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

Oxamyl

finalized: 14 January 2005

SUMMARY

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

On 25 August 2003, Ireland being the designated rapporteur Member State submitted in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, the DAR on oxamyl to the EFSA. The peer review was initiated on 13 October 2003 by dispatching the DAR for consultation of the Member States and the sole notifier DuPont. Subsequently, the comments received were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting in March 2004. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in June and July 2004.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 15 December 2004 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 nematicide and insecticides as proposed by the notifier which comprises broadcast application in potato to control the potato cyst nematode as well as suppressing early aphid infestations and Spraing at application rate of 4.0 kg/ha for early potatoes or up to 5.5 kg/ha for potatoes.

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

Analytical methods for the determination of residues of oxamyl are available for potatoes, soil, water, air and blood. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

Oxamyl is absorbed to a high degree, without evidence of accumulation. Oxamyl is extensively metabolised and the major metabolite was IN-A2213 and minor metabolites were IN-L2953 and IN-D2708. The acute oral and inhalatory toxicity is high (T+; R26/28) but dermal toxicity on the other hand is low. Oxamyl was neither an irritant nor a sensitizer in skin but it was a transient eye irritant. Effects observed during short term and long exposure were clinical signs as a consequence of decreased cholinesterase activity. Oxamyl was not genotoxic or carcinogenic and the reproductive performance was not affected by oxamyl. The soil metabolites IN-A2213 and IN-D2708 are not considered as relevant. The ADI, AOEL and ARfD are all set to 0.001 mg/kg bw/day based on the NOAEL of 0.1 mg/kg bw/day in the acute neurotoxicity study in the rat, with a safety factor of 100. However, it should be noted that a scientifically valid human study is available, where the NOAEL is 0.06 mg/kg bw/day, which could be used for derivation of the ARfD.
The dermal absorption is 0.04% for the granular formulation Oxamyl 10GR. Based on this value of dermal absorption, a treated area of 4.6 ha/day as well as a max. application rate of 5.5 kg a.s./ha, the estimated operator exposure was below AOEL according to calculations in the US PHED model when respiratory protective equipment (RPE) is applied during the loading and mixing and application procedures.

The metabolism of oxamyl in potatoes after granular application to soil does not yield metabolites of toxicological concern based on the assessment of available data (refer to point 2.8). It was also demonstrated that no parent oxamyl is present in potatoes treated in this manner. Consistently, no residues of oxamyl were quantified in any of the potatoes tuber samples from field trials conducted according critical GAP. Using a residue level equal to the LOQ of 0.02 mg/kg for food of plant origin in the chronic dietary risk assessment represents a worst-case scenario and leads to estimated intakes for consumers not exceeding 73% of the proposed ADI.
An acute risk for consumers from the consumption of potatoes grown according the examined representative GAP can not be stated as oxamyl residues are not present. However, EFSA notes that if oxamyl residues were present in potatoes at a level of 0.02* mg/kg then the ARfD for oxamyl of 0.001 mg/kg bw/day may be exceeded for certain consumer subgroups.
In aerobic conditions degradation of oxamyl in soil yields IN-A2213 (oxamyl oxyme) that is further degraded to IN-D2708 (DMOA) and then to CO_2 and unextractable soil components.
Metabolite IN-N0079 (*N*,*N*-dimethyl-1-cyanoformamide) appears at relatively high levels in the soil photolysis study. This is not a photolysis metabolite and its formation is catalyzed by ferrous ion. Degradation of oxamyl in soil is strongly pH dependent, with the longer half life for the single acidic soil studied. New data to assess effect of pH in the degradation was required to the notifier. Additional data presented by the notifier on the degradation of oxamyl in acidic soils has not been fully evaluated due to late submission. Furthermore, modelling for this substance and their

metabolites are necessary to fully characterize the impact of the degradation rate of oxamyl at different soil pHs. New data has been submitted in relation with this point on November 2004.
Oxamyl, IN-A2213, IN-D2708 and IN-N0079 are weakly adsorbed in soil. No pH dependence is observed for any of the compounds studied.
In sterile aqueous buffer solutions, hydrolysis of oxamyl is strongly pH dependent. At acidic pH the compound is stable.
Metabolites IN-A2213, IN-D2708 and water sediment metabolite IN-T2921 are stable at pH 4, 7 and 9. Aqueous photolysis may contribute to the degradation of oxamyl in the environment but it is not expected to contribute to the environmental degradation of the metabolites. Oxamyl is not readily biodegradable.
In water sediment systems, major metabolites in water were IN-A2213, IN-D2708, IN-N0079 and IN-T2921. The cumulative amounts of CO_2 evolved up to a maximum of 60.9 % AR. Only metabolite IN-D2708 was found in significant amounts in the sediment. Oxamyl degrades faster in the water phase with a half life between 0.4 and 1 day. Half life of metabolites in the total system is generally below 20 days except for IN-D2708 in one system. Potential risk for contamination of surface water and sediment by oxamyl and its metabolites IN-A2213 and IN-D2708 was assessed by FOCUS surface water modelling. Also Initial PECsw for water / sediment metabolites IN-N0079 and IN-T2921 has been calculated.
With respect to ground water contamination, it is concluded that there may be a high risk of contamination by oxamyl and its metabolites in certain circumstances, particularly if application is made on acidic soils that have not been fully assessed.

The risk to bees, non-target arthropods, soil micro-organisms, terrestrial plants and biological methods for sewage treatment is low with respect to oxamyl and the metabolites as far as investigated.

The risk to aquatic organisms can be considered low for all the drainage scenarios and the run-off pond scenario. For the 3 run-off stream scenarios from the FOCUSsw step 3 scenarios evaluated, the trigger was still breached indicating a high risk to aquatic organisms under these circumstances. Risk mitigation measures need to be taken into account at MS level to address this risk. The aquatic risk assessment has been conducted on the assumption that direct contamination (i.e. ‘drift’ of small granules) of surface water is not possible. A restriction highlighting the need to avoid the use of application machinery (i.e. pressurised systems) that may result in direct contamination of adjacent surface waters is proposed.

A high risk to birds and mammals from the use of oxamyl and the need to address this risk further was identified. A full risk assessment can only be concluded when the outstanding data is evaluated. Also the long term risk to earthworms is considered high as the TER (breaches the Annex VI trigger value of 5. The need to address this risk further was identified.

Key words: oxamyl, peer review, risk assessment, pesticide, nematicide, insecticide

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BACKGROUND

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

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Ireland submitted the report of its initial evaluation of the dossier on oxamyl, hereafter referred to as the draft assessment report, to the EFSA on 25 August 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 13 October 2003 to the Member States and the main notifier DuPont as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives of the Member States identified and agreed in an evaluation meeting on 12 March 2004 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier was attending this meeting.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the Bundesamt für Verbraucherschutz und Lebensmittel-sicherheit in Braunschweig, Germany. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 14 December 2004 leading to the conclusions as laid down in this report.

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

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

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

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

- the comments received
- the resulting reporting table (rev 1-2 of 26 March 2004)
- the consultation report

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

- the reports of the scientific expert consultation
- the evaluation table (rev 2-1 of 15 December 2004)

Given the importance of the draft assessment report including its addendum (compiled version of November 2004) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Oxamyl is the ISO common name for (*EZ*)-*N*,*N*-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio)acetamide (IUPAC).

Oxamyl, belonging to the class of oxime carbamate nematicide and insecticides, is applied to control nematode and aphid infestations levels early in the crop life cycle. Oxamyl is systemic and is taken up from the soil via the roots and is translocated to the leaves.

The representative formulated product for the evaluation was "Vydate 10G", a granular formulation (GR).

The representative uses evaluated comprise broadcast application in potato to control the potato cyst nematode as well as suppressing early aphid infestations and Spraing at application rate of 4.0 kg/ha for early potatoes or up to 5.5 kg/ha for potatoes.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of oxamyl as manufactured should not be less than 970 g/kg. At the time of evaluation no FAO/WHO specification was available. The content of oxamyl in the representative

formulation is 100 g/kg (pure). The assessment of the data package revealed no particular area of concern in respect of the identity, physical, chemical and technical properties of oxamyl and the representative formulation, but three data gaps were identified (boiling point/temperature of decomposition, auto-flammability, identity of impurities). The main data regarding identity and the physical/chemical properties of oxamyl are given in appendix 1.

Adequate analytical methods are available for the determination of oxamyl in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. Oxamyl as manufactured contains no relevant impurities (of toxicological and/or ecotoxicological concern).

Analytical methods for the determination of residues of oxamyl are available for potatoes, soil, water, air and blood.
An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed (see 3.2).

2. Mammalian toxicology

2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Oxamyl is absorbed to a high degree, 80% within 24 hours. The excretion is also rapid, 80.5% within 24 hours and 93% within 7 days. It is widely distributed and the highest concentration was found in blood, heart, liver, kidney, lungs, spleen and the gastro-intestinal tract (0.04-0.1 µg equvivalents/g). There was no evidence of accumulation. Oxamyl is extensively metabolised and the major route was hydrolysis to IN-A2213 followed by conjugation. Minor metabolites were considered to be conjugates of demethylated compounds (e.g. IN-L2953 and IN-D2708). The two metabolites were considered (at the expert meeting in July 2004) to be adequately tested in studies involving the parent compound (in respect of environmental concern). However, EFSA notes that the complete data package specified in guidance document for metabolites exceeding the 0.1 µg/L trigger in groundwater is not available for these metabolites.

2.2. ACUTE TOXICITY

The oral toxicity is high, with an oral LD50 of 3.1 mg/kg bw and 2.5 mg/kg bw in male and female rats, respectively. The toxicity during inhalation in rats was also high, LC50 0.056 mg/L air. The dermal toxicity on the other hand was found to be low. Oxamyl was not shown to be an irritant or a sensitizer in skin. Regarding eye irritation, the Rapporteur Member State initially proposed in the DAR that oxamyl was not an eye irritant in the rabbit. However, following a comment in the reporting table that it was a transient irritant although not classified and therefore this was changed to a transient irritant.
The following risk phrases T+; R26/28 "Very toxic by inhalation and if swallowed" are proposed on basis of the outcome in the acute studies.

2.3. SHORT TERM TOXICITY

The effects of oxamyl were studied in two 90-day studies (rat and dog), two 1-year dog studies and two 21-day dermal studies in the rabbit. The results from the 90-day study in the rat was only regarded as supplemental since it was not performed in accordance to GLP and the deviations from the guideline were substantial.

Effects observed were clinical signs as a consequence of decreased cholinesterase activity in the one year dog studies. The cholinesterase activity was not measured in the 90-day studies. Initially in the DAR, the Rapporteur Member State initially proposed the NOAEL to be 50 ppm (i.e. 1.36 mg/kg bw/day based on the second 1-year dog study in which only males were dosed. This was one of the issues that were discussed at the EPCO expert meeting (July 2004). In the first 1-year dog study clinical signs were observed in the females at 50 ppm (i.e. 1.46 mg/kg bw/day) and in the second study the only statistically significant finding was a decrease in erythrocyte cholinesterase activity at 1.36 mg/kg bw/day. The meeting agreed to lower the NOAEL value to 35 ppm (i.e. 0.93 mg/kg bw/day) due to the lack of females in the in the second study. The clear effect (clinical signs and tremors) in the females in the 1-year study should not be overruled by the second study.

Thus, the relevant oral NOAEL was an overall NOAEL for the one year dog studies of 0.93 mg/kg bw/day (i.e. 35 ppm), based on clinical signs and tremors and cholinesterase inhibition at 1.46 mg/kg bw/day, observed. The dermal NOAEL was also based on effects on cholinesterase activity, a decreased activity was determined in rabbits, erythrocytes however no clinical signs were manifested, and the relevant dermal NOAEL is 50 mg/kg bw/day.

2.4. GENOTOXICITY

Four *in vitro* studies and one *in vivo* study were performed. Oxamyl did not display mutagenic or genotoxic properties.

2.5. LONG TERM TOXICITY

Long term toxicity studies were performed in the rat and mouse. In addition, weanling rats as well as dogs were exposed for oxamyl during two years. Clinical signs such as hyperactivity, swollen legs or paws, sore skin and alopecia were observed in rats at 100-150 ppm whereas no pathological findings were recorded. No effects on brain or erythrocyte cholinesterase activity. However, the plasma cholinesterase activity in the rat was decreased and the relevant NOAEL for long term exposure was based on this effect 1.97 mg/kg bw/day.

Oxamyl was not demonstrated to be oncogenic or have a carcinogenic potential in rat, mouse or dog.

