benfluralin is pre-emergence with subsequent soil incorporation to *ca* 10 cm depth directly after application, soil photolysis is not expected to be a significant degradation route.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The rate of degradation of benfluralin was estimated from the results of the study described in 4.1.1 above and from an additional study performed at 24ºC and 75% moisture capacity at 0.33 bar with 3

[5] B12 = 2,6-dinitro-4-(trifluoromethyl)phenol
[6] ethyl propyl benzimidazole, U6#1 = 1-ethyl-7-nitro-2-prpyl-5-(trifluoromethyl)-1H-benzimidazole

soils (pH: 6.4-7.2; . organic carbon content 1.57-1.86%, clay content 13.6-33.2%). Half lives were obtained by fitting degradation curve to non-linear first order kinetics. DT_{50} values were in the range 20-86 days at 24ºC, indicating that benfluralin is moderate to medium persistent in soil. After normalisation to FOCUS reference conditions (20ºC and -10kPa soil moisture content) the single first order geometric mean DT_{50} resulted in 36.2 days (see addendum, January 2008). The degradation under anaerobic conditions was much faster than under aerobic conditions with first order DT_{50} of 6 hours.

Information on the rate of degradation in soil for metabolite B12 under aerobic conditions was not reported in the DAR, although a value of 291 days was quoted in section B.8.6.1 on groundwater contamination assessment. Explanations on the source and on the method of calculation of this DT_{50} value are still missing and therefore the reliability of this value can not be accepted. In addition, during the meeting of experts it was agreed that because an assessment of the relevance of metabolite B12 should be performed according to Guidance Document Sanco/221/2000 (rev.10), two additional soil DT_{50} values for metabolite B12 are required.

Field dissipation studies were conducted in northern Europe only (4 trials in northern France and Belgium). The meeting of experts considered the available studies sufficient to address the degradation of benfluralin under field conditions; however Member States may wish to investigate further the dissipation of benfluralin in soil for southern European conditions. The test compound was applied in May to bare soil followed by incorporation. Details on the degradation kinetics used to calculate the DT_{50} and the DT_{90} values were included in a corrigendum (February 2007) and agreed by the experts. Single first order (SFO) DT_{50} were 34-73 days (DT_{90} 115-242 days).

PECsoil were calculated for benfluralin for the most critical GAPs in lettuce (application rate of 1.71 kg a.s./ha, pre-sowing without interception, followed by incorporation into 10 cm soil layer) with the worst case field DT_{50} of 73 days.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The adsorption/desorption of benfluralin was investigated in 7 soils in satisfactory batch adsorption experiments. Calculated adsorption K_foc values varied from 8519 to 14400 mL/g (mean 10777 mL/g), indicating that benfluralin can be classified as immobile in soil. There was no evidence of a correlation of adsorption with soil pH.

Experimental data on adsorption/desorption characteristics for the minor non-transient metabolite B12 were not available for FOCUS groundwater model input. Therefore the applicant provided an estimated value of 2650 mL/g derived using the "pckocwin v1.66" program. This value was validated by reference to benfluralin. However, the experts of PRAPeR meeting 32 did not considered this approach to be adequate as the metabolite B12 is ionisable and will be dissociated under normal environmental conditions, and therefore it does not share any structural similarity with the parent. As a result, a data gap was identified for reliable Koc values for metabolite B12. The peer review agreed also that adsorption properties of the major degradation products B36 and U6#1 identified under anaerobic conditions are not relevant to conclude the risk assessment for the representative uses.

An aged (30 days) column leaching study was available. The majority of the radioactivity remained in the top column segment (0-6 cm) and the amount of radioactivity in the lower segments decreased with increasing depth (< 0.5% AR in the 24-30 cm soil depth). Radioactivity in the leachate ranged from 1.1% AR to 3.3% AR in the leachates with the major component identified as metabolite B12.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Benfluralin is hydrolytically stable at pH 4, 7 and 9 at 50º.

Aqueous photolysis may contribute to the environmental degradation of benfluralin ($DT_{50\ irr.}$ = 18 hours at 40ºN latitude). Photolytic degradation of benfluralin is characterized by formation of **des-alkyl benfluralin diamine**[7] (max 11.5% AR), **propyl benzimidazole**[8] (max. 16.4% AR), **methyl benzimidazole**[9] (max 11.5% AR), **ethyl propyl benzimidazole**[10] (max 19.5% AR) and methyl benzimidazole N-oxide[11] (< 10% AR), followed by their decline into the formation of CO_2. The benzimidazole metabolite structures result from cyclization of benfluralin alkyl groups under photolytic conditions.

A ready biodegradability test (OECD 301D) indicated that benfluralin is "not readily biodegradable" using the criteria defined by the test.

In a water-sediment study (2 systems studied at 20ºC in the laboratory, sediment pH 7.2-7.6, organic carbon content 0.7-2.1%) benfluralin volatilised to a great extent (63.2-64.9% AR after 100 days). The overall dissipation of benfluralin occurred with first order whole system DT_{50} being calculated as 1.1-1.3 days. The water phase dissipation DT_{50} was similarly rapid (< 1 day). The peer review concluded that sediment should be considered the faster degrading compartment in the water-sediment system next to volatilisation and therefore for benfluralin water and sediment DT_{50} of 999 days (worst case) and 4.9 days (mean of DT_{50sed}) were acceptable for use as FOCUSsw scenario input at steps 3 and 4.

The minor metabolite benfluralin diamine was identified and present at maximum of 1.7% AR after 7 days in the water phase and 6.5-8.7% AR after 2-7 days in the sediment. Several unidentified components were also observed in both the water and sediment layers, with individual components < 6.3% AR at any sampling interval in the whole system. The overall degradation of benfluralin diamine proceeded with a whole system DT_{50} value between 17 and 33 days.

FOCUS surface water modelling was evaluated up to step 3 (see addendum September 2007) and step 4 for benfluralin. Only the lettuce use (1.71 kg a.s./ha) was modelled with application either 1 February or 1 November to reflect year round use. Further details on the specific contribution from different entry routes for surface water contamination and on the method to implement 92.7% runoff mitigation with a 20 m vegetative buffer strip for step 4 calculations were provided in the addendum

[7] des-alkyl benfluralin diamine = 3-nitro-5(trifluoromethyl)-1,2-benzenediamine
[8] propyl benzimidazole = 4-nitro-2-propyl-6-(trifluoromethyl)-1H-benzimidazole
[9] methyl benzimidazole = 2-methyl-4-nitro-6-(trifluoromethyl)-1H-benzimidazole
[10] ethyl propyl benzimidazole = 1-ethyl-7-nitro-2-propyl-5-(trifluoromethyl)-1H-bezimidazole
[11] methyl benzimidazole N-oxide = 1H-benzimidazole,2-methyl-7-nitro-5-(trifluoromethyl)-3-oxide

(September 2007). Revised step 4 PEC calculations with a 20 m buffer zone with no run-off mitigation were also presented. The experts agreed that in this case PECsw values are driven mainly by the spray drift and that the available results were appropriate for use in risk assessment. The PECsw (20 m buffer zone, no run-off mitigation) are very similar to the PEC values that have been proposed in the original DAR except for PECsed in R1, R2 and R4 stream scenarios. The risk assessment for sediment dwellers have been recalculated considering the global max PECsed of 26.323 µg/kg (20 m buffer zone, no mitigation for run-off). Because of the potential volatilisation of benfluralin, the experts from the Member States considered that this conclusion should identify that in national assessments at the Member State level, the potential for surface water contamination as a result of volatilisation losses may require consideration. Note this has not been done in the available EU level assessment. It should also be noted that the available PECsw and PECsed values might not reflect the worst case if more than two successive lettuce crops per year are envisaged.

Based on the available information on the major degradation products formed in the aqueous photolysis study, the experts agreed that PEC surface water calculations should be provided for metabolites des-alkyl benfluralin diamine, propyl benzimidazole, methyl benzimidazole and ethyl propyl benzimidazole. The required calculations were provided in an addendum (January 2008) but results are not peer reviewed and the EFSA considered the information on the FOCUS modelling (input parameters and method to model the metabolites) insufficient to evaluate the study.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Predicted environmental concentrations in groundwater for benfluralin, metabolites B12 (minor, non-transient in aerobic soil degradation) and metabolites B36 and U6#1 (major in soil degradation under anaerobic conditions) were calculated using FOCUS PELMO 3.3.2. For the representative uses, carrot and cabbage were chosen as surrogates for chicory and lettuce, respectively. Single annual applications were modelled for consecutive years to bare soil, with incorporation to 15 cm depth to represent pre-sowing application. The model input parameters for benfluralin (mean $DT_{50(lab)}$ at 24ºC standardised to FOCUS moisture conditions (pF2) = 31 days; mean Koc = 10765 mL/g; 1/n = 1.031 and vapour pressure = 1.73 x 10^{-3} Pa at 25 ºC) were accepted by the experts, but concerns raised on the key end-points used for the metabolites. It was concluded that PECgw calculations are not required for metabolites B36 and U6#1 as anaerobic conditions are not relevant if applied for representative uses. On the contrary, two data gaps were identified for reliable Koc values and DT_{50} values for metabolite B12 to address the potential for contamination of groundwater for this metabolite (see sections 4.1.2 and 4.1.3). It should be noted that in the US EPA R.E.D FACTS for benfluralin (EPA-738-F-04-007) it is indicated that "….degradates 2,6-dinitro-4-trifluoromethyl-phenol was formed at 6% of parent in the soil metabolism study. Based on limited environmental fate information, it has the potential to contaminate groundwater, and was included in the drinking water assessment".

The 80th percentile results for each use and FOCUS-scenario combination for the annual average benfluralin concentration in the leachate at 1 m soil depth were below the 0.1 µg/L parametric

drinking water limit. It should be noted that available PECgw values for benfluralin might not reflect the worst case if successive lettuce crops per year are envisaged at Member State level.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of benfluralin (1.73×10^{-3} Pa at 20°C) means that benfluralin would be classified as moderately volatile, indicating losses due to volatilisation would be expected. This is confirmed by some of the experimental studies provided in the fate and behaviour section (aerobic soil metabolism and water/sediment studies). Based on the results of a laboratory wind tunnel experiment where radiolabelled benfluralin was applied to soil and to dwarf runner bean plants, it was estimated that in 24 hours the 15.8% and 16.8% of the applied radioactivity was lost to air compartment from soil and from plant leaves respectively. Calculations using the method of Atkinson for indirect photo oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half life estimated at about 5.7 hours (assuming an atmospheric hydroxyl radical concentration of 1.5×10^{6} OH radicals cm^{-3}) indicating that the benfluralin that will volatilise would be unlikely to be subject to long range atmospheric transport. In addition, benfluralin is incorporated into soil following application, a process that would reduce volatilisation rates.

5. Ecotoxicology

Benfluralin was discussed at the PRAPeR Expert's Meeting on ecotoxicology (PRAPeR 33) in October 2007. The impurity ethyl-butyl-nitrosamine was considered as ecotoxicological relevant. The maximum acceptable level was set by the experts on mammalian toxicology at the level of detection (see chapter 2).

5.1. RISK TO TERRESTRIAL VERTEBRATES

Benfluralin is applied pre-sowing or pre-planting by broadcast spray followed by incorporation in soil to control weeds. Hence no leafy crops or weeds are present in the field after the application. Benfluralin is not systemic and the uptake of plants is limited. Therefore exposure of herbivorous birds and mammals was considered as negligible.

TER values were calculated only for insectivorous birds for the worst case uses in lettuce (1 x 1.71 kg benfluralin/ha) and chicory (1 x 1.62 kg benfluralin/ha) assuming exposure via uptake of residues in ground dwelling arthropods. The acute and short-term TERs exceeded the Annex VI trigger of 10. The long-term TERs were 0.17 (lettuce) and 0.18 (chicory) indicating a potential high long-term risk to birds. Refinement of RUD values based on the data base of Fletcher et. al. was suggested (RUD of 0.5). The resulting TERs are 9.7 and 10.2, respectively. The refined RUD is based on the assumption that only large soil dwelling insects are eaten by insectivorous bird. The majority of the experts accepted the argumentation that bare soil is not an attractive feeding habitat for small insectivorous birds and that it is likely that birds feeding on bare soil would prefer large insects. It was agreed that earthworm-eating birds are of more relevance than small insectivorous birds in the risk assessment for applications on bare soil with subsequent soil incorporation and also that bare soil would not be a

preferred feeding habitat for small insectivorous mammals and that a risk assessment for vermivorous mammals should be conducted instead.

The first-tier risk assessment for earthworm-eating birds and mammals indicated a potential high long-term risk to birds (TER=1.2) and mammals (TER = 0.6). The risk assessment was refined with an experimentally determined BCF value for earthworms of 2.4. The refined long-term TERs were calculated as 5.21 (focal species lapwing, *Vanellus vanellus*) and 1.62 (small mammals) in the addendum. It was noted in the meeting that the organic matter content in the test system for the BCF determination was high (10%). This is likely to have influenced the bioavailability because of the high Koc value of benfluralin and hence may have led to an underestimation of the BCF factor. The experts agreed that a correction factor for the organic matter content should be applied in the calculation of the BCF factor. The experts considered blackbird (*Turdus merula*) as a better focal species because of its higher FIR/bw ratio compared to lapwing. A high long-term risk to earthworm-eating birds and mammals cannot be excluded and a data gap was identified for further refinement of the risk assessment. The long-term endpoint (NOAEL = 5.5 mg a.s./kg bw/d) used in the mammalian risk assessment was discussed and agreed by the experts.

The risk to fish-eating birds and mammals was assessed as low because the TER values were markedly above the trigger of 5. In addition chronic exposure to aquatic organisms is not expected because of the low DT_{50} (whole system) of 1.1-1.3 d.

No major soil metabolites were found in the soil degradation studies and therefore a risk assessment for birds and mammals is required for benfluralin only.

5.2. RISK TO AQUATIC ORGANISMS

The acute toxicity of technical benfluralin was tested with 5 fish species, 2 crustaceans, 1 mollusc and also with two algae species. The risk assessment for aquatic invertebrates is based on the lowest endpoint which was observed in a test with benfluralin (technical) and *Mysidopsis bahia*.
Chronic tests were conducted with *Oncorhynchus mykiss*, *Daphnia magna*, *Chironomus riparius* and *Lemna gibba*. The test with *Lemna gibba was* assessed as not valid and a data requirement was set. A new Lemna study was submitted and accepted in the expert meeting.

Acute tests with the formulation Bonalan were conducted with fish, daphnia and algae. The endpoints observed for daphnia and algae were more than two orders of magnitude lower than for technical benfluralin but not for fish. It was questioned in the meeting whether the endpoints observed in the studies with technical benfluralin and daphnia and algae are reliable and can be used for the risk assessment because the endpoints are far above the solubility of the test substance and the results are based on nominal concentrations. The large increase in toxicity in the test with the formulation observed for daphnia and algae may be due to the low solubility of benfluralin. No study with the formulation and higher aquatic plants was available and the meeting concluded that a study with formulated benfluralin and aquatic plants is necessary to conclude on the risk to aquatic organisms.

A no-spray buffer zone of 20m was included in the FOCUSstep4 calculations for the waterbodies stream and ditch. The standard distance from the field of 3.5 m was applied for the scenarios with pond as the representative water body.

Representative use in chicory:
The acute TERs were above the Annex VI trigger for algae and *Lemna gibba* indicating a low risk to primary producers in the aquatic environment. The TERs for fish were above the trigger of 100 in all drainage scenarios (D3, D4, D6) and in the run-off scenarios R1 and R4 but were below the trigger in the run-off scenarios R2 and R3. No full FOCUS scenario resulted in TERs above the trigger of 100 for aquatic invertebrates. Only the TERs for the part scenarios D4 (pond) and R1 (pond) exceeded the trigger of 100.

Representative use in lettuce:
The acute TERs were above the Annex VI trigger for algae and *Lemna gibba* indicating a low risk to primary producers in the aquatic environment. The TERs for fish were above the trigger of 100 in the full drainage scenarios D3, D6 and in the part scenario D4 (pond) and in the run-off scenarios R1 and R4. The Annex VI trigger was not met in the drainage scenario D4(stream) and in the run-off scenarios R2 and R3. No full FOCUS scenario resulted in TERs above the trigger of 100 for aquatic invertebrates. Only the TERs for the part scenarios D4 (pond) and R1 (pond) exceeded the trigger of 100.

The chronic TER values for fish and daphnia were calculated with 50 d twa-PECsw instead of initial PECsw. The experts agreed that time weighted average PECsw values can be used in the TER calculations for endpoints based on growth effects (fish early life stage study) but the rapid dissipation from the water phase has to be considered and the time period should not be longer than 5 times the DT_{50} (in this case 7days). The chronic endpoint for daphnia is based on reproduction and therefore should be compared to initial PECsw concentrations. A data gap was identified in the expert meeting for the applicant to provide a new chronic aquatic risk assessment taking into account the suggestions of the expert meeting and to refine further the acute risk to invertebrates.

No major metabolites were detected in the water-sediment study. The photolysis metabolites des-alkyl benfluralin diamine (358R, max. 11.9% at 1 d), propyl benzimidazole (371R, max. 15.4% at 8h), methyl benzimidazole (372 R, max. 15.8% at 2h) and ethyl propyl benzimidazole (379R, max. 19.5% at 8h) exceeded 10%. The photolytic degradation of benfluralin is fast (DT50 = 18.9h) and the metabolites are formed rapidly and hence should be addressed further. The RMS considered the risk as covered by the risk assessment of the parent assuming that the metabolites were formed in the ecotox studies with benfluralin. This explanation was considered not sufficient in the expert meeting since the presence of the metabolites was not analytically verified and the irradiation in the ecotox tests is not conducive to photolytic degradation. Therefore the experts kept the point open for the RMS to consider the risk to aquatic organisms from the photolysis metabolites. The applicant

provided a statement on the comparability of the toxicity of TR15 (1H-benzimidazole,2-ethyl -4-nitro-6-(trifluromethyl)) with the photolysis metabolites 371R, 372R and 379R. The ecotox endpoints for TR6 (358R) and TR15 suggest a lower acute toxicity of the photolysis metabolites compared to benfluralin. The RMS presented a chronic risk assessment for fish (chronic NOEC) with the metabolite 379R in the not-peer reviewed addendum from January 2008 assuming that 379R has the same toxicity as the parent. The usual initial worst case approach would be to consider a 10 times higher toxicity as the parent. The assumption of similar toxicity could be acceptable but should be supported by further argument on structural similarities with the parent or other metabolites, presence of the active site in the molecule or QSAR. The lowest regulatory endpoint is the chronic NOEC for fish and hence would cover the risk to the other groups of organisms. However the PECsw values are not peer-reviewed and the information provided in the addendum is insufficient to draw a conclusion on the reliability of the PECsw values (see point 4.2.1.). Therefore no final conclusion can be drawn on the risk to aquatic organisms at this stage and it is suggested to address the risk from the photolysis metabolites in the new aquatic risk assessment in line with the data gap identified in the section on fate and behaviour (see data gap above).

5.3. RISK TO BEES

The acute oral and contact toxicity tests with technical benfluralin and the formulation Bonalan resulted in LD_{50} values of >31.25 to >110.7 µg benfluralin/bee. The acute oral and contact HQ values for the worst case uses in lettuce and chicory were below the trigger of 50 except for the oral exposure route and the endpoint of the formulation (>31.25 µg benfluralin/bee) where HQ values of <54.7 and <51.8 were observed. However these HQ values are based on an LD50 greater than the highest tested dose and due to the application to bare soil and non-systemic properties exposure of bees is considered to be minimal. Overall it is concluded that the risk to bees from the representative uses is low.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Standard laboratory tests were conducted with the formulation Bonalan and the non target arthropods *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Poecilus cupreus* and *Chrysoperla carnea*. However the test design did not allow the determination of a reliable LR_{50} value and therefore no HQ values were calculated. No significant adverse effects were observed in the test with *P. cup*reus and *C. carnea* at the application rate of 9 L Bonalan/ha. Effects of >30% were observed in the tests with *T. pyri* and *A. rhopalosiphi* at an application rate of 9 L Bonalan/ha (equivalent to the proposed GAP in chicory (1.62 kg benfluralin/ha). The application rate for the use in lettuce is higher 9.5 L Bonalan/ha (or 1.71 kg benfluralin/ha) but no dose was applied to cover also this higher application rate in the standard glass plate test.

Extended laboratory tests were conducted with *T. pyri*, *A. rhopalosiphi* and *Aleochara bilineata*. No significant mortality was observed for *T. pyri* up to the tested rate of 14.5 L Bonalan/ha and for *A. rhopalosiphi* up to 2 L Bonalan/L. Leaf dwelling non-target arthropods are not expected to occur in the field in the absence of vegetation. If the off-field rate of 0.25 – 0.26 L Bonalan/ha (2.77% drift of

the application rates without vegetation distribution factor and correction factor) is compared to the results of the extended lab studies it can be anticipated that the amount of product reaching off-crop habitats is too low to cause significant adverse effects on leaf dwelling non-target arthropods. The risk assessment for non-target arthropods was discussed and agreed by the experts.

5.5. RISK TO EARTHWORMS

The acute toxicity to earthworms was tested with technical benfluralin and the formulation Bonalan. The chronic toxicity was tested with the formulation only. The corrected endpoints (endpoints divided by 2 since the logPow is >2) were LC_{50}s of >500 mg benfluralin/kg soil and 719 mg Bonalan/kg soil (=139 mg benfluralin/ha) and a NOEC of 157 mg Bonalan/kg soil (= 30.6 mg benfluralin/ha). The TER calculation was based on a PECsoil of 1.14 mg benfluralin/kg soil (initial) for the acute risk assessment and 0.908 mg benfluralin/kg soil (50 d twa) for the long-term risk assessment for the use of 1 x 1.71 kg benfluralin/ha in lettuce. The acute TERs were 439 (technical a.s.), 122 (formulated a.s.). and the long-term TER was 33.7 (formulated a.s.). The use of 50 d time weighted average PECs was not sufficiently justified. The updated long-term risk assessment based on initial PECs resulted in a TER of 27 which is also above the Annex VI trigger of 5.

No major soil metabolites were found under aerobic conditions. Two major metabolites were found under anaerobic conditions. However it is unlikely that anaerobic conditions would prevail in soils where lettuce and chicory are grown and hence the formation of significant amounts of anaerobic metabolites is not expected for the uses evaluated.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

Effects of the formulation Bonalan on springtails (*Folsomia candida*) was investigated in a 28-d reproduction test. The NOEC for reproductive effects was determined as 56.2 mg Bonalan/kg soil. Since the log P_{ow} is >2 the endpoint was divided by 2 giving a NOEC of 28.1 mg Bonalan/kg soil equivalent to 5.48 mg benfluralin/kg soil. This endpoint was compared to the 28-d twa PECsoil of 1.001 mg benfluralin/ks soil from the worst case application in lettuce resulting in a TER of 5.47. During the peer-review it was suggested that the initial PECsoil should be used also in the long-term risk assessment since the effects observed are based on reproduction which could in principle be induced by a short exposure peak. If compared to the initial PECsoil of 1.14 mg benfluralin/kg soil the TER would be 4.8 which is close to the trigger of 5. In the meeting it was agreed that the risk to soil non-target arthropods is sufficiently addressed for most environmental conditions but Member States could ask for further risk refinement if benfluralin is expected to degrade slowly under their local environmental conditions.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects of >25 % on soil respiration and nitrification were observed in tests with the formulation Bonlan up to an application rate of 45 L Bonalan/ha. The maximum application rate recommended in the GAP table is lower (about 9.5 L Bonalan/ha). Therefore the risk of adverse effects on soil microbial processes is considered to be low for the representative uses of benfluralin.