2.6. REPRODUCTIVE TOXICITY

Three studies were performed on rat in order to determine the reproductive effects of oxamyl (one-, two- and three-generation studies, all dietary). The reproductive performance was not affected by oxamyl. The relevant NOAEL for parental toxicity and pup development is 25 ppm (1.43 mg/kg bw/day. In the DAR (list of endpoints) it was stated that the target and critical effect was “adverse foetal body weights effects (F1 and F2 male and female) during lactation at parentally toxic doses

(rat)". However, this was made more explicit due to comments from a MS in the reporting table and in the final version of list of endpoints it is stated as follows "reduced pup survival and reduced litter size at the parentally toxic dose 150 ppm (rat)". A reduction in the mean number of pups born per litter and pups born alive per litter was noted in both generations ≥ 75 ppm. This may reflect an adverse effect *in utero* development of a fertility related effect. The main parental toxicity effects consisted of hyperactivity, reduced body weight (around 15%), body weight gain (premating, 33% and post mating 29%), and food consumption was also reduced (12-14%) whereas no gross pathological lesions or microscopic findings were observed.
Thus, the relevant NOAEL is 1.43 mg/kg bw/day (i.e. 25 ppm) in rats.

In order to examine teratogenic or developmental effects of oxamyl two studies in rat (gavage and dietary) and one study in rabbit (gavage) were performed.
In the DAR, the Rapporteur Member state concluded that the relevant developmental and maternal NOEL was 0.2 mg/kg bw/day. These effects were discussed at the Expert meeting in July 2004. The meeting concluded the effects at 0.5 mg/kg bw/day is a treatment related but indeed not an adverse effect since it was based on a decrease of 4% in the foetal body weight which is also within historical control as well as the bw decrease in the dams that also was considered minor, 9% since it was not statistically significant. Thus, the meeting agreed set to both the maternal and developmental NOAEL instead to 0.5 mg/kg bw/day.
The relevant developmental and maternal NOAEL is 0.5 mg/kg bw/day in the rat based on decreased foetal body weight and reduced body weight, respectively.

2.7. NEUROTOXICITY

Since oxamyl is a carbamate a general feature of this family of compound is a reduced cholinesterase activity. However, details of sampling and analysis were limited in most studies.

A delayed neurotoxicity study was performed in chickens and no overt findings were recorded.

The notifier has submitted a study performed on human volunteers (male) and the Rapporteur Member State presented the study in this section in the DAR and list of endpoints. Following discussion at the Expert meeting (July 2004) regarding the scientific validity of the study, the meeting agreed that the study was scientifically valid and that the outcome of the study should be presented under section "Other studies", B.6.8, the List of endpoint has been amended accordingly. The human study is therefore discussed in section 2.8 "Further studies" in the conclusion report.

In the DAR additional neurotoxicological studies were evaluated and presented in section B.6.8 "Further studies". The results of these study reports were not included in the original list of endpoints. These animal neurotoxicity studies were also open for discussion at the Expert meeting in July 2004 and the meeting agreed to present the conclusion from these studies under this section (i.e. B.6.7 Neurotoxicity studies) and the list of endpoints has been amended accordingly.

An acute neurotoxicity study was performed in rats (gavage) with dose levels up to 2 mg/kg bw/day and 1.5 mg/kg bw/day in males and females, respectively. Clinical signs indicative of cholinesterase inhibition such as low posture, salivation and tremor were recorded in the two highest dose levels. The absolute body weight was unaffected whereas the body weight gain and food consumption was reduced. This study was discussed at the Expert meeting (July 2004) and it was debated whether there were adverse effects at 0.1 mg/kg bw/day. However, the meeting agreed that these effects were within control range and that no clinical sign were observed at this dose level and that the cholinesterase inhibition was not statistically different from the control.
Thus, the meeting agreed that the relevant NOAEL for acute neurotoxicity was 0.1 mg/kg bw/day in both males and females.

A 90-day subchronic toxicity study in rats was performed. Clinical signs indicative of cholinesterase inhibition were seen in both sexes at ≥ 100 ppm. A number of treatment related effects were also observed for various FOB Parameters in the highest dose 250 ppm as well as food consumption and significant reductions in plasma, erythrocyte and brain cholinesterase activity.
The relevant NOAEL for subchronic neurotoxicity is 30 ppm (i.e. 1.69 bw/day for males and 2.03 for females).

2.8. FURTHER STUDIES

In this section toxicity studies on metabolites are presented. The soil metabolites IN-A2213 and IN-D2708 were predicted to be > 0.1 µg/l in groundwater according to FOCUS model calculations. Acute toxicity studies were provided and the acute lethal dose (ALD) for IN-A2213 was 11 mg/kg bw and the LD_{50} for IN- D2708 was 3540 mg/kg bw in rats. No tests on genotoxicity, carcinogenicity or reproduction toxicity were performed. However, since they are also metabolites in rats and mice they are assumed to have been adequately tested in the toxicity studies on the parent compound which has no genotoxic, reproduction toxicity or carcinogenic potential. This reliability of this conclusion in relation to the guidance document on relevant metabolites[3] was discussed at the Expert meeting (July 2004). The meeting agreed that the toxicity of the metabolites were adequately addressed; no further data was requested. Regarding the lack of three standard mutagenicity tests on the metabolites, the meeting agreed that there is not a need for performing these studies, only if they have not been formed in the rat and mice. In order to clarify and for transparency the rapporteur Member State presented a short statement why the metabolites have been addressed in the addendum to the DAR.
The conclusion from the Expert meeting was that the metabolites, IN-A2213 and IN-D2708, were not considered as relevant on basis of the available data. However, EFSA notes that the complete data package specified in guidance document for metabolites exceeding the 0.1 µg/L trigger in groundwater is not available for these metabolites.

[3] Guidance document on the assessment of relevance of metabolites in groundwater of substances under council directive 91/414EEC. SANCO/221/2000-rev.10

An acute human study, ethically approved, on male volunteers was submitted and presented in the DAR (under section B.6.7, Neurotoxicity studies). The scientific validity and whether this study could be used for the allocation of the ARfD, which was the case in the first version of the DAR and List of Endpoint, was discussed at the Expert meeting in July 2004. The meeting agreed on the study could be used from a scientific point of view. The NOAEL of 0.06 mg/kg bw/day was confirmed based on reduced plasma and erythrocyte cholinesterase activity at 0.09 mg/kg bw/day and that the results should be presented under section other studies. However, the safety factor for the human studies was not discussed on the meeting.

2.9. MEDICAL DATA

No incidents or accidents during the manufacturing process have been recorded. There are no data relating to exposure of the general public to oxamyl or epidemiological studies.

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

ADI

The Rapporteur Member State proposed initially in the DAR to base the ADI on NOAEL from the human volunteer study. Following a comment in the reporting table, the rapporteur Member State agreed and proposed to base the ADI on NOAEL 0.5 mg/kg bw/day from the developmental study in rats. However, at the EPCO expert meeting (July 2004) it was agreed to set ADI, AOEL as well as the ARfD on the NOAEL of 0.1 mg/kg bw/day from the acute neurotoxicity study in the rat (see 2.7 above) with a safety factor of 100.

The resulting ADI is 0.001 mg/kg bw/day.

AOEL

The Rapporteur Member State proposed in the DAR to base the AOEL on NOAEL from the human volunteer study. Following a comment in the reporting table, the Rapporteur Member State agreed and proposed to base the AOEL on NOAEL 0.5 mg/kg bw/day from the developmental study in rats. However, at the EPCO expert meeting (July 2004) it was agreed to set ADI, AOEL as well as the ARfD on the NOAEL of 0.1 mg/kg bw/day from the acute neurotoxicity study in the rat (see 2.7 above) with a safety factor of 100, correction factor for oral absorption not justified.

The resulting AOEL is 0.001 mg/kg bw/day.

ARfD

The Rapporteur Member State proposed in the DAR to base the ARfD on NOAEL from the human volunteer study. However, at the EPCO expert meeting (July 2004) it was agreed to set ADI, AOEL as well as the ARfD on the NOAEL of 0.1 mg/kg bw/day from the acute neurotoxicity study in the rat (see 2.7 above) with a safety factor of 100.

It should be noted that a scientifically valid human study is available, where the NOAEL is 0.06 mg/kg bw/day, which could be used for derivation of the ARfD. However, the safety factor for the human study was not discussed on the meeting, see point 2.8.

The ARfD based on animal data is 0.001 mg/kg bw/day.

2.11. DERMAL ABSORPTION

Two *in vivo* (rat) and two *in vitro* (rat, human and rabbit) dermal absorption studies were evaluated in the DAR for extrapolation of the dermal absorption of the formulation Oxamyl 10GR (Vydate®). There were two conclusions presented. Dermal absorption was 0.6 - 4.8% (8 hours) based on the results from the *in vivo* studies. Dermal absorption for human skin derived from estimations from the *in vitro* studies was 0.02% (6 hours).

The dermal absorption value was discussed at the Expert meeting (July 2004). The rapporteur Member State clarified that the figure for human dermal absorption for 10GR formulation was wrong and should be 0.04% instead. Furthermore, there have bee two scenarios for operator exposure and the data from the 10SL liquid formulation was used instead of granular formulation. The liquid formulation is the worst case and does not apply to the supported use. As the notifier only supports the granular formulation, the meeting agreed to use this data. **For the granular formulation Oxamyl 10GR** (Vydate®) **after extrapolation using *in vitro* data (with 6 hours exposure), the dermal absorption is 0.04%.**

The only supported use is the granular formulation. **The liquid formulation is not supported by data, except for dermal absorption studies, in the DAR.** It was agreed at the expert meeting that the dermal absorption for the liquid formulation (Oxamyl 10SL) after extrapolation using *in vitro* data (penetration rate approx. 1:3), should be 0.2%.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

Operator exposure

According to the Rapporteur Member State, the UK POEM or the German model do not facilitate the estimation of operator exposure during the application of granular formulations onto the soil. Therefore a field study was conducted to determine actual inhalation and dermal exposure to oxamyl during loading and application of Oxamyl 10GR (Vydate 10®). According to estimations based on this field study it was stated in the DAR that the exposure was below the AOEL.

The operator exposure was discussed at the Expert meeting (July 2004). One of the comments was whether the field study was appropriate to use since the calculated application rate was 1 kg a.s./ha and the indented uses involve application rates of 4-5.5 kg a.s./ha. In the meeting it was agreed that the study could be possible to use if a correction factor to extrapolate 1 kg a.s./ha to 4-5.5kg a.s./ha was added in order to mimic the higher applications rate. EFSA notes that this assumption is only true if it is a straight linear relationship, which has not been tested or demonstrated.

Furthermore, in the field study, **the treated area was only 4.6 ha/day**, which was considered rather low as compared to for instance work rate in UK of eg 24 ha/day. If the geometric mean is considered, the exposure for an application rate of 1 kg a.s./ha amounted to 8% of the AOEL, with the new dermal absorption value of 0.04%.. By using the correction factor of 5.3 for the higher

application rate, the estimated operator exposure is below the AOEL (37%) (see addendum to the DAR, presented after the discussion in the Expert Meeting).
Although, ten professionally and fully licensed applicators participated in the study, accidental spilling was noted. Using the highest exposure observed as a worst case scenario, EFSA calculated an exposure of 22% of the AOEL for the application rate of 1 kg a.s./ha and of 118% of the AOEL using the correction factor of 5.3 for the higher application rate. The calculations were taking into account PPE. The field study showed the inhalatory exposure to have the largest impact on the estimated exposure.

Another comment was related to the model used, the US PHED (American Pesticides Handlers Exposure Database), that more clarifications regarding applicability of this model were needed since it is not commonly used in the risk calculations within EU. Furthermore, the Rapporteur Member State should also consider applying safety clothes during mixing and loading. These issues have been dealt with in the addendum to the DAR (October 2004).

For comparative purposes an assessment of the operator exposure was performed using the US PHED model. The calculation was based in this case also on a treated area of 4.6 ha/day, a maximum application rate of 5.5 kg a.s./ha, the new value for dermal absorption of 0.04% and an inhalation of 100% (see addendum to the DAR). The total systemic exposure (75th percentile) was estimated to **920% of the AOEL without any PPE**. **When respiratory protective equipment (RPE) are applied in the model during the loading and mixing and application procedures, the intended usage rates of Oxamyl 10G (Vydate ®) are 92% of AOEL based on US PHED model**.

Worker exposure
Worker exposure was considered to be negligible.

Bystander exposure
Bystander exposure is not applicable.

3. Residues

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1 Primary crops

A number of plant metabolism studies were presented for oxamyl dealing with either foliar or granular applications on tobacco, peanuts, apples, oranges, tomatoes, beans, cotton and potatoes. Most of them date from the early 1970's and show various deficiencies, therefore they can only be considered as supporting. In one modern study the metabolism of oxamyl was investigated in potatoes by applying radiolabelled oxamyl as a granular to the soil. This study shows that the main and only identified component of the residue found in potato tubers and peels is the metabolite IN-D2708 (N,N'-Dimethyloxamic acid), corresponding to circa 70% of the TRR. Residues of oxamyl

and oxamyl oxime are not present in potato tubers even when the application is made at 1.5N the recommended GAP. The metabolite IN-D2708 was considered as non-toxicological relevant based on the assessment of available data (refer to point 2.8).
On the basis of the presented metabolism study the expert meeting on residues concluded that the residue of concern is defined as parent oxamyl for risk assessment and monitoring purposes. Due to the fact, that the investigation of the metabolic behaviour of oxamyl is limited to granular application on potatoes only, a final residue definition for plants in general can not be proposed. If future intended uses include foliar applications then further confirmatory metabolism studies with foliar application will be required in suitable representative crops.

The magnitude of oxamyl residues in potatoes tubers was determined in a total of 17 field residue trials conducted over two growing seasons in Northern and Southern European regions. Field-testing parameters, such as application rate, application time and sampling time were consistent with critical GAP (within the scope of $\pm$ 25% deviation). All residues were analyzed using validated methods. Oxamyl was the only residue determined with a limit of quantification (LOQ) of 0.02 mg/kg in 8 trials and of 0.01 mg/kg in 9 trials. At harvest (> 80 days after the granular application at planting) no residues were found in any of the potatoes tuber samples.

Because no quantifiable oxamyl residues (<0.02 mg/kg) were found in potatoes tubers at the time of harvest an investigation of effects of industrial or household processing was not necessary. Nevertheless a study simulating normal processing practice by using representative hydrolytic conditions was conducted and indicated that with increasing temperature oxamyl becomes increasing labile and degrades rapidly to oxamyl oxime.

3.1.2. Succeeding and rotational crops

Two crop rotation studies with radiolabelled material were undertaken to address the potential incorporation of soil residues into succeeding and rotational crops. These studies showed a comparable metabolism as in directly treated plants, but they also indicated that if crops are planted within 120 days of oxamyl application then residues of oxamyl and oxamyl oxime may be detected in the roots and aerial parts of these crops. Even if both of these studies had applications greater than the recommended GAP, at present the possibility of residues being detected in the rotational crops has to be minimized by setting a restriction to crop rotation. To revoke this restriction the expert meeting on residues proposed a data requirement on submission of data on rotational crop residue trials ('cold studies').

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

No quantifiable oxamyl residues were found in potatoes tubers at the time of harvest and oxamyl and/or its metabolites are not deemed to accumulate in animal tissue. Therefore metabolism studies in livestock are not necessary as long as residues in rotational crops used in animal diet are not detected and lead to a significant intake (>0.1 mg/kg diet) for animals.

Nevertheless studies on the metabolism of oxamyl in lactating goats and laying hens were submitted and evaluated in the DAR. These metabolism studies confirm that oxamyl is highly metabolized when fed to these animals and indicate that the only identifiable residue possible in the goat and hen is the non-specific analyte thiocyanate. No residues of oxamyl or oxamyl oxime will be detected in these animals.

Since this study is at present not necessary for the assessment of the representative uses, no residue definition or MRLs for food of animal origin are proposed. An animal feeding study was not required on the basis of the diets of food producing animals.

3.3. CONSUMER RISK ASSESSMENT

The chronic dietary risk assessment for consumers is based on the Theoretical Maximum Daily Intake (TMDI) calculation using the total diet of food of plant origin based on the WHO European diet model and the German diet model (4 -6 year old girl). In the calculations the LOQ of 0.02 mg/kg is used for all food of plant origin representing a worst-case scenario. Employing these models the contribution to the ADI of 0.001 mg/kg bw is 57% and 73 %, respectively.

There is no exposure to oxamyl residues from the consumption of potatoes grown according the representative GAP. Metabolism studies indicate that following granular application of oxamyl to the soil there will be no detectable residues (<0.01 mg/kg) of either oxamyl or its oxime present in the potato tubers. Therefore an acute risk for consumers from the consumption of potatoes grown according the representative GAP can not be stated.

3.4. PROPOSED MRLS

It was proposed by the RMS to set the maximum residue level (MRL) in potatoes to the limit of quantification (LOQ) of the analytical method of 0.02 mg/kg, resulting in an MRL of 0.02* mg/kg for potatoes. EFSA notes that if oxamyl residues were present in potatoes at a level of 0.02* mg/kg then the ARfD for oxamyl of 0.001 mg/kg bw/day (based on the animal studies) would be exceeded for certain consumer subgroups (up to 210% ARfD for toddlers, UK model), even though this is not expected to occur in practice when potatoes are treated according the representative GAP (refer to point 3.3). In fact an MRL at the LOQ of 0.02*mg/kg for potatoes has no influence on the actual level of residues arising from this particular GAP and may also allow a cost effective monitoring, as argued by the RMS. However, EFSA likes to highlight that in general for this kind of substances a lower LOQ may be appreciable for the sake of precautionary consumer protection.

In this regard the following is noted: Originally the published Dutch multi-residue method 2 (MRM 2, sub method 1) was insufficiently validated to be suitable for the determination of residues at 0.01 mg/kg. Taken into account the published amendment (improved clean up) by DeKok et al., it was demonstrated for different crops that the Dutch MRM 2 method can be used for the determination of residue of oxamyl at this level. The validation report includes also a confirmatory method based on LC-MS determination.

There is a range of CODEX MRL's in place and oxamyl was fully reviewed at the 2002 JMPR meeting. There is however a fundamental difference between the JMPR evaluations and that carried

out in the DAR which relates to the method of application (foliar vs. soil treatment). It is therefore not possible to make any comparisons between the CODEX MRLs and that proposed on European level.

4. Environmental fate and behaviour

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. Route of degradation in soil

Information of oxamyl metabolism in soil under dark aerobic conditions is provided by three separate studies where five different soils are used. The soils covered a range of pH values (4.8-7.8), clay contents (10.8 %-30.8 %) and organic matter contents (0.4 -4.4 %).

In aerobic conditions degradation of oxamyl in soil is initiated by the hydrolysis at the carbamate group to give **IN-A2213** (oxamyl oxime / methyl 2-(dimethylamino)-*N*-[[(methylamino)carbonyl]oxy]-2-oxoethanimidothioate, maximum 51 % AR after 7 days). This metabolite is further degraded to **IN-D2708** (DMOA / (dimethylamino) oxoacetic acid, maximum 34.7 % AR after 10 days) and then to CO_2 and unextractable soil components. At temperatures of 20-25 ^{o}C, mineralization was high in the studies performed at pH $\geq$ 7 (45 % AR by day 51 to > 70 % AR by day 60). Less mineralization (25 % AR by day 123) was observed in an acidic soil (pH = 4.8), mainly due to the overall slower degradation rate. By the end of the studies (51 to 123 days) amount of unextractable residues was always less than 25 %. In one of the studies unextractable residues were investigated and it was found that they were distributed among the fulvic acid fraction (33.4 % AR), the humic acid fraction (31.2 % AR) and the humin fraction (11.4 % AR).

One of the studies investigates the soil degradation under anaerobic conditions, where the same major metabolites were found indicating that oxamyl follows the same degradation pattern under aerobic and anerobic soil conditions.

Non identified components found in these studies account as a whole for less than 4 % of the applied radioactivity.

A new metabolite **IN-N0079** (DMCF, *N*,*N*-dimethyl-1-cyanoformamide) appears at relatively high levels in one of the soils employed in the soil photolysis study (maximum observed at day 7: 25 % AR in the irradiated sample and 18 % AR in the dark control). The fact that this metabolite appears also in the dark control indicates that it is not produced by photolysis but by reduction of IN-A2213. According to published literature, the formation of this metabolite is catalyzed by ferrous ion (Fe^{II}). Notifier was required to comment on the effect of ferrous ion and the degradation in the saturated zone by the Evaluation Meeting (March 2004) (Data requirement 4.2). However, no further information was considered necessary by the experts meeting (EPCO 7, June 2004) since it was deemed that risk assessment could be completed with the available information already summarized in the DAR.

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

Degradation rate of oxamyl is investigated in the same degradation studies used to establish the soil metabolism. Kinetic analysis is performed with Model Manager® v.1.1 software assuming first order kinetic for all degradation steps. Concentration *vs* time data are fitted to a model that considers direct transformation of oxamyl to IN-A2213 and of IN-A2213 to IN-D2708. Under this scheme, only degradation of metabolite IN-D2708 is assumed to contribute to the formation of CO_2 and unextractable residue. Degradation rate constants are obtained for each of the compounds in each of the soils studied. These first order rate constants are employed to calculate the corresponding DT_{50} and DT_{90}.

The studies available (temperature = 20 – 25 ^{o}C) indicate that in the range of pH between 7.0 and 7.8 oxamyl is low to moderately persistent with half life between 3 to 11.5 days, whereas in the highly acidic soil (pH = 4.8), which may have had a stressed microbial population, oxamyl is highly persistent (DT_{50} = 112 d).

Metabolite IN-A2213 degrades with a half-life between 1.7 and 17.5 days and metabolite IN-D2708 between 3.4 and 7.6 days.
In addition to the parent studies, two laboratory aerobic degradation studies in three soils with metabolites IN-D2708 (DT_{50} = 3.9 – 6.1 d at 20 ^{o}C) and IN-N0079 (DT_{50} = 4 to 41 min at 23 ^{o}C) are available.

Degradation of oxamyl in soil seems to be strongly pH dependent, with the longer half life being determined for the single acidic soil studied. Due to this fact, new data to assess the effect of pH on the degradation rate of oxamyl was required from the notifier by the Evaluation Meeting (March 2004) (Data requirement 4.1). In the experts meeting (EPCO 7, June 2004), RMS informed that a position paper summarising further soil degradation data had been submitted by the notifier just before the meeting. RMS informed the meeting that preliminary evaluation of these data confirmed that acidic soils would be a worst case for the degradation of the parent oxamyl, but a complete evaluation would be necessary to determine the effect of pH –dependent degradation for oxamyl on the level of metabolite formation. The meeting agreed that the new data was relevant to complete the assessment for Annex I and that further modelling for the active substance and its metabolites would be necessary to fully characterize the impact of the degradation rate of oxamyl at different soil pHs (New data requirement proposed at EPCO 7, data requirement 4.3). During Evaluation meeting 14-15 December 2004, Rapporteur informed the rest of Member States that new data has been received at 1st of November of 2004.
Under anaerobic conditions (pH = 7.7) degradation of oxamyl is slightly faster than in aerobic studies and degradation of metabolites IN-A2213 and IN-D2708 is slightly slower.

One experiment performed at 10 °C shows a degradation rate for oxamyl (DT_{50} = 16 d) considerably slower than the degradation rate at 20 °C (DT_{50} = 3 d) in the same soil. This would result in a Q_{10} = 5.5 and raised some concerns during the Evaluation Meeting (March 2004). RMS was required to present, in an addendum to the DAR, the literature data that supports still using the default value Q_{10} = 2.2 in FOCUS ground water modelling. This addendum (June 2004), containing 9 new data points from the literature reported a Q_{10} between 1.99 and 3.17. The EPCO 7 experts meeting (June 2004) agreed that these data supported the use of the default Q_{10} in the FOCUS gw calculations.

Field studies in potato cropping areas of England (Spalding, pH (0.01M $CaCl_2$) = 7.3 for 0-15 cm depth) and The Netherlands (Ottersum, pH (0.01M $CaCl_2$) = 6.7 for 0-15 cm depth) are available. The half-lives obtained from these field studies are 9.2 – 11 days for oxamyl, 1.7 – 4.6 days for IN-A2213 and 3.4 – 6.7 days for IN-D2708. Residues of oxamyl (max. 0.0096 mg/kg) and metabolite IN-A2213 (max. 0.0096 mg/kg) were found in the deepest core segments sampled (75-90 cm) in the English soils. No residues above LOQ (0.005 mg/g) were found below 45 cm in the Dutch site.

PEC soil values for oxamyl presented in the DAR by the RMS take into account good agricultural practices proposed for the representative use and the longest half life observed in field (DT_{50} = 11 d). The selection of the DT_{50} for PEC soil calculation was confirmed by experts meeting EPCO 7 (June 2004). This calculation may be considered representative of neutral and alkaline soils but may need to be revised to take into account the possibility that DT_{50} could be longer in acidic soils.

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

Batch adsorption / desorption studies are available for oxamyl and metabolites IN-A2213, IN-D2708 and IN-N0079 in different soils. Data indicate that oxamyl (Koc = 8- 39 mL/g), IN-A2213 (Koc = 4 - 11 mL/g), IN-D2708 (Koc = 2 -10 mL/g) and IN-N0079 (Koc = 2 - 25 mL/g) are weakly adsorbed in soil. No pH dependence is observed for any of the compounds studied. Neither column leaching studies nor lysimeter studies are available.