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

Herbicidal effects of technical benfluralin was investigated in tests with 3 monocotyledon and 7 dicotyledon plant species. The lowest EC_{50} of 3.25 kg benfluralin/ha for shoot weight of sorghum was compared to 0.047 kg benfluralin/ha (2.77 % of the applied rate of 1.71 kg benfluralin/ha) in lettuce. The resulting TER of 69 is above the trigger of 5 and hence the risk to non-target plants is considered to be low for all representative uses evaluated.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Respiration of activated sewage sludge was inhibited by 14.2 % at the highest tested dose of 1000 mg benfluralin/L. It is not expected that the concentrations of benfluralin in biological sewage treatment plants would reach a concentration of more than 1000 mg benfluralin/L if the product is applied according to the GAP and therefore the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definitions for risk assessment: benfluralin (and for anaerobic conditions only: B36[12] and U6#1[13])
Definitions for monitoring: benfluralin

Water

Ground water

Definitions for exposure assessment: benfluralin, B12
Definitions for monitoring: benfluralin (DT_{90} < 3 days), B12 (provisional; to be confirmed by a revised FOCUS gw modelling)

Surface water

Definitions for risk assessment:
Surface water: benfluralin (DT_{90} < 3 days), aqueous photodegradation products (des-alkyl benfluralin diamine[14], propyl benzimidazole[15], methyl benzimidazole[16], ethyl propyl benzimidazole[17]) and for anaerobic conditions only: B36 and U6#1
Sediment: benfluralin

[12] benfluralin diamine, B36 = N2-butyl-N2-ethyl-3-nitro-5-(trifluoro=methyl)benzene-1,2-diamine
[13] ethyl propyl benzimidazole, U6#1 = 1-ethyl-7-nitro-2-prpyl-5-(trifluoromethyl)-1H-benzimidazole
[14] des-alkyl benfluralin diamine = 3-nitro-5(trifluoromethyl)-1,2-benzenediamine
[15] propyl benzimidazole = 4-nitro-2-propyl-6-(trifluoromethyl)-1H-benzimidazole
[16] methyl benzimidazole = 2-methyl-4-nitro-6-(trifluoromethyl)-1H-benzimidazole
[17] ethyl propyl benzimidazole = 1-ethyl-7-nitro-2-propyl-5-(trifluoromethyl)-1H-bezimidazole

Definitions for monitoring: cannot be concluded based on currently available data

Air

Definitions for risk assessment: benfluralin

Definitions for monitoring: benfluralin

Food of plant origin

Definitions for risk assessment: benfluralin (provisional)

Definitions for monitoring: benfluralin (provisional)

Food of animal origin

Definitions for risk assessment: pending

Definitions for monitoring: pending

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
benfluralin	Moderate to medium persistent First order $DT_{50\ lab}$ = 20-86 days (24ºC and 75% moisture capacity at 0.33 bar)	Low risk to earthworms and soil micro-organisms further risk refinement for soil dwelling arthropods may be required in Member States with local environmental conditions under which benfluralin is expected to degrade slowly.
B12	No data, data required	No data available
B36 (anaerobic conditions)	No data, not required	No data available. Studies were submitted. with earthworms, soil micro-organisms and TR4 which was suggested by the applicant to be a surrogate for B36 (because of similar structural formula)
U6#1 (anaerobic conditions)	No data, not required	No data available

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
benfluralin	Immobile (K_{foc} 8519-14400 mL/g)	FOCUS PELMO 3.3.2: trigger not exceeded in all FOCUS scenarios	Yes	Yes	Yes
B12	No data, data required	No data, data required	No data provided, data required	No data provided; data might be required.	No data provided, data required
B36 (anaerobic conditions)	No data, not required	No data, not required	No data provided, no data required.	Identified in rat metabolism (about 5 % in faeces); no further data provided; no data required.	No data provided, no data required.
U6#1 (anaerobic conditions)	No data, not required	No data, not required	No data provided, no data required.	No data provided, no data required.	No data provided, no data required.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
benfluralin	Benfluralin is very toxic to fish and aquatic invertebrates, no full FOCUS scenario resulted in TERs above the Annex VI trigger even with a no-spray buffer zone of 20m. The chronic risk assessment is not finalised.

Compound (name and/or code)	Ecotoxicology
des-alkyl benfluralin diamine (aqueous photolysis)	Lower toxicity to aquatic organisms compared to benfluralin, risk assessment not finalised
propyl benzimidazole (aqueous photolysis)	No ecotox studies provided, risk assessment not finalised
methyl benzimidazole (aqueous photolysis)	No ecotox studies provided, risk assessment not finalised
ethyl propyl benzimidazole (aqueous photolysis)	No ecotox studies provided, risk assessment not finalised

Air

Compound (name and/or code)	Toxicology
benfluralin	Due to the physico-chemical properties of the compound, no satisfactory respirable dust aerosol could be generated; no classification is proposed

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- A two year storage stability study where the relevant impurity is analysed before and after storage as well as an emulsion stability test conducted at the lowest in use concentration (relevant for all uses evaluated, data gap identified by meeting of experts October 2007, date of submission unknown, refer to chapter 1).
- Validated method of analysis for the relevant impurity in the formulation (relevant for all uses evaluated, data gap identified by meeting of experts October 2007, date of submission unknown, refer to chapter 1).
- Address why the levels found of the relevant impurity in the storage study would mean that technical material that is out of specification has been used to formulate the product (relevant for all uses evaluated, data gap identified by meeting of experts October 2007, date of submission unknown, refer to chapter 1).
- Address why the UV spectrum were different depending on the pH, if a pH dependence is shown then parameters that would be affected by pH may have to be retested (relevant for all uses evaluated, data gap identified by meeting of experts October 2007, date of submission unknown, refer to chapter 1).
- The library of metabolite reference standards and detailed information about the undertaken identification work in the plant metabolism studies has not been submitted (relevant for the uses in lettuce, witloof, data gap identified by meeting of experts October 2007, date of submission unknown, refer to chapter 3).
- A new metabolism study in root crops. The study is required to address the primary metabolism in root crops (relevant for the use in chicory roots, data gap identified by meeting of experts October 2007, date of submission unknown, refer to chapter 3) and the metabolism in rotational crops (relevant for all representative uses evaluated, data gap identified by meeting of experts October 2007, date of submission unknown, refer to chapter 3).
- Potential surface water contamination for aqueous photolysis metabolites des-alkyl benfluralin diamine, propyl benzimidazole, methyl benzimidazole and ethyl propyl benzimidazole to be addressed (relevant for all representative uses evaluated; data gap identified in the PRAPeR meeting 32; data submitted in January 2008, not peer reviewed; refer to point 4.2.1).
- Reliable adsorption coefficients and degradation rates for metabolite B12 to allow the potential for contamination of groundwater for this metabolite to be addressed in new FOCUS groundwater modelling are required (relevant for all representative uses evaluated; data gap identified in the PRAPeR meeting 32; date of submission unknown; refer to point 4.2.2).
- Dependant on the outcome of the new FOCUS groundwater modelling for metabolite B12, an evaluation of the relevance of this metabolite following the guidance document on relevant metabolites (SANCO/221/2000) may also be necessary (data gap identified after the PRAPeR experts' meeting; refer to point 4.2.2).

- For situations where anaerobic conditions are expected to be relevant, potential groundwater contamination by metabolites B36 and U6#1 may need to be assessed (not essential to finalize the risk assessment at EU level, refer to point 4.2.2).
- A new refined long-term risk assessment for earthworm-eating birds and mammals (relevant for all representative uses evaluated; data gap identified in the expert meeting on ecotoxicology (PRAPeR 33) in October 2007; no submission date proposed by the applicant; refer to point 5.1).
- A new chronic aquatic risk assessment and further refinement of the acute risk to invertebrates are necessary including a risk assessment for the photolysis metabolites in accordance to the data gap in fate and behaviour (relevant for all representative uses evaluated; data gap identified in the expert meeting on ecotoxicology (PRAPeR 33) in October 2007; no submission date proposed by the applicant; refer to point 5.2).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide on lettuce and chicory (salad and root production) full details of the GAP can be found in the attached end points.

The representative formulated product for the evaluation was "Bonalan", an emulsifiable concentrate (EC).

Adequate methods are available to monitor benfluralin in plants, soil water and air. However for water and plants the residue definition has not been concluded on and further data may be required. For products of animal origin it is currently not clear if a residue definition is required and therefore further methods may be required in the future. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that at least some limited quality control measurements of the plant protection product are possible. There are still some outstanding issues related to a relevant impurity, R65 classification, emulsion stability, efficiency of the tank cleaning procedure and testing at different pH for various parameters.

In mammalian metabolism studies, benfluralin showed a rapid but incomplete (30%) oral absorption, wide distribution in the body with preference for the liver, kidney, fat and blood compartments and rapid excretion, mainly via faeces; biliary excretion was a minor pathway. No potential for accumulation was observed. Parent compound was the most prominent compound recovered in faeces, while in urine a large number of minor metabolites was found.

Benfluralin has a low acute toxicity, but showed irritating and sensitizing properties which require classification with R36/38 – irritating to eyes and skin – and R43 – may cause sensitisation by skin contact. Due to the physico-chemical properties of the compound, no satisfactory respirable dust aerosol could be generated. Main target organs in short term and long term studies were the liver and kidneys. Classification with R40 – limited evidence of a carcinogenic effect – is proposed, based on neoplastic changes observed in the liver of rats and mice and thyroid tumours in rats upon long term exposure. Benfluralin showed no potential for genotoxicity or neurotoxicity. No effects on fertility or on reproductive parameters were observed as well as any adverse effects on development or teratogenicity. Relevant short term NOAEL was the dose level or 17 mg/kg bw/day from the 90-day oral study in rat, and the relevant long-term NOAEL was at the 0.5 mg/kg bw/day dose level from the 2-year study in rat.

The acceptable daily intake (ADI) is set at 0.005 mg/kg bw/day considering an assessment factor of 100; the acceptable operator exposure level (AOEL) is 0.05 mg/kg bw/day set using an assessment factor of 100 with a correction of 30 % for oral absorption (overall assessment factor of 333); no acute reference dose (ARfD) is allocated.

The outcome of the risk assessment for the representative plant protection product Bonalan, an emulsifiable concentrate (EC) containing 180 g benfluralin/L, showed that the estimated operator exposure was below the AOEL if personal protective equipment (PPE) as gloves is used, at least during the mixing and loading operations, according to the German model. Calculated exposure levels for bystanders was minimal compared to the AOEL. The dermal absorption was estimated to be 0.6% when handling the concentrate formulation and 4.45% for the in-use field dilution.

There was no need for an estimation of workers exposure since benfluralin is used as a pre-emergence herbicide applied directly to soils.

The plant metabolism of benfluralin was investigated in lettuce (category leafy crops), alfalfa and peanuts (pulses/ oilseed crop category). The Meeting of experts considered that the detailed information on the undertaken preliminary work on the metabolites characterisation/ identification should be submitted in order to conclude on the validity of these studies. No metabolism study was submitted to support a use in root and tuber crops. The experts in residues have concluded that further data is necessary to finalise the residue definition for primary and rotational crops, the livestock exposure assessment and eventually the consumer risk assessment. At the current stage, a residue definition and MRLs can only provisionally be proposed, but need to be reconsidered upon receipt of the necessary data. Based on the presumption that the only relevant residues for consumer exposure is parent benfluralin in primary crops, the estimated chronic intake would be less than 1% of the ADI of benfluralin for the considered consumer groups.