In the Evaluation Meeting (March 2004) a Member State questioned the validity of some adsorption data with 1/n values > 1.1 (open point 4.4). The issue was discussed in the EPCO 7 experts meeting (June 2004). Experts concluded that a 1/n > 1.1 or <0.7 does not necessarily indicate that the study is invalid and the studies were considered acceptable.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. Surface water and sediment

In sterile aqueous buffer solutions, hydrolysis of oxamyl is strongly pH dependent. Half life is less than 3 hours at pH 9, 8 days at pH 7 and at pH 5 the compound is considered stable. Metabolites IN-A2213, IN-D2708 and water sediment metabolite **IN-T2921** (DMEA or DMO, *N*,*N*-

dimethylethanediamide) are stable at pH 4, 7 and 9. Hydrolysis of metabolite IN-N0079 is pH dependent. Half life is 3 days at pH 9, and may be considered stable at pH 7 and 4.

Aqueous photolysis may contribute to the degradation of oxamyl in the environment (DT_{50} = 7.4 d, continuously irradiated with light source equivalent to summer sunlight in Delaware (USA), pH = 5, 25 ^{o}C) with IN-A2213 as the main product. Photolysis is not expected to contribute to the environmental degradation of metabolites IN-A2213, IN-D2708, IN-N0079 and IN-T2921 due to the low molar absorption coefficients (ε) at wavelengths (λ) above 290 nm.

Oxamyl is not readily biodegradable.

A study with two water / sediment systems is available. The study was performed in natural water / sediments with neutral, slightly alkaline water (pH = 7.3, 7.5) and slightly acidic sediments (pH = 6.7, 6.1). Major metabolites in water were IN-A2213 (maximum = 48.8 % AR by day 2), IN-D2708 (maximum = 66.8 % AR by day 30), IN-N0079 (maximum = 52.9 % AR by day 2) and IN-T2921 (maximum = 11.4 % AR by day 14). The high levels of metabolite IN-N0079 were observed in only one of the systems. The appearance of this metabolite is explained by the reduction mediated by the ferrous ion near or within the anaerobic sediment phase that was facilitated by the vigorous agitation of the system during the application of the test product. The cumulative amounts of CO_2 evolved by the end of the study accounted for 27.9% AR and 60.9 % AR.

Only metabolite IN-D2708 was found in significant amounts in the sediment (maximum = 12.1 % AR by day 61). Neither oxamyl nor any other of the metabolites was found at levels above 5 % AR in the sediment.

Oxamyl degrades rapidly with a whole-system half life between 0.4 and 1 day. Since both water systems were slightly alkaline it is likely that a component of this rapid degradation was the result of chemical hydrolysis. Half life of metabolites in the total system is generally below 20 days except for IN-D2708 in one system for which a half-life of 169 days was calculated.

Potential risk for contamination of surface water and sediment by oxamyl and its metabolites IN-A2213 and IN-D2708 was initially assessed by calculation of PECsw (and PECsed) using a pre released version of FOCUS surface water modelling tools. This was not fully accepted by the Evaluation Meeting (Open point 4.1). Recalculation with final FOCUSsw models and scenarios was presented by RMS in an addendum to the DAR (June 2004) that was discussed in the experts meeting (EPCO 7, June 2004). Step 1 and Step 2 were run for oxamyl and metabolites IN-A2213 and IN-D2708 and Step 3 for oxamyl in water alone. Calculated PECsw and PECsed were agreed by the experts meeting and used in the ecotoxicological risk assessment. Since water / sediment metabolites IN-N0079 and IN-T2921 were not addressed by these calculations, the experts meeting (EPCO 7 June 2004) asked the RMS to present initial PECsw for these metabolites in order to have a complete data set (Open point 4.8). The calculation of the initial PECsw for these metabolites has been included by

the RMS in the latest version of the end points list and used to confirm the ecotoxicological risk assessment for these metabolites.

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

Predicted environmental concentrations in groundwater (PECgw) of oxamyl and the metabolites IN-A2213 and IN-D2708 were obtained using average corrected DT_{50} and averaged 1/n and Kfoc (Tables B.8.6.1-2 and B.8.6.1-3 in the DAR). When calculations were performed using FOCUS PRZM 2.2.1 model the trigger value of 0.1 µg / L was exceeded by oxamyl and metabolite IN-D2708 in one scenario and in two scenarios by metabolite IN-A2213. Results generated using FOCUS_PEARL_1.1.1 model are consistently higher and the trigger is exceeded in four scenarios by oxamyl, in eight scenarios by IN-A2213 and in seven scenarios by IN-D2708. A recent opinion of EFSA's Panel on Plant Health, Plant Protection Products and their Residues (PPR) of 14 September 2004 highlights the differences among the models used to run FOCUS ground water scenarios and concludes that "*in the absence of scientific consensus for example on crucial parameters such as the dispersion length, and in view of the principally different concepts of modelling the water flow, the PPR Panel recommends that the risk assessment should be based on two models, PEARL and either PELMO or PRZM (i.e., one representative for each concept), rather than on a single model*".[4] Therefore, results of both modelling exercises should be considered.

Evaluation meeting forwarded to an experts meeting the discussion on possible groundwater contamination (open point 4.2). The results from the FOCUS ground water calculations were discussed by the EPCO 7 expert meeting (June 2004). The meeting concluded that there may be a high risk for ground water contamination in certain circumstances, particularly if application is made on acidic soils that have not been fully assessed due to the lack of data in the original dossier. The need for new modelling taking into account the effect of soil pH on potential groundwater contamination by oxamyl and metabolites was identified by the experts meeting (data requirement 4.3). The relevance of metabolites IN-A2213 and IN-D2708 needed to be fully addressed according Guidance document SANCO 221/2000 rev 10 and the issue was forwarded to the corresponding ecotoxicology (EPCO 6) and toxicology (EPCO 9) meetings.

Finally, EFSA highlights that a number of studies are available on the degradation of oxamyl and its metabolites in the saturated subsoil (two anaerobic and two aerobic soils) that give some insight on the effect of the anaerobic conditions, the effect of low pH's (pH = 4.5 – 6) and the presence of ferrous iron on the degradation of oxamyl and the formation and degradation of metabolite IN-N0079. These studies were evaluated by the RMS in the DAR but results were not directly used in the

[4] Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models. The EFSA Journal (2004) 93, 1-20; http://www.efsa.eu.int/science/ppr/ppr_opinions/627_en.html

assessment of the potential of ground water contamination. Potential for refinement of the risk assessment based on these studies is envisaged (See B.8.4.4.2).

In conclusion, the effect of oxamyl degradation pH dependence on the potential groundwater contamination by oxamyl and metabolites and potential groundwater contamination by metabolite IN-N0079 are not fully assessed. Consequently, risk assessment with respect to ground water contamination may not be considered completed.

4.3. FATE AND BEHAVIOUR IN AIR

Concentrations of oxamyl in the air compartment are expected to be negligible, due to low volatility and short persistence in the atmosphere.

5. Ecotoxicology

5.1. RISK TO TERRESTRIAL VERTEBRATES

The risk to birds and mammals is assessed by the RMS according to the revised EPPO scheme for terrestrial vertebrates (02/9285 revised, September 2002).
The risk to birds was discussed in the EPCO 8 Expert meeting in June 2004 and the used approach was not accepted by this meeting. The data available at the EPCO meeting 8 indicates a high acute risk to small birds from the ingestion of granules. The meeting noted that a small number of granules is sufficient to kill a small bird and that the size of granules is comparable with weed seeds. A much more detailed risk assessment is needed and therefore a new data requirement was set at the EPCO meeting for a refined avoidance study using Vydate 10GR and conducted with relevant birds for European agricultural landscapes under more realistic exposure conditions. Due to comments received on the DAR during the commenting period, 2 more data requirements were set at the evaluation meeting in March 2004. These data were made available to the RMS after the EPCO 8 meeting and are not evaluated by the RMS. The first data requirement concerns the submission of the full study report providing information on the number of granules available on the soil surface and the second concerns the submission of the full report of the study on the release of the active ingredient from the granule (DuPont-3025).

The RMS was asked in the EPCO 8 expert meeting to recalculate the risk for earthworm eating birds according to SANCO/4145/2000. Additional data, which will affect the risk assessment for birds, is awaited. Therefore, the RMS did not recalculate the risk for earthworm eating birds at this stage.

Although the risk to mammals was not scheduled to be discussed at the EPCO 8 expert meeting, it was decided that the risk to mammals needed to be revised too in light of the remarks made on the risk assessment for birds.

The EPCO 8 Expert meeting indicated further the need for a restriction highlighting the need to ensure that immediate incorporation of applied granules is required to ensure that the potential risk to birds and mammals is minimised.

Based on the data available at the EPCO 8 expert meeting a high risk to birds and mammals from the use of oxamyl and the need to address this risk further was identified. A full risk assessment can only be concluded when the outstanding data is evaluated.

5.2. RISK TO AQUATIC ORGANISMS

Daphnia magna was the most sensitive species from all aquatic species tested with oxamyl. No studies were considered necessary with the lead formulation as it is considered possible to extrapolate from data obtained in the corresponding studies on the active substance.

The acute risk to aquatic organisms was calculated using PEC values calculated by using the final FOCUS surface water modelling tools. This risk calculation is available in the addendum to the DAR (May 2004) which was discussed at the EPCO 8 expert meeting of June 2004.

The resulting TER-values for the acute risk breached the Annex VI trigger value of 100 for step 1 and step 2 Focus scenarios indicating a high acute risk to aquatic organisms. Therefore the exposure assessment was further refined with calculating Focus step 3 PECsw values.

For the step 3 Focus scenarios the acute risk to aquatic organisms can be considered low for all the drainage scenarios and the run-off pond scenario (Annex VI trigger not breached). For the 3 run-off stream scenarios from Focus step 3, the trigger was still breached indicating a high acute risk to aquatic organisms under these circumstances. Risk mitigation measures need to be taken into account at MS level to address this risk.

A study on the long term toxicity to fish and daphnia is available with oxamyl. *Daphnia magna* is the most sensitive organism. In the addendum to the DAR (May 2004) the long term risk to aquatic organisms was calculated using time weighted average PECsw values. The use of these PECtwa values was questioned during the EPCO 8 Expert meeting and the RMS was asked to provide a statement on the appropriateness of the use of these values. A revised long term risk assessment for aquatic organisms is available in the addendum to the DAR (October 2004) in which the RMS used initial PECsw values to calculate the risk instead of the PECtwa values as this was an error.

As for the acute risk assessment it was necessary to run step 3 Focus scenarios as the Annex VI trigger value of 10 was breached for Focus step 1 and 2 indicating a high long term risk to aquatic organisms. Also for the long term risk assessment the risk to aquatic organisms can be considered low for all the drainage scenarios and the run-off pond scenario from Focus step 3 (Annex VI trigger not breached). For the 3 run-off stream scenarios from Focus step 3, the trigger was still breached indicating a high long term risk to aquatic organisms under these circumstances. Risk mitigation measures need to be taken into account at MS level to address this risk.

Due to the late submission of this addendum it was not peer reviewed by other MS or discussed in an EPCO expert meeting. EFSA agrees with this revised long term risk assessment for aquatic organisms of the rapporteur Member State.

No studies with sediment dwelling organisms are considered necessary as in the 2 water sediment studies, oxamyl was not detected on or after day 14 at levels greater than 10% of the applied radio-activity in the sediment. Only the metabolite IN-D2708 was detected at levels above 10% in the sediment but the NOEC for Daphnia exceeds 0.1 mg/L for this metabolite so also for this metabolite no study to sediment dwelling organisms is considered necessary.

Oxamyl is not an herbicide so studies on aquatic plants are not considered necessary.

Furthermore the metabolites IN-A2213, IN-D2708, IN-N0079 and IN-T2921 were tested. IN-A2213, IN-D2708 and IN-T2921 are more than one order of magnitude less toxic to aquatic organisms than the compound and IN-0079 almost 1 order of magnitude. TER values were calculated for IN-A2213 and IN-D2708 and the risk can be considered low (Annex VI trigger not breached). The risk for IN-0079 and IN-T2921 were not calculated in the DAR although they are major surface water metabolites. Therefore EFSA presents the TER values here in this conclusion. Using PECsw values for these metabolites calculated from the maximum amount of parent expected from FOCUSsw Step 2 modelling which are available the resulting acute TER values are 230 (22400/97.5) based on *O. mykiss* for IN-0079 and >4940 (>123000/24.9) for IN-T2921. Therefore can the risk to aquatic organisms from these metabolites also be regarded as low (Annex VI trigger not breached). No long term toxicity testing with the metabolites is considered necessary as they are not more acutely toxic than the parent.

Both the acute and long term risk assessment has been conducted on the assumption that direct contamination (i.e. 'drift' of small granules) of surface water is not possible. A restriction highlighting the need to avoid the use of application machinery (i.e. pressurised systems) that may result in direct contamination of adjacent surface waters is considered necessary.

As the log Pow is below 3, no study on bioconcentration in fish is considered necessary.

5.3. RISK TO BEES

Acute contact and oral toxicity studies both with oxamyl and a 10SL formulation are available. The resulting HQ values breach the appropriate Annex VI trigger value indicating a high risk to bees.
The representative use evaluated is a granule which is incorporated at planting. Oxamyl shows systemic activity, being translocated within the plant and so there is the possibility of exposure of foraging bees via the nectar of treated crops. The physico-chemical properties of oxamyl are such that very low to minimal residues will arise in plant tissues (see Section on residues). This has been investigated through plant residue trials, which indicate that there are no residues of oxamyl present in the plant tissue to which bees may be exposed if foraging in a flowering crop.
Consequently, it is considered that the risk to honey bees from the representative use of Oxamyl 10 GR can be regarded as low due to the very limited field exposure.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Toxicity to non-target arthropods was high in laboratory studies on the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. Extended laboratory studies were conducted with the lead formulation and 3 crop relevant ground dwelling species: *Poecilus cupreus, Aleochara bilineata* and *Pardosa* spp. The observed effects were below 50% at the highest application rate of 3.85 mg a.s./kg soil (PECsoil max. = 3.67 mg a.s./kg soil)and therefore the Escort II trigger value was not breached.
No foliage dwelling species were tested as it is considered very unlikely that these arthropods can come in contact with the product during the short period of granule incorporation because there will be no crop foliage available during planting of potato and very low to minimal residues will arise in plant tissues from the use of Oxamyl 10GR in potatoes.

5.5. RISK TO EARTHWORMS

Studies on the acute toxicity to earthworms from oxamyl, the lead formulation and the metabolites IN-A2213, IN-D2708, IN-0079 and IN-T2921 are available. After the EPCO 7 Expert meeting PECsoil values for the metabolites IN-0079 and IN-T2921 were made available. As the TER values for these metabolites were not recalculated by the RMS, EFSA presents the recalculated values in the conclusion. For both metabolites a maximum PECsoil of 3.67 mg/kg soil can be assumed which results in a TER value of 174.4 and 272.5 for IN-0079 and IN-T2921 respectively. The TER-values resulting from the endpoints derived from these studies do not breach the Annex VI trigger value indicating a low acute risk to earthworms for the representative use.
Studies on the long term toxicity to earthworms with the lead formulation are available. The TER-values resulting from the endpoints derived from these studies (1.7<TER<1.9 for an incorporation depth of 10 cm, 3.5<TER<3.8 for an incorporation depth of 20 cm), breach the Annex VI trigger value of 5 indicating a high long term risk to earthworms for the representative use. To address this risk the RMS set a data requirement for an earthworm field study which was confirmed during the evaluation meeting of March 2004. This study was made available by the notifier after the EPCO 8 expert meeting of June 2004 and was evaluated by the RMS in the addendum to the DAR (October 2004). The evaluation of this study and the corresponding risk assessment was not peer reviewed by EFSA or by an EPCO expert meeting.

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

The RMS did not consider further studies on other non-target macro-organisms necessary as the DT_{90} in soil is less than 100 days. The EPCO 8 Expert Meeting stated the risk assessments to other soil organisms may need to be revised due to the outcome of the results of the outstanding study. The RMS did not conduct the risk assessment following the EPCO 8 Expert Meeting because although the outstanding study was evaluated, it had not been peer reviewed.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of oxamyl, the lead formulation and the metabolites IN-A2213, IN-D2708, IN-N0079 and IN-T2921 were tested on soil microbial respiration and nitrogen transformation. No deviations of

more than 25 % after 90 days were observed (i.e. no breaching of the Annex VI trigger value) at doses which cover the max. PEC_s and hence the risk to soil non-target micro-organisms is considered to be low.

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

A study on the effects of an oxamyl 24 SC formulation on non-target terrestrial plants is available. The EC50 for emergence and early seedling growth is above 2.24 kg a.s./ha. This tested dose is below the maximum application rate of the representative use. The risk to non-target plants is considered low due to the fact that the lead formulation is a granule which is incorporated in the soil so no 'drift' is expected; Therefore no studies at higher application rates are considered necessary.

Furthermore the insecticidal activity of the metabolites IN-A2213, IN-D2708, IN-N0079 and IN-T2921 was tested. Some plant protection was shown by reducing of feeding of *Diabrotica undecimpunctata*, but when the compounds were sprayed directly on the larvae of this species, no insecticidal activity was shown.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

An inhibition of 20.9% of the respiration rate was noted at the highest concentration tested of 100 mg a.s./L. Therefore an EC_{50}-value could not be set. The risk for biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definitions for risk assessment: oxamyl, IN-A2213, IN-D2708, IN-N0079.
Definitions for monitoring: oxamyl

Water

Ground water

Definitions for risk assessment: oxamyl, IN-A2213, IN-D2708, IN-N0079.
Definitions for monitoring: oxamyl

Surface water

Definitions for risk assessment: oxamyl, IN-A2213, IN-D2708, IN-N0079, IN-T2921.
Definitions for monitoring: oxamyl

Air

Definitions for risk assessment: oxamyl
Definitions for monitoring: oxamyl

Food of plant origin

Definitions for risk assessment: Oxamyl (*based on granular application in root and tuber crops only*)

Definitions for monitoring: Oxamyl (*based on granular application in root and tuber crops only*)

Food of animal origin

Definitions for risk assessment: not necessary/ not proposed

Definitions for monitoring: not necessary/ not proposed

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
oxamyl	pH ≥ 7.0 low to moderate persistent ($DT_{50\ lab}$ = 3 – 11.5 d) pH < 7 available information indicates that the compound may be highly persistent in acidic soils (pH 4.8; $DT_{50\ lab}$ = 112 d). However, further information is needed to complete the assessment.	See points 5.5, 5.6 and 5.7
IN-A2213	Low to moderate persistent ($DT_{50\ lab}$ =1.7 – 17.5 days)	Acute risk to earthworms is considered to be low (trigger not breached). The risk to soil non-target micro-organisms is considered to be low. Long term risk to earthworms can be derived from the field study with earthworms which was not peer reviewed due to late submission (see point 5.5).
IN-D2708	Low persistent ($DT_{50\ lab}$ = 3.9 – 7.6 days).	Acute risk to earthworms is considered to be low (trigger not breached). The risk to soil non-target micro-organisms is considered to be low. Long term risk to earthworms can be derived from the field study with earthworms which was not peer reviewed due to late submission (see point 5.5).

Compound (name and/or code)	Persistence	Ecotoxicology
IN-N0079 (Not found in standard aerobic/anaerobic studies. Formation catalysed by Fe (II))	Low to moderate persistent ($DT_{50\ lab}$ = 4 - 41 days)	Acute risk to earthworms is considered to be low (trigger not breached). The risk to soil non-target micro-organisms is considered to be low. Long term risk to earthworms can be derived from the field study with earthworms which was not peer reviewed due to late submission (see point 5.5).

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 activity	Ecotoxicological activity
oxamyl	Highly mobile	Yes	Yes, to be assessed by Member States	Yes, assessed in the DAR	Yes, assessed in the DAR
IN-A2213	Highly mobile	Yes	Assessed not to show insecticidal activity	Concluded to be not toxicological relevant based the available data	Assessed not to be ecotoxicological relevant
IN-D2708	Highly mobile	Yes	Assessed not to show insecticidal activity	Concluded to be not toxicological relevant with the available data	Assessed not to be ecotoxicological relevant

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 activity	Ecotoxicological activity
IN-N0079	Highly mobile	Not calculated (formation catalysed by Fe (II))	Assessed not to show insecticidal activity	Not assessed	Not assessed

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
oxamyl (only water phase)	See point 5.2.
IN-A2213 (only water phase)	The risk to aquatic organisms is considered low (Annex VI trigger not breached) based on an acute toxicity study with fish, an acute toxicity study with *Daphnia magna* and a toxicity study with algae.
IN-D2708 (water and sediment)	The risk to aquatic organisms is considered low (Annex VI trigger not breached) based on an acute toxicity study with fish, an acute and long term toxicity study with *Daphnia magna* and a toxicity study with algae. Based on the long term toxicity to *Daphnia magna* no studies on sediment dwelling organisms were considered necessary.
IN-N0079 (only water phase)	The risk to aquatic organisms is considered low (Annex VI trigger not breached) based on an acute toxicity study with fish, an acute toxicity study with *Daphnia magna* and a toxicity study with algae.
IN-T2921 (only water phase)	The risk to aquatic organisms is considered low (Annex VI trigger not breached) based on an acute toxicity study with fish, an acute toxicity study with *Daphnia magna* and a toxicity study with algae.

Air

Compound (name and/or code)	**Toxicology**
oxamyl	No air contamination expected

LIST OF STUDIES TO BE GENERATED OR STILL ONGOING

- boiling point or temperature of decomposition (the study has been submitted to the RMS but has not been evaluated; refer to point 1)
- auto-flammability of the dry technical material (the study has been submitted to the RMS but has not been evaluated; refer to point 1)
- identity of impurities (submission date proposed by the notifier: unknown; data requirement was identified during the EPCO 6 meeting; a statement regarding the specificity has been submitted to the RMS, which addresses the annex point only partially; refer to point 1)
- data on rotational crop residue trials ('cold studies') to address the proposed time restriction of 120 days after oxamyl application (relevant for all representative uses evaluated; not essential for risk assessment; no submission date proposed by the notifier; refer to point 3.1.2)
- degradation in acidic soils must be addressed; a position paper with results of different studies presented by the notifier confirms the concern (relevant for all representative uses evaluated; the position paper has been submitted to the RMS, refer to point 4.1.2)
- modelling to fully characterise the risk of oxamyl and its metabolites in soil and groundwater at different pHs is needed (relevant for all representative uses evaluated, new data has been submitted to the RMS; refers to point 4.2.2).
- a refined avoidance study using Oxamyl 10GR (Vydate ®) and conducted with relevant birds for European agricultural landscapes under more realistic exposure conditions (relevant for all representative uses evaluated; submission date proposed by the notifier: July 2005; refer to point 5.1)
- full study report providing information on the number of granules available on the soil surface. (relevant for all representative uses evaluated; the study has been submitted to the RMS but has not been evaluated; refer to point 5.1).
- the full report of the study on the release of the active ingredient from the granule (DuPont-3025); (relevant for all representative uses evaluated; the study has been submitted to the RMS but has not been evaluated; refer to point 5.1).
- earthworm field study; (relevant for all representative uses evaluated; the study has been submitted to the RMS and has been evaluated by the RMS but not peer reviewed; refer to point 5.5).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as proposed by the applicant which comprises broadcast application in potato to control the potato cyst nematode as well as suppressing early aphid infestations and Spraing at application rate of 4.0 kg/ha for early potatoes or up to 5.5 kg/ha for potatoes.

Analytical methods for the determination of residues of oxamyl are available for potatoes, soil, water, air and blood. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

Oxamyl is absorbed to a high degree, 80%. It is widely distributed; highest concentration was found in blood, heart, liver, kidney, lungs, spleen and the gastro-intestinal tract. There was no evidence of accumulation. Oxamyl is extensively metabolised and the major metabolite was IN-A2213, minor metabolites were IN-L2953 and IN-D2708. The oral toxicity is high, with an oral LD50 of 3.1 mg/kg bw and 2.5 mg/kg bw in male and female rats, respectively. The toxicity during inhalation in rats was also high, LC50 0.056 mg/L air, dermal toxicity on the other hand was low. Oxamyl was not shown to be an irritant or a sensitizer in skin and it was a transient eye irritant. **The following risk phrases T+; R26/28 "Very toxic by inhalation and if swallowed"** are proposed. Effects observed during short term exposure were clinical signs as a consequence of decreased cholinesterase activity. The relevant oral NOAEL was an overall NOAEL for the one year dog studies of 0.93 mg/kg bw/day. The dermal NOAEL of 50 mg/kg bw/day was also based on effects on cholinesterase activity.
Oxamyl did not display mutagenic or genotoxic properties. During long term exposure, clinical signs such as hyperactivity, swollen legs or paws, sore skin and alopecia were observed. The relevant NOAEL for long term exposure was 1.97 mg/kg bw/day based on decreased plasma cholinesterase activity in the rat. Oxamyl was not demonstrated to be oncogenic or have a carcinogenic potential in rat, mouse or dog.
The reproductive performance was not affected by oxamyl. The relevant NOAEL for parental toxicity and pup development is 25 ppm (1.43 mg/kg bw/day) in the rat, a reduction in the mean number of pups born per litter and pups born alive per litter. The relevant developmental and maternal NOAEL is 0.5 mg/kg bw/day in the rat based on decreased foetal body weight and reduced body weight, respectively.
The relevant NOAEL for acute neurotoxicity was 0.1 mg/kg bw/day in rats based on clinical signs indicative of cholinesterase inhibition such as low posture, salivation and tremor were recorded in the two highest dose levels. During subchronic exposure, clinical signs indicative of cholinesterase inhibition were seen in rats at ≥ 100 ppm and the relevant NOAEL is 30 ppm (i.e. 1.69 mg/kg bw/day for males and 2.03 mg/kg bw/day for females).
The soil metabolites IN-A2213 and IN-D2708, predicted to be > 0.1 µg/L in groundwater, have been adequately assessed in the toxicity studies on the parent compound since they are also animal metabolites and they are not considered as relevant (confirmed at the expert meeting) based on the available data. However, EFSA notes that the complete data package specified in guidance document for metabolites exceeding the 0.1 µg/L trigger in groundwater is not available for these metabolites.
An acute human study, ethically approved, was submitted and it was agreed at the expert meeting that it could be used from a scientific point of view. The NOAEL of 0.06 mg/kg bw/day was confirmed based on reduced plasma and erythrocyte cholinesterase activity at 0.09 mg/kg bw/day. However, it was agreed on the meeting not to use it for the allocation of the ARfD but rather an animal study was chosen.