The consumer risk assessment will have to be revised when the outstanding data and information was evaluated.

Studies submitted on the environmental fate and behaviour of benfluralin were reviewed and found to be either acceptable, non acceptable or supplemental. Des-alkyl benfluralin diamine, propyl benzimidazole, methyl benzimidazole and ethyl propyl benzimidazole were identified as major

degradates photolytically produced, but an assessment of potential surface water contamination by these metabolites can not be concluded. Reliable data on degradation in soil and adsorption properties for metabolite B12 were not available for FOCUS modelling and therefore the assessment of the potential of groundwater contamination needs to be addressed.
The peer review concluded that for the applied for intended uses a complete exposure assessment for the major anaerobic metabolites B36 and U6#1 is not necessary.

A potential high risk was identified for earthworm eating-birds and mammals. The suggested refinements were not accepted in the expert meeting and a data gap was identified for a new refined long-term risk assessment for earthworm eating birds and mammals. Risk mitigation measures such as a 20m no-spray buffer zone is required to achieve TERs above the Annex VI trigger for fish. However no full FOCUS scenario resulted in acute TERs above the trigger for aquatic invertebrates. The chronic TER values for fish and daphnia were calculated with 50 d twa-PECsw instead of initial PECsw. The experts rejected the use of 50 d twa PECsw for reproductive effects. For effects on growth it was agreed to use time weighted average PECsw but the fast dissipation of benfluralin from the water phase needs to be taken into account and the time period should not be longer than 5 times the DT_{50} (in this case 7days). A data gap was identified in the expert meeting for the applicant to provide a new chronic aquatic risk assessment taking into account the suggestions of the expert meeting and to refine further the acute risk to invertebrates. No final conclusion can be drawn on the risk to aquatic organisms from the photolysis metabolites at this stage and should be addressed in the new aquatic risk assessment in line with the data gap identified in the section on fate and behaviour. The risk assessment for soil non-target arthropods resulted in a TER of 4.8 based on an initial PEC soil of 1.14 mg benfluralin/kg from the worst case application in lettuce. Since the TER value is close to the trigger of 5 and based on initial PECs it was agreed in the expert meeting that the risk to soil non-target arthropods is sufficiently addressed for most environmental conditions but Member States could ask for further risk refinement if benfluralin is expected to degrade slowly under their local environmental conditions.

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

- The estimated operator exposure was below the AOEL if PPE are used (gloves), at least during mixing and loading operations (refer to point 2.12).

Critical areas of concern

- The consumer risk assessment cannot be finalised due to lack of data.
- Potential for ground water contamination of the metabolite B12 needs to be assessed.
- The risk assessment for earthworm-eating birds and mammals need further refinement.
- The aquatic risk assessment needs further refinement (no full FOCUS scenario resulted in TERs above the trigger including a no-spray buffer zone of 20 m).

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

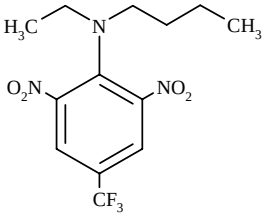
(Abbreviations used in this list are explained in appendix 2)

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

Active substance (ISO Common Name) ‡	Benfluralin
Function (e.g. fungicide)	Herbicide

Rapporteur Member State	Belgium
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*N*-butyl-*N*-ethyl-α,α,α-trifluoro-2,6-dinitro-*p*-toluidine
Chemical name (CA) ‡	*N*-butyl-*N*-ethyl-2,6-dinitro-4-(trifluoromethyl) benzenamine
CIPAC No ‡	285
CAS No ‡	1861-40-1
EC No (EINECS or ELINCS) ‡	217-465-2
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	960 g/kg (industrial scale production)
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured	ethyl-butyl-nitrosamine : max. 0.1 mg/kg
Molecular formula ‡	$C_{13}H_{16}F_3N_4O_4$
Molecular mass ‡	335.3 g/mol
Structural formula ‡	

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	66.4 °C (99.9%)
Boiling point (state purity) ‡	Not applicable (decomposition)
Temperature of decomposition (state purity)	205°C (99.9%)
Appearance (state purity) ‡	odourless solid, colour characterized by a hue of 2.5Y, a value of 8.5 and a chroma of 10 (Munsell colour system) (99.9%);
Vapour pressure (state temperature, state purity) ‡	1.73 x 10^{-3} Pa at 20°C (99.9%)
Henry's law constant ‡	9.1 $Pa.m^3.mol^{-1}$ at 20°C (99.9%)
Solubility in water (state temperature, state purity and pH) ‡	deionized (unbuffered) water, 20°C : 0.0648 mg/L (99.9%)
	Effect of pH does not need to be addressed (molecule will not be ionized at environmentally relevant pH values)
Solubility in organic solvents ‡ (state temperature, state purity)	at 20°C (99.9%) n-heptane 42.4 g/L xylene > 250 g/kg 1,2-dichloroethane > 250 g/kg methanol 39.1 g/L n-octanol 23.4 g/L acetone > 250 g/kg ethyl acetate > 250 g/kg
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable (water solubility is < 1 mg/L)
Partition co-efficient ‡ (state temperature, pH and purity)	pH 7.9-8.6, 20°C : log Pow = 5.19 (99.9%)
	Effect of pH does not need to be addressed (molecule will not be ionized at environmentally relevant pH values)
Dissociation constant (state purity) ‡	Benfluralin is estimated to have a pKa of – 0.59 This indicates that molecule will not be ionized at environmentally relevant pH values.

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

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	(99.9%) :

	λ_{max} (nm)	ε (L.mol^{-1}.cm^{-1})
acidic (pH 1.7)	248 298 448	4390 4580 3870
unbuffered (neutral; pH 5.9)	239 283	9180 8010
basic (pH 11.9)	238 283 431	7550 6370 3720

Flammability ‡ (state purity)	not highly flammable (97.5%) self ignition temperature = 304°C (97.5%)
Explosive properties ‡ (state purity)	not explosive (96.2%)
Oxidising properties ‡ (state purity)	not oxidising (97.5%)

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

Summary of representative uses evaluated *

Crop and/ or situation (a)	Member State or Country	Product name	FG 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		
Lettuce *Lactuca sativa*	Belgium	Bonalan	F	Weeds (grasses & dicots)	EC	180	Broadcast spray & incorporation in soil	Pre-sowing or pre-planting. From April to Sept.	1	N/A	0.27-1.08	150-600	1.62	Not relevant	High spray volume (600l/ha) is used when Bonalan is mixed with liquid fertilizers. No use under greenhouses. [1]; [2]; [3]
	Italy	Bonalan	F	Weeds (grasses & dicots)	EC	180	Broadcast spray & incorporation in soil	Pre-sowing or pre-planting. In Spring + fall.	1	N/A	0.23-0.57	300-500	1.17-1.71	Not relevant	No use under greenhouses [1]; [2]; [3]
	Spain	Quilan (= Bonalan)	F	Weeds (grasses & dicots)	EC	180	Broadcast spray & incorporation in soil	Pre-sowing or pre-planting From Sept. to April	1	N/A	0,28-0,43	400-600	1,71	Not relevant	Application before transplant or direct sowing. No use under greenhouses. Key market segment in Spain. [1]; [2]; [3]

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

Crop and/ or situation	Member State or Country	Product name	FG or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
(a)			(b)	(c)	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	(l)	(m)
Witloof Chicory *Cichorium endivia* (chicon / endive production)	Belgium	Bonalan	F	Weeds (grasses & dicots)	EC	180	Broadcast spray & incorporation in soil	Pre-sowing	1	N/A	0.27-1.08	150-600	1.620	Not relevant	High spray volume (600l/ha) is used when Bonalan is mixed with liquid fertilizers. [1]; [2]; [3]
	France	Bonalan	F	Weeds (grasses & dicots)	EC	180	Broadcast spray & incorporation in soil	Pre-sowing	1	N/A	0.18-0.72	150-600	1.080	Not relevant	[1]; [2]; [3]
Chicory root for processing *Cichorium intybus* (“coffee”, fructose, inulin production)	Belgium	Bonalan	F	Weeds (grasses & dicots)	EC	180	Broadcast spray & incorporation in soil	Pre-sowing	1	N/A	0.27-1.08	150-600	1.620	Not relevant	High spray volume (600l/ha) is used when Bonalan is mixed with liquid fertilizers. [1]; [2]; [3]

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

Crop and/ or situation (a)	Member State or Country	Product name	FG 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		
	France	Bonalan	F	Weeds (grasses & dicots)	EC	180	Broadcast spray & incorporation in soil	Pre-sowing	1	N/A	0.18-0.72	150-600	1.080	Not relevant	[1]; [2]; [3]

[1] Hand-held application risk assessment was not finalised as it was withdrawn by the applicant during the peer-review;

[2] Data gaps were identified in section 3;

[3] Data gaps were identified in section 5.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L.
(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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

‡ Endpoints identified by 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 (analytical technique)	GC-FID (ISTD) CIPAC 285/TC/M/3.1 (UV) CIPAC 285/TC/M/3.2 (GC-FID, ISTD)
Impurities in technical as (analytical technique)	GC-FID (conf. by MS); relevant impurity (ethyl-butyl-nitrosamine) : HPLC-MS/MS
Plant protection product (analytical technique)	active substance : GC-FID (ISTD) CIPAC 285/EC/M/3.1 (UV) CIPAC 285/EC/M/3.2 (GC-FID, ISTD) relevant impurity (ethyl-butyl-nitrosamine) : open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Benfluralin
Food of animal origin		None
Soil		Benfluralin
Water	surface	Open
	drinking/ground	Open
Air		Benfluralin

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Single method GRM 00.20 : GC-ECD (Benfluralin); LOQ = 0.01 mg/kg (high moisture crops); ILV available Confirmatory method: GC-MS
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required (not necessary to define residue or propose MRL's)
Soil (analytical technique and LOQ)	Single method GRM 99.03 : GC-ECD (Benfluralin); LOQ = 0.01 mg/kg Confirmatory method: GC-MS

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

Water (analytical technique and LOQ)	Single method GRM 03.03 : GC-MS (Benfluralin); LOQ = 0.05 µg/L (surface water, groundwater, drinking water)
Air (analytical technique and LOQ)	Single method GRM 02.28 : GC-MS (Benfluralin); LOQ ≈ 0.15 µg/m³
Body fluids and tissues (analytical technique and LOQ)	Not required (active substance is not classified as toxic or highly toxic)

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	none

‡ Endpoints identified by 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 (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Rapid (< 48 h) and incomplete (30 %) based on urinary and carcass/tissue levels (20 %) within 7 days and biliary (10 %) excretion within 24 h
Distribution ‡	Widely distributed; slight preference for fat, liver, kidney, blood
Potential for accumulation ‡	No evidence for accumulation
Rate and extent of excretion ‡	Rapid and extensive (77 - 91 %) within 48 h, mainly faecal (73 %), 18 % via urine, 10 % via bile
Metabolism in animals ‡	Benfluralin was subject to di-dealkylation and reduction, and further metabolised into numerous polar compounds, each present at < 1 % of the dose. Parent compound present at about 35 %.
Toxicologically relevant compounds ‡ (animals and plants)	Benfluralin
Toxicologically relevant compounds ‡ (environment)	Benfluralin

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	
Rat LD_{50} dermal ‡	> 5000 mg/kg bw	
Rat LC_{50} inhalation ‡	2.16 mg/L air < LC_{50} < 5 mg/L air /4 h (dust, nose only)	
Skin irritation ‡	Irritant, based on the repeated dermal studies	**R38**
Eye irritation ‡	Irritant	**R36**
Skin sensitisation ‡	Sensitising (M & K and Buehler test)	**R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	kidney tubule pigmentation (♀), kidney weight decrease (rat); liver weight increase (rat, dog); liver/spleen pigmentation (haemosiderosis?), (dog); RBC effects (rat, dog)	
Relevant oral NOAEL ‡	90-day rat: 17 mg/kg bw/day 1-year & 90-day, dog 25 mg/kg bw/day	
Relevant dermal NOAEL ‡	21-day, rabbit: systemic: 500 mg/kg bw/day (increased liver weight); local: < 100 mg/kg bw/day (skin inflammation)	