The ADI, AOEL and ARfD are all set to 0.001 mg/kg bw/day based on the NOAEL of 0.1 mg/kg bw/day in the acute neurotoxicity study in the rat, with a safety factor of 100. However, it should be noted that a scientifically valid human study is available, where the NOAEL is 0.06 mg/kg bw/day, which could be used for derivation of the ARfD.
The dermal absorption is 0.04% for the granular formulation **Oxamyl 10GR (Vydate®).** Based on this value of dermal absorption, a treated area of 4.6 ha/day as well as a max. application rate of 5.5 kg a.s./ha the operator exposure **was estimated to be 92% of AOEL according to calculations in the US PHED model when respiratory protective equipment (RPE) are applied** during the loading and mixing and application procedures for Oxamyl 10GR (Vydate ®). Without any PPE, the exposure was estimated to 920% of the AOEL. Worker exposure was considered being negligible and bystander exposure is not applicable.

The metabolism of oxamyl in potatoes after granular application to soil does not yield metabolites of toxicological concern based on the assessment of available data (refer to point 2.8). It was also demonstrated that no parent oxamyl is present in potatoes treated in this manner. Consistently, no residues of oxamyl were quantified in any of the potatoes tuber samples from field trials conducted according critical GAP. Using a residue level equal to the LOQ of 0.02 mg/kg for food of plant origin in the chronic dietary risk assessment represents a worst-case scenario and leads to estimated intakes for consumers not exceeding 73% of the proposed ADI.
An acute risk for consumers from the consumption of potatoes grown according the examined representative GAP can not be stated as oxamyl residues are not present. However, EFSA notes that if oxamyl residues were present in potatoes at a level of 0.02* mg/kg then the ARfD for oxamyl of 0.001 mg/kg bw/day may be exceeded for certain consumer subgroups.

In aerobic conditions degradation of oxamyl in soil yields **IN-A2213** (oxamyl oxyme) that is further degraded to **IN-D2708** (DMOA) and then to CO_2 and unextractable soil components.
A new metabolite **IN-N0079** (*N*,*N*-dimethyl-1-cyanoformamide) appears at relatively high levels in one soil in the soil photolysis study. This metabolite is not a photolysis metabolite and, according published literature, its formation is catalyzed by ferrous ion (Fe (II)).
Degradation of oxamyl in soil seems to be strongly pH dependent, with the longer half life being determined for the single acidic soil studied. Due to this fact, new data to assess effect of pH in the degradation was required to the notifier by the Evaluation Meeting (March 2004). Additional data presented by the notifier on the degradation of oxamyl in acidic soils has not been fully evaluated due to late submission. Furthermore, modelling for this substance and their metabolites are necessary to fully characterize the impact of the degradation rate of oxamyl at different soil pHs. New data has been submitted in relation with this point on November 2004.
Field studies are available in potatoes cropping areas of England and The Netherlands.
Oxamyl, IN-A2213, IN-D2708 and IN-N0079 are weakly adsorbed in soil. No pH dependence is observed for any of the compounds studied.
In sterile aqueous buffer solutions, hydrolysis of oxamyl is strongly pH dependent and at pH 5 the compound is considered stable.

Metabolites IN-A2213, IN-D2708 and water sediment metabolite **IN-T2921** (DMEA or DMO, *N*,*N*-dimethylethanediamide) are stable at pH 4, 7 and 9. Aqueous photolysis may contribute to the degradation of oxamyl in the environment but it is not expected to contribute to the environmental degradation of metabolites IN-A2213, IN-D2708, IN-N0079 and IN-T2921. Oxamyl is not readily biodegradable.

In water sediment systems, major metabolites in water were IN-A2213, IN-D2708, IN-N0079 and IN-T2921. The appearance of metabolite IN-N0079 is explained by the reduction mediated by the ferrous ion near or within the anaerobic sediment phase. The cumulative amounts of CO_2 evolved by the end of the study accounted for 27.9% AR and 60.9 % AR. Only metabolite IN-D2708 was found in significant amounts in the sediment. Oxamyl degrades faster in the water phase with a half life between 0.4 and 1 day. Half life of metabolites in the total system is generally below 20 days except for IN-D2708 in one system for which a half-life of 169 days was calculated. Potential risk for contamination of surface water and sediment by oxamyl and its metabolites IN-A2213 and IN-D2708 was assessed by FOCUS surface water modelling. Step 1 and Step 2 were run for oxamyl and metabolites IN-A2213 and IN-D2708 and Step 3 for oxamyl in water alone. Also initial PECsw for water / sediment metabolites IN-N0079 and IN-T2921 has been calculated.

With respect to ground water contamination, it is concluded that there may be a high risk of contamination by oxamyl and its metabolites in certain circumstances, particularly if application is made on acidic soils that have not been fully assessed.

The risk to bees, non-target arthropods, soil micro-organisms, terrestrial plants and biological methods for sewage treatment is low with respect to oxamyl and the metabolites as far as investigated.

The risk to aquatic organisms can be considered low for all the drainage scenarios and the run-off pond scenario (Annex VI trigger not breached). For the 3 run-off stream scenarios from the FOCUSsw step 3 scenarios evaluated, the trigger was still breached indicating a high risk to aquatic organisms under these circumstances. Risk mitigation measures need to be taken into account at MS level to address this risk. The aquatic risk assessment has been conducted on the assumption that direct contamination (i.e. 'drift' of small granules) of surface water is not possible. A restriction highlighting the need to avoid the use of application machinery (i.e. pressurised systems) that may result in direct contamination of adjacent surface waters is proposed.

Based on the data available at the EPCO 8 expert meeting, a high risk to birds and mammals from the use of oxamyl and the need to address this risk further was identified. Submission and evaluation of respective data may lead to a revision of the current risk assessment for birds and mammals.

Also the long term risk to earthworms is considered high as the TER (1.7<TER<1.9 for an incorporation depth of 10 cm, 3.5<TER<3.8 for an incorporation depth of 20 cm) breaches the Annex VI trigger value of 5. The need to address this risk further was identified. Evaluation of respective data (not peer reviewed as not available during the expert meeting) may lead to a revision of the current risk assessment for earthworms.

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

- The operator exposure was below AOEL if PPE and respiratory equipment (RPE) is used during mixing and loading as well as during application, based on an treated area of 4.6 ha/day (refer to point 2.12).
- A label recommendation should be in place, which recommends that rotational crops should not be planted within 120 days of an oxamyl application to soil. This is required to minimize the possibility of residues being detected which will exceed the limit of quantification for oxamyl which is the likely the MRL (refer to point 3.1.2).
- Potential environmental relevance of metabolite IN-N0079 in soil may need to be assessed for soils containing ferrous ion (Fe (II) (Anaerobic conditions are usually required) (refer to point 4.1.1).
- Potential ground water contamination should be considered for vulnerable conditions (refer to point 4.2.2).
- A restriction highlighting the need to ensure that immediate incorporation of applied granules is required to ensure that the potential risk to birds and mammals is minimised (refer to point 5.1).
- Risk mitigation measure has to be taken into account at MS level to address the risk to aquatic organisms, e.g. for run-off stream scenarios (refer to point 5.2).

Critical areas of concern

- For the operator exposure, it is necessary to consider the use of PPE and respiratory equipment (RPE) during mixing and loading as well as during application and an additional limitation of the treated area to 4.6 ha/day in order to derive an estimated operator exposure below the AOEL (refer to point 2.12).
- Risk assessment with respect to ground water contamination and soil ecotoxicology by the parent and metabolites needs to be completed for acidic soils (refer to point 4.2.2).
- A high risk to birds and mammals from the use of oxamyl and the need to address this risk further was identified. A full risk assessment can only be concluded when the outstanding data is evaluated (refer to point 5.1).
- For the 3 run-off stream scenarios from the FOCUSsw step 3 scenarios evaluated, the trigger was still breached indicating a high risk to aquatic organisms under these circumstances. Risk mitigation measures need to be taken into account at MS level to address this risk. The aquatic risk assessment has been conducted on the assumption that direct contamination (i.e. 'drift' of small granules) of surface water is not possible. A restriction highlighting the need to avoid the use of application machinery (i.e. pressurised systems) that may result in direct contamination of adjacent surface waters is proposed (refer to point 5.2).
- The long term risk to earthworms is considered high as the TER (1.7<TER<1.9 for an incorporation depth of 10 cm, 3.5<TER<3.8 for an incorporation depth of 20 cm) breaches the

Annex VI trigger value of 5. The need to address this risk further was identified (refer to point 5.5).

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

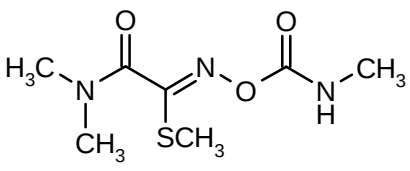
(Abbreviations used in this list are explained in appendix 2)

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

Active substance (ISO Common Name)	Oxamyl
Function (*e.g.* fungicide)	Nematicide and insecticide

Rapporteur Member State	Ireland
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	N,N-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio) acetamide
Chemical name (CA)	Methyl 2-(dimethylamino)-N-methylamino)carbonyl]oxy]-2-oxoethanimidothioate
CIPAC No	342
CAS No	23135-22-0
EEC No (EINECS or ELINCS)	245-445-3
FAO Specification (including year of publication)	Data not available
Minimum purity of the active substance as manufactured (g/kg)	970 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None identified.
Molecular formula	$C_7H_{13}O_3N_3S$
Molecular mass	219.3 g/mol
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	98.5 °C- 100 °C (99.9%)
Boiling point (state purity)	Data available but not evaluated
Temperature of decomposition	Open point *(depending on the evaluation of the boiling point study)*
Appearance (state purity)	White crystalline solid
Relative density (state purity)	1.313 g/cm³ (density) at 20 °C (100%)
Surface tension	73.1 mN/m at 20 °C (conc. 0.953 g/L)
Vapour pressure (in Pa, state temperature)	5.12×10^{-5} Pa at 25 °C
Henry's law constant (Pa m^3 mol^{-1})	4.89×10^{-8} x Pa x m^3 x mol^{-1} at 25 °C
Solubility in water (g/l or mg/l, state temperature)	148.1g/l at 20°C at pH 5.0 (for stability reasons)
Solubility in organic solvents (in g/l or mg/l, state temperature)	Solvent *n*-heptane 10.5 mg/L dichloromethane > 250 methanol > 250 acetone > 250 ethyl acetate 3.14 xylene 41.3 [all in g/L]
Partition co-efficient (log POW) (state pH and temperature)	The log Po/w at 25 °C and pH 5 = - 0.44
Hydrolytic stability (DT50) (state pH and temperature)	The half life of oxamyl was determined to be > 31 days at pH 5 and 25 °C 8 days at pH 7 and 25 °C 3 hours at pH 9 and 25 °C
Dissociation constant	pKa estimated to be = -2.11
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	At 25 °C the ε at 290nm was determined to be At pH 2 = 61.6 At pH 7 = 80.1 At pH>10 = 1154
Photostability (DT50) (aqueous, sunlight, state pH)	$t_{1/2}$ was determined to be = 7 days at pH 5 and at 25 °C
Quantum yield of direct phototrans-formation in water at Σ > 290 nm	0.0187
Flammability	Data required
Explosive properties	Oxamyl does not classify as explosive.

List of representative uses evaluated*

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F/G/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 a.s. (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		
Potato, main crop	NE; SE	Vydate	F	Nematodes and some other insect pests	GR	100	Evenly soil incorporated to a depth of 10 cm	At planting	1	Not relevant.	-	-	4.0-5.5 kg/ha. [Depending on soil type.]	--	
Potato, early potatoes	NE; SE	Vydate	F	Nematodes and some other insect pests	GR	100	Evenly soil incorporated to a depth of 10 cm	At planting	1	Not relevant.	-	-	4.0 kg/ha	12 weeks	

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

Appendix 1.2: Methods of Analysis

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

Technical as (principle of method)	Technical oxamyl, with acetanilide as internal standard, is diluted in aqueous phosphoric acid (pH= 2.7). Sample is analysed by HPLC with uv detection at 240nm.
Impurities in technical as (principle of method)	Impurities coded 13703, A2213, D2256, E2321, D2293, U1746, L2020 and 31144 are treated in the same manner as technical oxamyl. The analysis is carried out using HPLC with uv detection at 205nm. Quantitation is by comparison with known standards. Impurities methanol, cylclohexanone and triethyl amine are analysed by GC with an FID detector following the dissolution of the sample in NN-dimethylformamide.
Plant protection product (principle of method)	Same analytical method as for the technical oxamyl.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Food samples are extracted with acetone, cleaned up by SPE (aminopropyl-bonded silica cartridges). The sample is then analysed using RP HPLC coupled to a post column hydrolyser which releases the methyl amine and which is in turn derivatised with o-phthaldehyde. The residue is quantified using a fluorescence detector. **LOQ** was validated for selected crops at 0.01 to 0.1 mg/kg. Recovery levels were higher at the 0.01mg/kg as opposed to the 0.05 and 0.1mg/kg spiking levels indicating that the analysis of oxamyl using this analytical method may be difficult.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	(Sample is extracted using ethyl acetate. The extract is cleaned up using GPC after which it is hydrolysed to transform any oxamyl present into its oxime. Sample is then analysed by GC with an FID detector. **LOQ** for this method was validated at 0.01 to 0.1 mg/kg) **Note: No requirement for analytical method for food of animal origin as no residue definition is proposed.**

Soil (principle of method and LOQ)	Soil is extracted using formic acid:methanol: acetonitrile (5:39:156). The extract is centrifuged and the supernatant is evaporated to dryness prior to being dissolved in methanol/0.1% formic acid in 10mM ammonium acetate (10:90). Analysis was carried out using HPLC/MS/MS using the parent ion 236.9 m/z to daughter ion 71.8 m/z for oxamyl and the parent ion 162.6 m/z to daughter ion 72.1 m/z for the oxime. LOQ: The method was validated at 0.0055 mg/kg for both the oxamyl and the oxime.
Water (principle of method and LOQ)	Water was cleaned by eluting through an SPE SAX cartridge in sequence with an SPE Oasis HLB cartridge. The sample was then analysed using HPLC/MS/MS using the parent ion 236.9 m/z to daughter ions 72 m/z and 90 m/z. LOQ: The method was validated for 0.1µg/l in ground, drinking and surface waters.
Air (principle of method and LOQ)	Air was sucked through an Supelpak 20E XAD-2 porous polymer. This adsorbent was extracted using acetonitrile and the extract was analysed using HPLC/MS. The method was validated at a spiking level equivalent to 0.24 µg/m^3.
Body fluids and tissues (principle of method and LOQ)	A method of analysis was presented for the determination of oxamyl in urine and in blood serum. The sample was extracted with ethyl acetate, cleaned up using GPC and analysed using GC/MS or GC/FPD. The method was validated in the range 0.01 to 0.1 mg/kg.

Classification and proposed labelling (Annex IIA, point 10)

With regard to physical/chemical data	No Classification required

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of absorption:	Rapid: 80% within 24 hours at 1 mg/kg bw
Distribution:	Widely distributed after 7 days: highest concentrations in whole blood (0.1 µg equivalents/g) and in heart, liver, kidney, lungs, spleen and the gastro-intestinal tract (0.04 to 0.09 µg equivalents/g)
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	Initially rapid: 80.5% within 24 hours (80% in urine): 93% after 7 days (91% in urine): no sex-related differences in the excretion pattern
Metabolism in animals	Extensive: 0-11% unchanged oxamyl excreted by 24 hours: oxamyl hydrolysis to IN-A2213 followed by glucuronide conjugation: other metabolites include IN-N0079, IN-L2953, IN-D2708, and IN-KP532: extensive incorporation of tissue radioactivity into amino acids
Toxicologically significant compounds (animals, plants and environment)	Parent compound; the main metabolites, IN-A2213 and IN-D2708, are generated *in vivo* and are considered to be adequately tested in studies involving DPX-D1410 based on the available data.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	3.1 mg/kg bw (male rat); **R28** 2.5 mg/kg bw (female rat)
Rat LD_{50} dermal	5027 mg/kg bw (male rabbit) >2000 mg/kg bw (female rabbit)
Rat LC_{50} inhalation	0.056 mg/l air, nose only; **R26**
Skin irritation	Non-irritant (rabbit)
Eye irritation	Transient irritant (rabbit)
Skin sensitisation (test method used and result)	42% oxamyl technical in cyclohexanone and water: non-sensitizing (Buehler)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Clinical signs of cholinergic perturbation
Lowest relevant oral NOAEL / NOEL	0.93 mg/kg bw/day (equal to 35 ppm; 1-year dog) based on clinical signs of cholinesterase inhibition at 1.46 mg/kg bw/day
Lowest relevant dermal NOAEL / NOEL	50 mg/kg bw/day (21-day rabbit, female) based on decreases in plasma and erythrocyte cholinesterase activity
Lowest relevant inhalation NOAEL / NOEL	No data, not required

Genotoxicity (Annex IIA, point 5.4)

Genotoxicity	No genotoxic potential

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

Target/critical effect	Decreased plasma cholinesterase activity (rat)
Lowest relevant NOAEL / NOEL	1.97 mg/kg bw/day (male rat) based on reduced plasma cholinesterase activity in rat
Carcinogenicity	No evidence of carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	Reduced pup survival and reduced litter size at the parentally toxic dose of 150 ppm (rat)
Lowest relevant reproductive NOAEL /	25 ppm (1.43 mg/kg bw/day)
Developmental target / critical effect	Decreased foetal body weight (rat)
Lowest relevant developmental NOAEL / NOEL	0.5 mg/kg bw/day for maternal and developmental toxicity

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Target / critical effects	No evidence for delayed neurotoxicity Erythrocyte cholinesterase inhibition and clinical signs of cholinergic perturbation
Acute Neurotoxicity NOAEL	0.1 mg/kg bw/day (rat gavage) based on decreased body weight gain & food consumption; inhibition of plasma, erythrocyte and brain cholinesterase and clinical signs; FOB and motor activity effects

Subchronic neurotoxicity NOAEL	1.69 mg/kg bw/day (equivalent to 30 ppm; rat 90-day dietary) based on decreased body weight & food consumption; inhibition of plasma, erythrocyte and brain cholinesterase and clinical signs; FOB and motor activity effects

Other toxicological studies (Annex IIA, point 5.8)

Acute lethal dose INA-2213	11,000 mg/kg (male rat)
10-dose subacute INA-2213	No NOAEL; histopathological changes, clinical signs and body weight loss at 1000 mg/kg bw/day (male rat)
Oral LD_{50} INN-79	LD_{50} = 6675 mg/kg (6370-6990 mg/kg) (male rat)
Acute lethal dose INN-79	450 mg/kg (male rat)
10-dose subacute INN-79	No NOAEL; body weight, organ weight and liver effects at 90 mg/kg bw/day (male rat)
90-day oral INN-79	$NOEL_{parental}$ = 50 ppm (4.0 (male) and 4.2 (female) mg/kg bw/day) based on reduced body weight and altered clinical chemistry parameters in both sexes $NOEL_{fertility}$ = 450 ppm (34.3 (male) and 35.7 (female) mg/kg bw/day) $NOEL_{developmental}$ = 150 ppm (11.4 (male) and 12.6 (female) mg/kg bw/day) based on decreased body weight in F_1 pups during lactation
Ames test INN-79	Not mutagenic
Oral LD_{50} IND-2708	LD_{50} = 3540 mg/kg (male rat)
Neurotoxicity DPX-D1410 NOAEL / NOEL	0.06 mg/kg (Acute human gavage)

Medical data (Annex IIA, point 5.9)

	No incidents or accidents during the manufacturing process. No data relating to exposure of the general public to oxamyl or epidemiological studies.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.001 mg/kg bw/day	Acute neurotoxicity study (rat)	100
AOEL	0.001 mg/kg bw/day	Acute neurotoxicity study (rat)	100
ARfD (Acute Reference Dose)	0.001 mg/kg bw/day	Acute neurotoxicity study (rat)	100

Dermal absorption (Annex IIIA, point 7.3)

Dermal absorption of Oxamyl 10GR (Vydate ®) based on *in vivo* data and correction made with *in vitro* results is: 0.04%.

Acceptable exposure scenarios (including method of calculation)

Operator	Estimated exposure scenarios of Oxamyl 10GR (Vydate ®), **based on a treated area of 4.6 ha/day**: 1) Based on US PHED model (5.5 kg a.i./ha) 920% of AOEL, without PPE 92% of AOEL, With RPE* (M/L and Appl.) 2) Based on a field study, with PPE a) **rate 1 kg a.i./ha** 8% of AOEL geometric mean 22% of AOEL worst case b) with correction **factor 5.3** to simulate the rate 4-5.5 kg a.i./ha: 37% of AOEL, geometric mean 118% of AOEL worst case
Workers	Considered to be negligible
Bystanders	Not applicable

* Respiratory Protective Equipment, M/L= Mixing and loading, Appl. = Application

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	Classification: Very toxic by inhalation and if swallowed Label: Symbol: T+; Indication of danger: Very Toxic Risk phrase: R26/28 Very toxic by inhalation and if swallowed Safety phrases: S2, Keep out of the reach of children S36/37, Wear suitable protective clothing and gloves S45, In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

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	One acceptable metabolism study in potatoes was provided. A number of metabolism studies from the 1970's were presented for a range of crops. These studies were not considered to be acceptable as stand alone metabolism studies. If the GAP for oxamyl is extended then additional metabolism studies will be required.
Rotational crops	Two studies were submitted which between them studied the uptake of oxamyl into beetroot, cabbage, sorghum, barley and lettuce. These studies indicated that only in the case of soil aged for 30 days pre-planting were residues of oxamyl detected in the rotational crops. Both of these studies had applications greater than the recommended potato GAP but it is considered prudent that a label recommendation should be in place, which recommends that rotational crops should not be planted within 120 days of an oxamyl application to soil. This is required to minimize the possibility of residues being detected which will exceed the limit of detection for oxamyl which is the likely MRL.
Plant residue definition for monitoring	Parent oxamyl.
Plant residue definition for risk assessment	As for monitoring.
Conversion factor (monitoring to risk assessment)	None.

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

Animals covered	Goat and hens
Animal residue definition for monitoring	None required
Animal residue definition for risk assessment	None required
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	The metabolism is similar but faster
Fat soluble residue: (yes/no)	No

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

.....	If crops are planted within 120 days of oxamyl application then residues of oxamyl may be detected in the roots and aerial parts of these crops

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

.....	Residues of oxamyl are stable in a range of fruit and vegetables when they are stored in a freezer for up to 1 year

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

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant:	Poultry:	Pig:
An animal feeding study was not required on the basis of the diet of food animals. Metabolism studies in the goat and in hens indicate that the only identifiable residue possible in the goat and hen is thiocyanate. No residues of oxamyl or its oxime will be detected in these animals.			
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

Summary of uses supported by available residue data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Potatoes	North	9 trials all containing residues of oxamyl < 0.02 mg/kg.	Potato GAP is fully supported. Residues of oxamyl will not be detected. This is further confirmed by the potato metabolism study supplied as part of the dossier.		
Potatoes	South	8 trials all containing residues of oxamyl < 0.02 mg/kg.	Potato GAP is fully supported. Residues of oxamyl will not be detected. This is further confirmed by the potato metabolism study supplied as part of the dossier.		

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

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

ADI	0.001 mg/kg bw/day
TMDI (European Diet) (% ADI) TMDI (German Diet, 4-6 years old girl)	57.0 % 73.0 %
NEDI (% ADI)	Not required
Factors included in NEDI	Not necessary to use any factors
ARfD	0.001 mg/kg bw/day
Acute exposure (% ARfD)	There is no exposure to oxamyl residues from the consumption of potatoes. Metabolism studies indicate that following granular application of oxamyl there will be no detectable residues of either oxamyl or its oxime present in the potato tubers. In this situation there is no requirement to assess acute exposure as oxamyl is the molecule with the acute toxicity.

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
None required.			