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

Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Benfluralin is unlikely to be genotoxic	

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

Target/critical effect ‡	Liver, thyroid (rat, mouse)	
Relevant NOAEL ‡	0.5 mg/kg bw/day; 2-year, rat 6 mg/kg bw/day; 18-month, mouse	
Carcinogenicity ‡	hepatocellular tumours (rat, mouse), thyroid tumours, (rat)	**R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parents: ↓body weight (gain), ↑liver weight; Offspring: ↓body weight ($F_{1/2}$), ↑ pup mortality (F_1); Reproduction: No effect on reproductive performance.	
Relevant parental NOAEL ‡	5.5 mg/kg bw/day	
Relevant reproductive NOAEL ‡	278 mg/kg bw/day (highest dose)	
Relevant offspring NOAEL ‡	5.5 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	No developmental adverse effects (rat, rabbit) Rabbit (maternal toxicity): ↓bw gain, ↓food consumption	
Relevant maternal NOAEL ‡	Rat: 225 mg/kg bw/day Rabbit: 50 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 1000 mg/kg bw/day Rabbit: 225 mg/kg bw/day (highest dose)	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data, no concern from other studies - not required	

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

Repeated neurotoxicity ‡	No data, no concern from other studies - not required	
Delayed neurotoxicity ‡	No data, no concern from other studies - not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data
Studies performed on metabolites or impurities ‡	No data

Medical data ‡ (Annex IIA, point 5.9)

Based on the reports of the medical surveillance on manufacturing plant personnel from the applicant, no effects were anticipated. One case of occupationally related skin sensitisation was reported in the open literature.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.005 mg/kg bw/day	rat, 2-year study	100
AOEL ‡	0.05 mg/kg bw/day	rat, 90-day study	333*
ARfD ‡	Not allocated – not necessary		

*100 with a correction for low oral absorption (30%)

Dermal absorption ‡ (Annex IIIA, point 7.3)

Bonalan (EC formulation containing 180 g benfluralin/L)	Concentrate: 0.6 % Spray dilutions: 4.5 % Rat *in vivo* and comparative *in vitro* (human/rat skin)

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

Exposure scenarios (Annex IIIA, point 7.2)

Operator	The estimated exposure for Bonalan according to the German model (application rate 1.71 kg a.i./ha) was below AOEL, only if PPE (gloves during M/L) are worn. Tractor mounted equipment: UK POEM % of AOEL Without PPE: 573 % PPE (gloves during M/L & application): 101 % German model % of AOEL Without PPE: 103 % PPE (gloves during M/L): 90 % PPE (gloves during M/L and gloves, protective garment and sturdy footwear during M/L & application): 8 % Knapsack sprayers: Not considered
Workers	No risk identified for evaluated uses
Bystanders	Bystander exposure is below the AOEL (0.33 % of AOEL)

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Substance (name)	**Xn** "Harmful" **Xi; R36/38** "Irritating to eyes and skin" **Xn; R40** "Limited evidence of a carcinogenic effect" **R43** "May cause sensitization by skin contact"

‡ Endpoints identified by 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	Leafy crops (lettuce) and oilseeds/pulses (peanuts, alfalfa)[18] The use on industrial chicory (fructose, inuline production) is not covered by a root crop metabolism study.
Rotational crops	Available data do not fully address metabolism in rotational crops for various reasons as detailed in the report of PRAPeR 35. Given the notified use is an application to soil, primary crop metabolism data covering 3 different crops that demonstrates a similar metabolic pattern could be used to address outstanding rotational crop issues. Whether or not further data on rotational crops are required depends upon the outcome of a metabolism study on rooting crops.
Plant residue definition for monitoring	Benfluralin (provisional)
Plant residue definition for risk assessment	Benfluralin (provisional)
Conversion factor (monitoring to risk assessment)	None (provisional)

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

Animals covered	Metabolism studies on ruminants and poultry were provided but not peer reviewed. Upon submission of data addressing identified gap for primary and rotational crops reconsideration of animal intakes might be required.
Animal residue definition for monitoring	None agreed.
Animal residue definition for risk assessment	None agreed.
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 Po/w : 5.19).

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

	A root metabolism study is required in order to address primary and rotational crop metabolism. Depending on the outcome further rotational crop data might be required.

[18] PRAPeR 35 concluded that the detailed information on the undertaken preliminary work on the metabolites characterisation / identification should be submitted in order to conclude on the validity of these studies. Until then the proposed residue definition should be considered provisional.

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

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

Residues of Benfluralin in lettuce stored for 0, 1, 6 and 12 months at –18 °C ranged between 92 % and 104 % of the fortified values and can therefore be considered as stable for a minimum of 12 months under frozen storage conditions. This study is also valid for witloof chicory (endive production).

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Intake calculations for livestock according to EU Guidance Doc.7031/VI/95 rev.4 are not necessary as lettuce, chicory roots/leaves and endive heads are not feeding stuffs used in the nutrition of the 4 indicator livestock species. Upon submission of data addressing identified gap for primary and rotational crops reconsideration of animal intakes might be required.		
Potential for accumulation (yes/no):	Not assessed.		
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not assessed.		
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	n/a	n/a	n/a
Liver	n/a	n/a	n/a
Kidney	n/a	n/a	n/a
Fat	n/a	n/a	n/a
Milk	n/a	n/a	n/a
Eggs	n/a	n/a	n/a

‡ Endpoints identified by 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 estimated from trials according to the representative use	HR (c)	STMR (b)
Lettuce	North Europe	Lettuce heads : 4 trials characterised as follows : 1.559-1.763 kg a.s./ha, 1 application before planting, PHI : 40-41 days. Benfluralin residue values : nd (< 0.01)-nd (< 0.01)- (< 0.01) - <0.01 mg/kg.	In the trials performed on lettuce in Northern Europe, a single application of BONALAN was applied pre-planting at a target rate of 1620 g a.s./ha (actual treatment dose rate : 1725-1763 g a.s./ha) and a spray volume of 200-400 L/ha. Immediately after application, Benfluralin was incorporated into the soil. Lettuce plants were planted into the treated soil within one day after application. Samples of untreated and treated lettuce heads were collected at normal harvest, 41 days after the treatment corresponding to the growth stage BBCH 49. In the South of Europe, lettuce received one application of the formulation BONALAN. The application was made on bare soil before planting at a nominal rate of 1710 g a.s./ha (actual application rate : 1818 – 1890 g a.s./ha) and between 79 and 87	0.01* mg/kg	0.01 mg/kg	0.01 mg/kg
	South Europe	Lettuce heads : 2 trials characterised as follows : 1.818-1.890 kg a.s./ha, 1 application before planting, PHI : 79, 87 days. Benfluralin residue values : nd (<0.01)-<0.01 mg/kg.				

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

			days prior to harvest. Lettuce heads were sampled at commercial harvest date. *Remark* : The residue data base can be considered as complete according to the EU Guidance Doc.7525/VI/95-rev.7, &2.6 "Non-relevant residues" : When the residues of an active substance are foreseen to be under the LOD – case of early applications of herbicides - and at least 2 residue trials confirm this then no further trials are normally necessary".			
Use not supported by metabolism data: Industrial chicory (fructose, inulin production)	North Europe	Chicory roots and leaves : 8 trials characterised as follows : 1.526-1.741 kg a.s./ha, 1 application before sowing, PHI : 118-203 days. -Benfluralin residue values : *Roots* : nd (<0.01)-<0.01- nd (<0.01)- nd (<0.01)-<0.01- nd (<0.01)- nd (<0.01)- nd (<0.01)mg/kg *Leaves* : nd (<0.01)- nd (<0.01)- nd (<0.01)- nd (<0.01)- nd (<0.01)-<0.01- nd (<0.01)- nd (<0.01)mg/kg.	The chicory crop received one application of BONALAN (EF-1533). The applications were made on bare soil before sowing at a nominal rate of 1620 g a.s./ha and between 118 and 163 days prior to harvest. Chicory roots and tops were sampled at harvest. Each trial consisted in 2 plots : one untreated and one treated. The treated plot received a single application of BONALAN EC at a nominal rate of 1620 g a.s./ha (actual rate of 1526 – 1741 g a.s./ha) prior to sowing the	0.01* mg/kg (chicory roots)	0.01 mg/kg	0.01 mg/kg

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

			chicory crop. Samples of chicory roots and leaves were taken at growth stage BBCH 49. The trials conducted in Belgium and North of France were undertaken during 2000 and 2001.			
Witloof chicory (Endive production)	North Europe	Endive heads : 6 trials characterised as follows : 1.59-1.789 kg a.s./ha, 1 application before sowing, PHI : 192-218 days. Benfluralin residue values : nd (<0.01)-nd (<0.01)-nd (<0.01)-nd (<0.01)-nd (<0.01)-nd (<0.01) mg/kg	The trials were undertaken during 2001 in Belgium and North of France. Each trial consisted of 2 plots, one untreated and one treated. In each trial, the treated plot received a single application of BONALAN EC (EF-1533) at a nominal rate of 1620 g a.s./ha (actual rates of 1.59 and 1.64 kg a.s./ha). Following application, the formulation was incorporated into the top 5 to 10 cm of soil prior to sowing of the endive crop. In both trials, samples of root were lifted by hand. The roots were dipped in a fungicide solution and stored for 2 weeks in a dark cold room. The leaves were then cut off the roots and discarded. The roots were then placed in a hydroponic tank and the new leaves were then	0.01* mg/kg	0.01 mg/kg	0.01 mg/kg

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

			harvested by hand at growth stage BBCH 99, equivalent to 196 and 218 days after application.			

(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 representative use
(c) Highest residue

‡ Endpoints identified by 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	0.005 mg/kg b.w./day.
TMDI (% ADI) according to WHO European diet	**Provisional**[19]**:** - 0.034 % (German model) - 0.11 %, 0.05 %, 0.17 % respectively for adults, children and toddlers (UK long term exposure model – High consumption intakes)
TMDI (% ADI) according to national (to be specified) diets	**Provisional**[20]**:** 0.09 % (WHO European diet)
IEDI (WHO European Diet) (% ADI)	Not required.
NEDI (specify diet) (% ADI)	Not required.
Factors included in IEDI and NEDI	n/a
ARfD	Not required.
IESTI (% ARfD)	n/a
NESTI (% ARfD) according to national (to be specified) large portion consumption data	n/a
Factors included in IESTI and NESTI	n/a

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Effects on the level of the residues Such studies are not required for the following reasons : The TMDI is below 10 % of the ADI				

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

[19] Based on provisionally proposed residue definition. The consumer risk assessment cannot be finalised, pending the submission of data that address the primary root crop metabolism, rotational crops and livestock intake

[20] Based on provisionally proposed residue definition. The consumer risk assessment cannot be finalised, pending the submission of data that address the primary root crop metabolism, rotational crops and livestock intake

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

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

Provisional until the residue definition for monitoring is confirmed.

Crops	MRLs (mg/kg)
Lettuce	0.01*
Chicory roots	0.01*
Witloof chicory	0.01*

* LOQ

‡ Endpoints identified by 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 ‡	1.7% AR at day 125 (Benfluralin is volatile: 8.3% AR in the traps at day 125)
Non-extractable residues after 100 days ‡	42.3% AR at day 125
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	B12 5.2% AR at day 64, 5.1% AR at day 91

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

Anaerobic degradation ‡

Mineralization after 100 days	**1.3% AR at day 120**
Non-extractable residues after 100 days	50.2 % at day 120
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Benfluralin diamine: maximum level of 23.2% AR at day 1 (DT_{50} = 2.3 d) Ethyl propyl benzimidazole: maximum level of 25.0% in the total system at day 2 (DT_{50} = 27.2 d)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not required The active substance is incorporated in the soil.

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

Method of calculation	First order, non linear regression. Temperature correction assuming a Q_{10} factor of 2.2
Laboratory studies (range or median, with n value, with r^2 value) ‡	DT_{50lab} (24°C, aerobic): 36.5, 20, 34, 86 days, arithmetic mean 44 days, geometric mean 38.2 days (4 soils, r^2 = 0.987-0.996) DT_{50lab} (24°C, 10 kPa aerobic): 23, 13.8, 24, 65 days, arithmetic mean **31** days, geometric mean 26.4 days (4 soils, for PEC gw modelling purposes, r^2 = 0.987-0.996) DT_{50lab} (20°C, 10 kPa aerobic): 31, 19, 33, 90 days, arithmetic mean **43** days, geometric mean 36.2 days (4 soils, for PEC gw modelling purposes, r^2 = 0.987-0.996)

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

	Data gap for metabolite B12
	DT_{90lab} (20°C, aerobic): 89.7 to 385 days, mean 199 days (4 soils, extrapolated from 24°C)
	DT_{50lab} (10°C, aerobic): mean 133 days (calculation, extrapolated DT50 determined in aerobic studies at 24°C)
	DT_{50lab} (20°C, anaerobic): 0.25 days, i.e. 6 hours (1 soil, 20°C, r^2 = 0.9743)
	degradation in the saturated zone: ‡ anaerobic study available
Field studies (state location, range or median with n value) ‡	single first-order (SFO) kinetics DT_{50f}: 34 to 73 days, mean 53 days (4 sites in Belgium and Northern France, r^2 = 0.879-0.951)
	DT_{90f}: 115 to 242 days, mean 175 days (4 sites in Belgium and Northern France)

Site location	**Soil type**	**$DT_{50(field)}$ (days)**	**$DT_{90(field)}$ (days)**	**R^2**
N France, EU (N), 1997	clay loam	40	131	0.879
Belgium, EU (N), 1997	silty clay loam	64	211	0.951
Belgium, EU (N), 1998	silty clay loam	73	242	0.919
N France, EU (N), 1998	silt loam	34	115	0.938

Soil accumulation and plateau concentration ‡	not required since the field DT90 are lower than 1 year

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡ pH dependence (yes / no) (if yes type of dependence) ‡	K_{OC}: 8519 to 14400 mL/g, mean 10777 mL/g (7 soils). 1/n: 0.918 to 1.139, mean 1.031 (7 soils). K_D: 21.0 to 383.6 mL/g (7 soils). No pH dependence observed. *Data gap for metabolite B12*

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

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

Column leaching ‡	Not required
Aged residues leaching ‡	US EPA Guideline Aged for (d): 30 d Time period (d): not given Precipitation (mm): 550 mm Leachate: 3.1-1.1% total residues/radioactivity in leachate, mainly as metabolite 2,6-dinitro-4-(trifluoromethyl)phenol.
Lysimeter/ field leaching studies ‡	Not available

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	First order kinetics
Application data	Application rate of 1.71 kg a.s./ha (lettuce), 1 appl., pre-sowing (no interception), followed by incorporation into the soil (10 cm soil layer as worst case) Worst case field DT50: 73 days

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		1.140	-	-	
Short term	24h	1.129	1.135	-	-
	2d	1.119	1.129	-	-
	4d	1.098	1.119	-	-
Long term	7d	1.067	1.103	-	-
	28d	0.874	1.001	-	-
	50d	0.709	0.908	-	-
	100d	0.441	0.736	-	-
Plateau concentration		x mg/kg after n yr			

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

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4, 50°C : hydrolytically stable (99.9%)
	pH 7, 50°C : hydrolytically stable (99.9%)
	pH 9, 50°C : hydrolytically stable (99.9%)
Photolytic degradation of active substance and metabolites above 10 % ‡	pH 5, 20°C : DT_{50} = 2.1 hrs (98% radiochemical, xenon burner with UV filter (cut off λ < 290 nm)) no relevant metabolites (all metabolites of transient character)

photodegradates	%AR after 8 hours	%AR after 7 d	DT50 (d)
Des-alkyl benfluraline diamine	9.9-11.5	6.1-6.5	6.9
Propyl benzimidazole	14.3-16.4	5.8-6.8	6.1
Methyl benzimidazole	11.2-11.5	7.6-7.9	8.6
Methyl benzimidazole N-oxide	6.3	2.7-3.0	6.2
Ethyl propyl benzimidazole	10.5-19.5	ND	0.2

environmental half-life of benfluralin in an aquatic system in summer and winter months at latitudes of 40°N and 50°N as follows.

Summer
Lat 40°N, t ½ = 18 hours
Lat 50°N, t ½ = 18.9 hours

Winter
Lat 40°N, t ½ = 50.2 hours
Lat 50°N, t ½ = 118.1 hours

Quantum yield of direct phototransformation in water at Σ > 290 nm	ϕ = 2.12 x 10^{-5} (98% radiochemical, xenon burner with UV filter (cut off λ < 290 nm))
Readily biodegradable ‡ (yes/no)	No; degradation equal to 5% of the calculated biological demand after 28 days

Degradation in water/sediment	- DT_{50} water ‡	0.74-0.75 days
	- DT_{90} water ‡	2.4-2.5 days (1^{st} order, r^2= 0.873-0.966, n= 2)

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

- DT_{50} whole system ‡ - DT_{90} whole system ‡	1.3-1.1 days 4.4-3.7 days (1st order, r^2= 0.897-0.931, n= 2)
Mineralization	2.5-1.7 %AR (at 100 d, study end, n= 2)
Non-extractable residues	26.0-31.4% AR (at 100 d, study end, n=2)
Distribution in water / sediment systems (active substance) ‡	Maximum of 43.4-39.7 %AR in sediment after 0 day. DT_{50} in sediment 7.8-2.0 days (DT_{90} 25.9-6.8 days, 1st order, r^2= poor fit, n= 2)
Distribution in water / sediment systems (metabolites) ‡	Water: Benfluralin diamine max of <0.1-1.7% (7 days, n= 2) Sediment: Benfluralin diamine max of 6.5-8.7% (2-7 days, n= 2 [DT_{50} 23-33 days, 1st order, r^2= 0.918-0.699, n= 2])

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

Parent	
Method of calculation	Modelling using FOCUS model(s), with appropriate FOCUS sw scenarios, according to FOCUS guidance. Model(s) used: FOCUSsw model Scenarios: D3 ditch, D4 (pond, stream), D6 ditch, R1 (pond, stream), R2 stream, R3 stream, R4 stream Crop: chicory (leafy vegetable chosen as surrogate), lettuce (leafy vegetable chosen as surrogate) Mean parent $DT_{50lab\ soil}$ 44 days; mean of four soils at 24°C and moisture content of 75% 1/3 bar. This DT50 value was normalised for water content at field capacity (10 kPa) at 24°C to **31** days. K_{oc}: parent, 9999 mL/g, $^1/_n$= 1.031 Molecular weight : 335.3 g/mol Water solubility 0.0648 mg/L at 20°C Vapour Pressure : 1.73 x 10^{-3} Pa at 25°C parent DT_{50lab} water: 999 d (stable in water) Mean parent $DT_{50lab\ sediment}$: 4.9 d at 20°C
Application rate	Spring Application to Chicory: 1.62 kg as/ha (15 March), with soil incorporation to 15 cm. Application to bare soil Year round Application to Lettuce: 1.71 kg as/ha (1 February or 1 November), with soil incorporation to

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

	15 cm. Application to bare soil
Main routes of entry	Drift, drainage and run off

FOCUS Step 4 refined initial concentrations (global maximum) using a 20m VBS (with no run-off mitigation for R Scenarios)

Water	No	Lettuce (1 Nov)		Lettuce (1 Feb)	
Body	Spray	PECsw	PECsed	PECsw	PECsed
	Zone	(µg as/L)	(µg as/kg)	(µg as/L)	(µg as/kg)
D3 d	20 m	0.799	0.243	0.801	0.291
D4 p	3.5 m	0.154	0.301	0.154	0.319
D4 s	20 m	0.888	0.061	0.867	0.045
D6 d	20 m	0.777	0.090	0.793	0.175
R1 p	3.5 m	0.154	0.372	0.154	0.307
R1 s	20 m	0.715	2.496	0.695	1.470
R2 s	20 m	0.948	3.250	0.925	26.323
R3 s	20 m	0.985	15.173	1.011	0.244
R4 s	20 m	0.717	0.352	0.717	0.297

Metabolite

Method of calculation	*Data gap for PECsw calculation for photolysis metabolites des-alkyl benfluralin diamine, propyl benzimidazole, methyl benzimidazole and ethyl propyl benzimidazole was identified in the PRAPeR meeting*

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

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

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: FOCUSPELMO 3.3.2 Scenarios: Chateaudun, Hamburg, Jokioinen, Kremsmünster, Porto, Sevilla, Thiva Crop: chicory (carrot chosen as surrogate), lettuce (cabbage chosen as surrogate) Mean parent DT_{50lab} 44 days; mean of four soils at 24°C and moisture content of 75% 1/3 bar. This DT50 value was normalised for water content at field capacity (10 kPa) at 24°C to **31** days, (43 days at 20°C). K_{oc}: parent, mean 10765 mL/g, $^1/_n$= 1.031. Molecular weight : 335.3 g/mol Pka: 20 Water solubility 0.0648 mg/L at 20°C Vapour Pressure : 1.73 x 10^{-3} Pa at 25°C
Application rate	Spring Application to Chicory: 1.62 kg as/ha (15 March), with soil incorporation to 15 cm. Application to bare soil Year round Application to Lettuce: 1.71 kg as/ha (1 February or 1 November), with soil incorporation to 15 cm. Application to bare soil

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

$PEC_{(gw)}$

80th percentile annual average leachate concentration (µg/L) - Benfluralin

Scenarios	Chateaudun	Hamburg	Jokioinen	Kremsmünster	Okehampton	Piacenza	Porto	Sevilla	Thiva
Application to chicory	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Application to lettuce (spring)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Application to lettuce (autumn)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

From lysimeter / field studies

Parent	1st year	2nd year	3rd year
No data – not required.			

Metabolites

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	*Data gap for metabolite B12*
Application rate	*Data gap for metabolite B12*

$PEC_{(gw)}$

Maximum concentration	-
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance.)	*Data gap for metabolite B12*

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

Direct photolysis in air ‡	Not required
Quantum yield of direct phototransformation	$\phi = 2.12 \times 10^{-5}$ (98% radiochemical, xenon burner with UV filter (cut off $\lambda < 290$ nm))
Photochemical oxidative degradation in air ‡	overall OH rate constant $K_{OH} = 22.2703 \times 10^{-12}$ cm^3/molecule.sec

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

	→ estimated half life in atmosphere = 5.763 hrs or 0.48 d (assuming global OH-concentration of 1.5 x 10^6 OH radicals/cm^3 and 12 hour day) ⇒ a.s. is not persistent in the atmosphere
Volatilisation ‡	from plant surfaces: 16.8% loss of the applied a.s. after 24 h
	from soil: 15.8% loss of the applied a.s. after 24 h
Metabolites	-

PEC (air)

Method of calculation	Not required

$PEC_{(a)}$

Maximum concentration	Not required

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil:	benfluralin
	Surface Water:	benfluralin
	Sediment:	benfluralin
	Ground water:	benfluralin
	Air:	benfluralin

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

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	A survey of the monitoring data has been done by the notifier. Benfluralin does not appear to be included in the monitoring programs conducted by the national or regional authorities of the countries surveyed (which included 15 EU member states, Norway and Switzerland), indicating that Benfluralin is not considered a priority substance.
Ground water (indicate location and type of study)	A survey of the monitoring data has been done by the notifier. Benfluralin does not appear to be included in the monitoring programs conducted by the national or regional authorities of the countries surveyed (which included 15 EU member states, Norway and Switzerland), indicating that Benfluralin is not considered a priority substance.

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

Air (indicate location and type of study)	Not available

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data (Annex IIA, point 10)

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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)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Colinus virginianus	benfluralin	Acute	> 2000	-
Anas platyrhynchos	benfluralin	Short-term	> 793	> 5000
Colinus virginianus	benfluralin	Short-term	> 909	> 5000
Anas platyrhynchos	benfluralin	Long-term	49.3	288
Colinus virginianus	benfluralin	Long-term	8.6	96
Mammals ‡				
Rat	benfluralin	Acute	> 5000	-
Rat	benfluralin	Long-term	5.5	-
Additional higher tier studies ‡ Not required.				

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

Crop and application rate: lettuce, 1 x 1.71 kg a.s./ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Insectivorous bird (early)	Acute	92.5	> 21.6	10
	Short-term	51.6	> 15.4	10
	Long-term	51.6	0.17	5
Earthworm-eating bird	Long-term	1.65	5.21	5
Fish-eating bird	Long-term	0.112	77	5
Higher tier refinement (Birds)				

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

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Insectivorous bird (early)	Acute	3.56	> 562 (residues)	10
	Short-term	0.89	> 892 (residues)	10
	Long-term	0.89	9.7 (residues)	5
Tier 1 (Mammals) Benfluralin is applied pre-sowing or pre-planting, therefore no leafy crops or weeds are present in the field at the time of application. Once incorporated, benfluralin is among the least mobile herbicides, and this limits its bioavailability for plant uptake. Therefore, benfluralin is a non-systemic herbicide. Herbivorous birds and mammals are considered not to be at risk due to the absence of contaminated vegetation.				
Earthworm-eating mammal	Long-term	3.40	1.62	5
	Acute			10
Fish-eating mammal	Long-term	0.069	80	5
Higher tier refinement (Mammals) Not required				
	Acute			10
	Long-term			5

Crop and application rate : chicory, 1 x 1.62 kg a.s./ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Insectivorous bird (early)	Acute	87.6	> 22.8	10
	Short-term	48.9	> 16.2	10
	Long-term	48.9	0.18	5
Earthworm-eating bird	Long-term	*	*	5
Fish-eating bird	Long-term	0.112	77	5
Higher tier refinement (Birds)				
Insectivorous bird (early)	Acute	3.37	> 594 (residues)	10
	Short-term	0.84	> 941 (residues)	10
	Long-term	0.84	10.2 (residues)	5
Tier 1 (Mammals)				

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

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Benfluralin is applied pre-sowing or pre-planting, therefore no leafy crops or weeds are present in the field at the time of application. Once incorporated, benfluralin is among the least mobile herbicides, and this limits its bioavailability for plant uptake. Therefore, benfluralin is a non-systemic herbicide. Herbivorous birds and mammals are considered not to be at risk due to the absence of contaminated vegetation.				
Earthworm-eating mammal	Long-term	*	*	5
Fish-eating mammal	Long-term	0.069	80	5
Higher tier refinement (Mammals)				
Not required.				

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

[2] for cereals indicate if it is early or late crop stage

[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

*The refinement of the risk assessment (BCF) and focal species was not agreed in the expert meeting.

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 (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	*benfluralin*	96 h (semi-static)	Mortality, LC_{50}	**0.081 mg a.s./L** (mm)
Lepomis macrochirus	*benfluralin*	96 h (semi-static)	Mortality, LC_{50}	6.0 mg a.s./L (mm)
Cyprinodon variegatus	*benfluralin*	7 d (flow-through)	Mortality, LC_{50} (96 h) Mortality, LC_{50} (168 h)	> 1.1 mg a.s./L (mm) 1.7 mg a.s./L (mm)
Oncorhynchus mykiss	*benfluralin*	96 h (static)	Mortality, LC_{50}	5.3 mg a.s./L (mm)
Brachydanio rerio	*benfluralin*	96 h (static)	Mortality, LC_{50}	23.3 mg a.s./L (mm)
Oncorhynchus mykiss	*benfluralin*	49 d (flow-through)	Growth, NOEC	**0.0019 mg a.s./L** (mm)
Oncorhynchus mykiss	*Bonalan*	96 h (flow-through)	Mortality, EC_{50}	2.993 mg form/L (**0.58 mg a.s./L**) (nom)

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Aquatic invertebrate				
Daphnia magna	*benfluralin*	48 h (static)	Mortality, EC_{50}	**> 100 mg a.s./L** (nom)
Mysidopsis bahia	*benfluralin*	96 h (flow-through)	Mortality, EC_{50}	**0. 043 mg a.s./L** (mm)
Crassostrea virginica	*benfluralin*	96 h (flow-through)	Mortality, EC_{50}	0.100 mg a.s./L (mm)
Daphnia magna	*benfluralin*	21 d (flow-through)	Reproduction, NOEC	**0.0155 mg a.s./L** (mm)
Daphnia magna	*Bonalan*	48 h (static)	Mortality, EC_{50}	35.6 mg form/L (**6.91 mg a.s./L**) (nom)
Sediment dwelling organisms				
Chironomus riparius	benfluralin	27 d (static) sediment-water	NOEC	**0.231 mg a.s./L** (mm) **0.112 mg a.s./kg** (mm)
	Metabolite 2	28 d (static)	NOEC	
Algae				
Pseudokirchneriella subcapitata	*benfluralin*	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	**> 100 mg a.s./L** (nom) **> 100 mg a.s./L** (nom)
Anabaena flos-aquae	*benfluralin*	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	**> 100 mg a.s./L** (nom) **> 100 mg a.s./L** (nom)
Pseudokirchneriella subcapitata	*Bonalan*	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	**0.23 mg a.s./L** (mm) 0.73 mg a.s./L (mm)

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Higher plant				
Lemna gibba	*benfluralin*	7 d (semi-static)	Fronds, EC_{50}	E_bC_{50} = 0.018 mg a.s./L E_rC_{50} > 0.032 mg a.s./L **E_yC_{50} = 0.017 mg a.s./L** (mm)
	Preparation	14 d (static)	Fronds, EC_{50}	
	Metabolite 1	14 d (static)	Fronds, EC_{50}	
Microcosm or mesocosm tests Not required.				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

Bonalan (Benfluralin 180 EC Herbicide) : formulation containing 182 g/L benfluralin (batch n°: C0523-37)

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

FOCUS Step1

FOCUS Step 2

FOCUS Step 3

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 4

Only the worst and best case scenarios are represented. Calculations for all scenarios are presented in the DAR.

Crop and application rate : lettuce (1 Feb), 1 x 1.71 kg a.s./ha

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg a.s./L)	Buffer zone distance	Max. PEC_{sw}[4]	TER	Annex VI trigger[5]
R 3	stream	*Oncorhyn-chus mykiss*	96 h	0.081	20 m	1.010	80.2	100
R 1	pond				3.5 m	0.372	218	100
R 3	stream	*Oncorhyn-chus mykiss*	49 d	0.0019	20 m	1.010	1.88	10
R 1	pond				3.5 m	0.372	5.11	10
R 3	stream	*Oncorhyn-chus mykiss*	96 h	0.58	20 m	1.010	574	100
R 1	pond				3.5 m	0.372	1559	100

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

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg a.s./L)	Buffer zone distance	Max. PEC_{sw}[4]	TER	Annex VI trigger[5]
R 3	stream	*Mysidopsis bahia*	96 h	0.043	20 m	1.010	42.6	100
R 1	pond				3.5 m	0.372	116	100
R 3	stream	*Daphnia magna*	21 d	0.0155	20 m	1.010	15.3	10
R 1	pond				3.5 m	0.372	41.7	10
R 3	stream	*Daphnia magna*	48 h	6.91	20 m	1.010	6842	100
R 1	pond				3.5 m	0.372	18575	100
R 3	stream	*Pseudokirch-neriella subcapitata*	72 h	> 100	20 m	1.010	>99010	10
R 1	pond				3.5 m	0.372	>268817	10
R 3	stream	*Pseudokirch-neriella subcapitata*	72 h	0.23	20 m	1.010	228	10
R 1	pond				3.5 m	0.372	618	10
R 3	stream	*Lemna gibba*	7 d	0.017	20 m	1.010	16.8	10
R 1	pond				3.5 m	0.372	45.7	10

[1] drainage (D1-D6) and run-off (R1-R4)

[2] ditch/stream/pond

[3] include critical groups which fail at Step 3.

[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used

[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Bonalan (Benfluralin 180 EC Herbicide) : formulation containing 182 g/L benfluralin (batch n°: C0523-37)

Crop and application rate : lettuce (1 Feb), 1 x 1.71 kg a.s./ha

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
R 2	stream	*Chironomus riparius*	27 d static	0.112	20 m	12.012	9.32	10
D 3	ditch				20 m	0.291	385	10

[1] drainage (D1-D6) and run-off (R1-R4)

[2] ditch/stream/pond

[3] include critical groups which fail at Step 3.

[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used

[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

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

Crop and application rate: chicory (15 March), 1 x 1.62 kg a.s./ha

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
R 3	stream	*Oncorhyn-chus mykiss*	96 h	0.081	20 m	0.954	84.9	100
R 1	pond				3.5 m	0.352	230	100
R 3	stream	*Oncorhyn-chus mykiss*	49 d	0.0019	20 m	0.954	199	10
R 1	pond				3.5 m	0.352	5.40	10
R 3	stream	*Oncorhyn-chus mykiss*	96 h	0.58	20 m	0.954	608	100
R 1	pond				3.5 m	0.352	1648	100
R 3	stream	*Mysidopsis bahia*	96 h	0.043	20 m	0.954	45.1	100
R 1	pond				3.5 m	0.352	122	100
R 3	stream	*Daphnia magna*	21 d	0.0155	20 m	0.954	16.2	10
R 1	pond				3.5 m	0.352	44.0	10
R 3	stream	*Daphnia magna*	48 h	6.91	20 m	0.954	7243	100
R 1	pond				3.5 m	0.352	19631	100
R 3	stream	*Pseudokirch-neriella subcapitata*	72 h	> 100	20 m	0.954	>104822	10
R 1	pond				3.5 m	0.352	>284090	10
R 3	stream	*Pseudokirch-neriella subcapitata*	72 h	0.23	20 m	0.954	241	10
R 1	pond				3.5 m	0.352	653	10
R 3	stream	*Lemna gibba*	7 d	0.017	20 m	0.954	17.8	10
R 1	pond				3.5 m	0.352	48.3	10

[1] drainage (D1-D6) and run-off (R1-R4)

[2] ditch/stream/pond

[3] include critical groups which fail at Step 3.

[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used

[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Bonalan (Benfluralin 180 EC Herbicide) : formulation containing 182 g/L benfluralin (batch n°: C0523-37)

Crop and application rate: chicory (15 March), 1 x 1.62 kg a.s./ha

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
R 2	stream	*Chironomus*	27 d	0.112	20 m	4.168	26.9	10

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

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
D 6	ditch	*riparius*	static		20 m	0.294	3782	10

[1] drainage (D1-D6) and run-off (R1-R4)

[2] ditch/stream/pond

[3] include critical groups which fail at Step 3.

[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used

[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Bioconcentration				
	benfluralin	Meta-boliteC	Meta-bolite2	Meta-bolite3
$logP_{O/W}$	5.19	-	-	-
Bioconcentration factor (BCF) ‡	* 1563.6 – 1580.4 (whole fish) * 651.4 – 665.0 (fillet) * 2576.9 – 2604.1 (viscera)	-	-	-
Annex VI Trigger for the bioconcentration factor	100	-	-	-
Clearance time (days) (CT_{50})	1.28 (whole fish) 1.61 (fillet) 1.16 (viscera)	-	-	-
(CT_{90})	4.24 (whole fish) 5.34 (fillet) 3.85 (viscera)	-	-	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	< 3 % residues in whole fish, benfluralin was the primary residue, metabolite C was the next most abundant	-	-	-

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

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
benfluralin ‡	> 110.7 µg a.s./bee	> 100.0 µg a.s./bee
Bonalan[1]	> 31.25 µg a.s./bee	> 100.0 µg a.s./bee
Metabolite 1	No data available – Not required.	
Field or semi-field tests Not required.		

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Bonalan : EC formulation containing 182 g/Lbenfluralin (batch n° : C0523-37)

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

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

Crop and application rate: lettuce, 1 x 1.71 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
benfluralin	contact	< 17.1	50
benfluralin	oral	< 15.4	50
Bonalan	contact	< 17.1	50
Preparation	oral	< 54.7	50

Crop and application rate : chicory, 1 x 1.62 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
benfluralin	contact	< 16.2	50
benfluralin	oral	< 14.6	50
Bonalan	contact	< 16.2	50
Preparation	oral	< 51.8	50

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

Laboratory tests with standard sensitive species

No such tests were performed.

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

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
Typhlodromus pyri	proto-nymphs	Bonalan, glass plates, 14 d	83.6 g a.s./ha, initial	Corrected mortality Reproduction	3.4 % - 18.4 %	50 % 50 %
			1673 g a.s./ha, initial	Corrected mortality Reproduction	39.3 % - 61.2 %	50 % 50 %
Aphidius rhopalosiphi	adults	Bonalan, glass plates, 48 h	83.6 g a.s./ha, initial	Corrected mortality Reproduction	100.0 % -	50 % 50 %
			1673 g a.s./ha, initial	Corrected mortality Reproduction	100.0 % -	50 % 50 %
Poecilus cupreus	adults	Bonalan, sand, 14 d	83.6 g a.s./ha, initial	Corrected mortality Food consumption	% + 15.0 %	50 % 50 %
			1673 g a.s./ha, initial	Corrected mortality Food consumption	% + 17.6 %	50 % 50 %
Crysoperla carnea	larvae	Bonalan, glass plates, 17 d	83.6 g a.s./ha, initial	Corrected mortality Reproduction	2.5 % - 15.7 %	50 % 50 %
			1673 g a.s./ha, initial	Corrected mortality Reproduction	12.0 % + 2.5 %	50 % 50 %
Typhlodromus pyri	proto-nymphs	Bonalan, bean leaves, 14 d	165 g a.s./ha, initial	Corrected mortality Reproduction	- 5.3 % - 11.1 %	50 % 50 %
			824 g a.s./ha, initial	Corrected mortality Reproduction	- 5.3 % + 3.03 %	50 % 50 %
			1647 g a.s./ha, initial	Corrected mortality Reproduction	1.8 % - 20.2 %	50 % 50 %
			2654 g a.s./ha, initial	Corrected mortality Reproduction	15.8 % - 13.1 %	50 % 50 %

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

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
			3294 g a.s./ha, initial	Corrected mortality Reproduction	10.5 % - 47.5 %	50 % 50 %
Aphidius rhopalosiphi	adults	Bonalan, barley seedlings, 24 h + 10 d	366 g a.s./ha, initial	Corrected mortality Reproduction	3.3 % - 34.0 %	50 % 50 %
			518 g a.s./ha, initial	Corrected mortality Reproduction	76.7 % - 33.5 %	50 % 50 %
			732 g a.s./ha, initial	Corrected mortality Reproduction	86.7 % -	50 % 50 %
			1035 g a.s./ha, initial	Corrected mortality Reproduction	96.7 % -	50 % 50 %
			1464 g a.s./ha, initial	Corrected mortality Reproduction	96.7 % -	50 % 50 %
Aleochara bilineata	adults	Bonalan, 28 d + 35 d	1647 g a.s./ha, initial	Corrected mortality Reproduction	- 3.99 % - 5.4 %	50 % 50 %

[1] indicate whether initial or aged residues

[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

[3] indicate if positive percentages relate to adverse effects or not

Corrected mortality : positive values : adverse effects

Reproduction : negative values : adverse effects; positive values : no adverse effects

Food consumption : negative values : adverse effects; positive values : no adverse effects

Bonalan : EC formulation containing 185.84 g/L benfluralin (batch n° : C0484-40)

Bonalan : EC formulation containing 183 g/L benfluralin (batch n° : HM 877)

Field or semi-field tests
Not required. Laboratory and extended laboratory tests are available and no higher tier testing is required.

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

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia fetida	benfluralin ‡	Acute 14 days	LC_{50} > 1000 mg a.s./kg soil dw LC_{50corr} > 500 mg a.s./kg soil dw
Eisenia foetida foetida	Bonalan	Acute 14 days	LC_{50} = 1437 mg form/kg soil dw LC_{50corr} = 139.5 mg a.s./kg soil dw
Eisenia fetida andrei	Bonalan	Chronic 8 weeks	NOEC = 314.8 mg form/kg soil dw $NOEC_{corr}$ = 30.8 mg a.s./kg soil dw
Eisenia fetida	benfluralin diamine	Acute 14 days	LC_{50} = 360 mg/kg soil dw
Other soil macro-organisms			
Soil mite	Not required		
Collembola			
Folsomia candida	Bonalan	Chronic 28 d	NOEC = 11 mg form/kg soil dw $NOEC_{corr}$ = 5.5 mg a.s./kg soil dw
Soil micro-organisms			
Nitrogen mineralisation	Bonalan	28 d	+ 1.5 % effect at day 28 at 9 L form/ha, equivalent to 2.2 mg a.s./kg soil dw
			+ 0.50 % effect at day 28 at 45 L form/ha, equivalent to 11 mg a.s./kg soil dw
	Bonalan	28 d	+ 4.87 % effect at day 42 at 9 L form/ha, equivalent to 2.2 mg a.s./kg soil dw
			+ 4.90 % effect at day 42 at 45 L form/ha, equivalent to 11 mg a.s./kg soil dw
Carbon mineralisation	Bonalan	28 d	- 0.3 % effect at day 28 at 9 L form/ha, equivalent to 2.2 mg a.s./kg soil dw
			- 2.9 % effect at day 28 at 45 L form/ha, equivalent to 11 mg a.s./kg soil dw

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

Test organism	Test substance	Time scale	End point[1]
	Bonalan	28 d	- 0.76 % effect at day 42 at 9 L form/ha, equivalent to 2.2 mg a.s./kg soil dw
			+ 2.29 % effect at day 42 at 45 L form/ha, equivalent to 11 mg a.s./kg soil dw
Field studies[2] Not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})

[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Bonalan : EC formulation containing 182 g/L benfluralin (batch n° : C0523-37)
Bonalan : EC formulation containing 183 g/L benfluralin (batch n° : HM 877)

Toxicity/exposure ratios for soil organisms

Crop and application rate: lettuce, 1 x 1.71 kg a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia fetida	benfluralin ‡	Acute	1.140	439	10
Eisenia foetida foetida	Bonalan	Acute	1.140	122	10
Eisenia fetida andrei	Bonalan	Chronic	1.140	27.0	5
Other soil macro-organisms					
Soil mite	Not required.				
Collembola					
Folsomia candida	Bonalan	Chronic	1.140	4.82	5

[1] to be completed where first Tier triggers are breached

[2] indicate which PEC soil was used (e.g. plateau PEC)

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) [2] vegetative vigour	ER_{50} (g/ha) emergence	Exposure[1] (g/ha)[2]	TER	Trigger
sorghum	benfluralin	-	3.25	0.047	69	5

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

Ganzelmeier drift values : 90th percentile drift value for 1 application at 1 m : 2.77 %

Additional studies (e.g. semi-field or field studies)

Not required.

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	Endpoint
Activated sludge	EC_{50} (3 h) > 1000 mg a.s./L
Pseudomonas sp	-

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	benfluralin
water	benfluralin
sediment	benfluralin
groundwater	benfluralin

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	N, R50/53

	RMS/peer review proposal
Preparation	N, R51/53

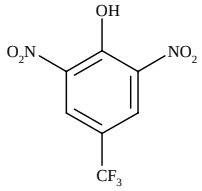
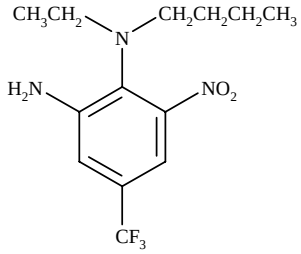
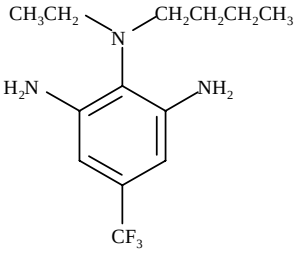
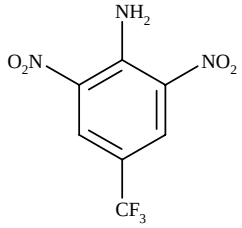
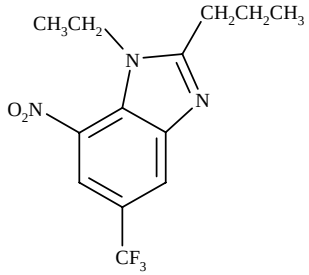
‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

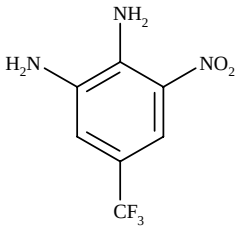
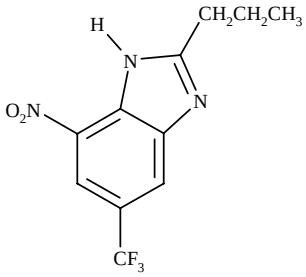
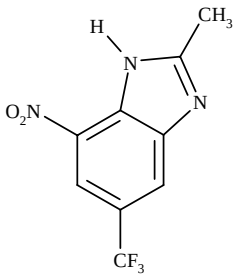
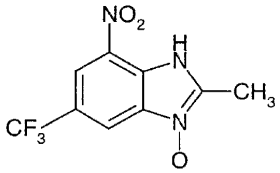
APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	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 pressure liquid chromatography or high performance 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; dosis letalis media
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
RPE	respiratory protective equipment
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

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
B12	2,6-dinitro-4-(trifluoromethyl)-phenol	
B36 Benfluralin diamine	N2-butyl-N2-ethyl-3-nitro-5-(trifluoromethyl)benzene-1,2-diamine N^2-butyl-N^2-ethyl-3-nitro-5-(trifluoromethyl)-1,2-benzenediamine	
B37	N^2-butyl-N^2-ethyl-5-(trifluoromethyl)-1,2,3-benzenetriamine	
B3	2,6-dinitro-4-(trifluoromethyl)-benzenediamine	
U6#1 379R Ethyl propyl benzimidazole	1-ethyl-7-nitro-2-propyl-5-(trifluoromethyl)-1H-benzimidazole	

358R, TR6, des-alkyl benfluralin diamine	3-nitro-5(trifluoromethyl)-1,2-benzenediamine 3-nitro-5-(trifluoromethyl)-1,2-benzenediamine	
371R, propyl benzimidazole	7-nitro-2-propyl-5-(trifluoromethyl)-1H-benzimidazole	
372R, methyl benzimidazole	2-methyl-7-nitro-5-(trifluoromethyl)benzimidazole	
methyl benzimidazole N-oxide	1H-benzimidazole,2-methyl-7-nitro-5-(trifluoromethyl)-3-oxide	
TR15	1H-benzimidazole,2-ethyl -4-nitro-6-(trifluromethyl)