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

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

Potatoes.	0.02* mg/kg
All other fruit and vegetable crops	LOD for oxamyl

Appendix 1.5: Fate and Behaviour in the Environment

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

Mineralisation after 100 days	CO_2 maximum levels = 25.6-108.5% (at final sampling timepoints, 31-179 days) (n = 6 incubations; 5 soils tested – 3 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C)
Non-extractable residues after 100 days	NER maximum levels = 17.7-26.4% (time of maximum occurrence = 21-179 days) (n = 6 incubations; 5 soils tested – 3 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C)
Relevant metabolites - name and/or code, % of applied (range and maximum)	IN-A2213 and IN-D2708 were major degradation products in soil; IN-A2213 maximum levels = 7.6-51.0% (time of maximum occurrence = 1-60 days) (n = 6 incubations; 5 soils tested – 3 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C); IN-D2708 maximum levels = 20.3-39.5% (time of maximum occurrence = 10-90 days) (n = 5 incubations; 4 soils tested – 2 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C) [In a fifth soil (Drummer #6), which may have had a stressed microbial population due to its strongly acidic nature, IN-D2708 was not detected]

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

Anaerobic degradation	n = 1 soil (11 days aerobic incubation followed by 60 days anaerobic incubation) Mineralisation: CO_2 = 12.0% after 60 days Non-extractable residues: 18.4% after 60 days Metabolites (soil and flood water extraction): IN-A2213 maximum = 69.5% at day 20 IN-D2708 maximum = 23.1% at day 32
Soil photolysis	n = 2 soils Mineralisation: CO_2 = 7.9-27.4% after 20 days (irradiated samples), CO_2 = 37.5-42.9% after 20 days (non-irradiated samples) Non-extractable residues: 45.4-62.1% after 20 days (irradiated samples), 5.3-7.9% after 20 days (non-

	irradiated samples) Metabolites: IN-A2213 – maximum = 12.2-13.4%, at 7-12 days (irradiated samples), maximum = 11.3-18.1%, at 7-20 days (non-irradiated samples) IN-N0079 – maximum = 3.8-25.0%, at day 7 (irradiated samples), maximum = 0.9-18.3%, at 7-20 days (non-irradiated samples) [Not considered to be a photolysis metabolite. Produced by Fe II catalysis] Uncharacterised polar fraction – maximum = 21.1-23.8%, at 12-20 days (irradiated samples), maximum = 6.5-11.0% at 7-20 days (non-irradiated samples) [The oxamyl content of the radiolabelled starting material was only 78%. Other components were IN-A2213 (9.0%) and a polar fraction (10.9%).]

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

Method of calculation	Laboratory: Aerobic studies on parent – non-linear simple first order regression of parent and metabolite(s) in series, simultaneous fit (ModelManager®, version 1.1) Aerobic studies on metabolites – linear simple first order regression Anaerobic study – linear simple first order regression Soil photolysis study – simple first order kinetics, accounting for the effect of non-photolytic degradation Saturated zone degradation studies – linear simple first order regression Field studies: Non-linear simple first order regression of parent and two metabolites in series, simultaneous fit (ModelManager®, version 1.1)
Laboratory studies (range or median, with n value, with r^2 value)	Aerobic studies: Oxamyl DT_{50lab} (20-25 °C, aerobic): 3.0, 4.1, 7.9, 11.5 days (r^2 = 0.973-0.988), mean = 6.6 days IN-A2213 DT_{50lab} (20-25 °C, aerobic): 1.7, 1.8, 5.9, 6.4 days (derived from studies on oxamyl – r^2 =

	0.973-0.988), mean = 4 days [In one additional soil (Drummer #6), which was strongly acidic (pH of 4.8) and may have had a stressed microbial population, DT_{50lab} values (20 °C, aerobic) were 112 days for oxamyl and 17.5 days for IN-A2213 (r^2 = 0.998).] IN-D2708 DT_{50lab} (20-25 °C, aerobic – derived values): 3.4, 3.6, 5.0, 7.6 days (r^2 = 0.973-0.988), mean = 4.9 days; (20 °C, aerobic – direct experimental values): 3.9, 4.8, 6.1 days (r^2 = 0.828-0.887), mean = 4.9 days [Overall mean = 4.9 days (n = 7)] IN-N0079 DT_{50lab} (23 °C, aerobic – direct experimental values): 4, 25, 41 minutes (r^2 = 0.976-0.998), mean = 23 minutes Degradation data under acidic soils is required.
	Oxamyl DT_{90lab} (20-25 °C, aerobic): 9.9-38.2 days (n = 4 soils, r^2 = 0.973-0.988), mean = 22.0 days IN-A2213 DT_{90lab} (20-25 °C, aerobic): 5.7-21.3 days (derived from studies on oxamyl – n = 4 soils, r^2 = 0.973-0.988), mean = 13.2 days [In one additional soil (Drummer #6), which was strongly acidic (pH of 4.8) and may have had a stressed microbial population, and was not representative of a conventional European agricultural soil, DT_{90lab} values (20 °C, aerobic) were 373 days for oxamyl and 58.2 days for IN-A2213 (r^2 = 0.998).] IN-D2708 DT_{90lab} (20-25 °C, aerobic – derived values): 11.2-25.4 days (n = 4 soils, r^2 = 0.973-0.988), mean = 16.3 days; (20 °C, aerobic – direct experimental values): 12.8-20.2 days (n = 3 soils, r^2 = 0.828-0.887), mean = 16.3 days [Overall mean = 16.3 days (n = 7)] IN-N0079 DT_{90lab} (23 °C, aerobic – direct experimental values): 13-135 minutes (n = 3 soils, r^2 = 0.976-0.998), mean = 77 minutes
	(10 °C, aerobic): laboratory values Oxamyl DT_{50lab} (10 °C, aerobic): 16.4 days (n = 1 soil, r^2 = 0.992) IN-A2213 DT_{50lab} (10 °C, aerobic): 21.5 days (n = 1 soil, r^2 = 0.992) IN-D2708 DT_{50lab} (10 °C, aerobic): 65.9 days (n 1 soil, r^2 = 0.992) Oxamyl DT_{90lab} (10 °C, aerobic): 54.4 days (n = 1 soil, r^2 = 0.992)

IN-A2213 DT_{90lab} (10 °C, aerobic): 71.3 days (n = 1 soil, r^2 = 0.992) IN-D2708 DT_{90lab} (10 °C, aerobic): 219 days (n = 1 soil, r^2 = 0.992) Arrhenius analysis of nine additional data points from two studies published in the scientific literature gives Q_{10} (10-20 °C) values for oxamyl of 1.99, 2.66 and 3.17 (refer to 'Environmental Fate and Behaviour' addendum of June 2004). This suggests that a Q_{10} (10-20 °C) value in the approximate range of 2 to 3 may be more representative for oxamyl than the Q_{10} (10-20 °C) value of 5.5 reported in the original monograph (which was only based on two data points).
Anaerobic soil: Oxamyl DT_{50lab} (25 °C, anaerobic): 6 days (n = 1 soil, r^2 = 0.945) IN-A2213 DT_{50lab} (25 °C, anaerobic): 24 days (n = 1 soil, r^2 = 0.968) IN-D2708 DT_{50lab} (25 °C, anaerobic): 20 days in 1 soil, r^2 = 0.741) Oxamyl DT_{90lab} (25 °C, anaerobic): 19 days (n = 1 soil, r^2 = 0.945) IN-A2213 DT_{90lab} (25 °C, anaerobic): 81 days (n = 1 soil, r^2 = 0.968) IN-D2708 DT_{90lab} (25 °C, anaerobic): 68 days (n = 1 soil, r^2 = 0.741) [Rates are whole-system values (soil and flood water combined).]
Soil photolysis: Oxamyl DT_{50lab} (irradiated samples): 1.7-3.1 days (continuous irradiation) (n = 2 soils, r^2 = 0.88-0.95) Oxamyl DT_{50lab} (dark control samples): 17.3-17.9 days (n = 2 soils, r^2 = 0.43-0.77) Oxamyl DT_{50lab} (corrected): 1.9-3.8 days (n = 2 soils, r^2: not applicable)
Degradation in the saturated zone (10 °C): Oxamyl DT_{50lab} (aerobic): 37->120 days (n = 2 subsoils, r^2 = 0.76 for one subsoil and not calculated for the other subsoil) Oxamyl DT_{50lab} (anaerobic): 0.9-1.7 hours (n = 2 subsoils, r^2 = 0.95 for one subsoil and not calculated

	for the other subsoil) IN-A2213 DT_{50lab} (aerobic): 239-630 days (n = 2 subsoils, r^2 = 0.78-0.83) IN-A2213 DT_{50lab} (anaerobic): 158-231 days (n = 2 subsoils, r^2 = 0.81-0.93) IN-D2708 DT_{50lab} (aerobic): 11-859 days (n = 2 subsoils, r^2 = 0.53-0.83) IN-D2708 DT_{50lab} (anaerobic): 1209-1355 days (n = 2 subsoils; r^2 = 0.29-0.42) IN-N0079 DT_{50lab} (aerobic): 1.1-12.4 days (n = 2 subsoils, r^2 = 0.72-1.00) IN-N0079 DT_{50lab} (anaerobic): 10.7-45.3 days (n = 4 subsoils, r^2 = 0.76-0.89), mean = 29 days
Field studies (state location, range or median with n value)	DT_{50f}: UK, England, Lincolnshire, Spalding (bare soil): Oxamyl $DT_{50field}$: 11.0 days (n = 1, r^2 = 0.969) IN-A2213 $DT_{50field}$: 4.6 days (n = 1, r^2 = 0.969) IN-D2708 $DT_{50field}$: 3.4 days (n = 1, r^2 = 0.969) The Netherlands, Limburg, Ottersum (bare soil): Oxamyl $DT_{50field}$: 9.3 days (n = 1, r^2 = 0.979) IN-A2213 $DT_{50field}$: 1.7 days (n = 1, r^2 = 0.979) IN-D2708 $DT_{50field}$: 6.7 days (n = 1, r^2 = 0.979)
	DT_{90f}: UK, England, Lincolnshire, Spalding (bare soil): Oxamyl $DT_{90field}$: 36.0 days (n = 1, r^2 = 0.969) IN-A2213 $DT_{90field}$: 14.9 days (n = 1, r^2 = 0.969) IN-D2708 $DT_{90field}$: 11.4 days (n = 1, r^2 = 0.969) The Netherlands, Limburg, Ottersum (bare soil): Oxamyl $DT_{90field}$: 30.7 days (n = 1, r^2 = 0.979) IN-A2213 $DT_{90field}$: 5.63 days (n = 1, r^2 = 0.979) IN-D2708 $DT_{90field}$: 22.2 days (n = 1, r^2 = 0.979)
Soil accumulation and plateau concentration	Not applicable

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f/K_{oc} K_d pH dependence (yes/no) (if yes type of dependence)	Oxamyl: K_f: 0.05-0.41 mL/g (mean = 0.18 mL/g, 4 soils) K_{foc}: 4-37 mL/g (mean = 16 mL/g, 4 soils) 1/n: 0.946-1.27 (mean = 1.07, 4 soils) K_d: 0.09-0.44 mL/g (mean = 0.19 mL/g, 5 soils) K_{oc}: 8-39 mL/g (mean = 17 mL/g, 5 soils) [K_{foc} = K_f normalized to organic carbon content, K_{oc} = K_d normalized to organic carbon content] IN-A2213: K_f: 0.048-0.20 mL/g (mean = 0.11 mL/g, 5 soils) K_{foc}: 4-10 mL/g (mean = 7 mL/g, 5 soils) 1/n: 0.87-1.24 (mean = 1.03, 5 soils) K_d: 0.051-0.20 mL/g (mean = 0.11 mL/g, 5 soils) K_{oc}: 4-11 mL/g (mean = 7 mL/g, 5 soils) IN-D2708: K_f: 0.05-0.39 mL/g (mean = 0.17 mL/g, 5 soils) K_{foc}: 6-14 mL/g (mean = 10 mL/g, 5 soils) 1/n: 0.532-0.762 (mean = 0.67, 5 soils) K_d: 0.03-0.31 mL/g (mean = 0.11 mL/g, 5 soils) K_{oc}: 2-10 mL/g (mean = 6 mL/g, 5 soils) IN-N0079 (unstable in the presence of soil): K_f: not calculated K_{foc}: not calculated 1/n: not calculated K_d: 0.03-0.31 mL/g (mean = 0.11 mL/g, 5 soils) K_{oc}: 2-25 mL/g (mean = 8 mL/g, 5 soils) No pH dependence for oxamyl or its metabolites.

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

Column leaching	Not required
Aged residues leaching	Not required
Lysimeter/ field leaching studies	Not required

PEC (soil) (Annex IIIA, point 9.1.3)

Oxamyl

Method of calculation	Kinetics: first order DT_{50} – calculations performed with lab and field values: 5 days (average of normalised first order laboratory values; corrected to a moisture content of pF2 and, where necessary, a temperature of 20 °C) 11 days (longest value from field studies) Soil depth: 10 cm, 20 cm
Application rate	Crop: potatoes % plant interception: none (granule incorporation at time of planting or drilling) Number of applications: 1 Application rate: 5.5 kg a.s./ha

DT_{50} = 11 days

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	3.67 (10 cm) 1.83 (20 cm)	- (10 cm) - (20 cm)	Not applicable	Not applicable
Short term 24h	3.44 (10 cm) 1.72 (20 cm)	3.55 (10 cm) 1.78 (20 cm)	Not applicable	Not applicable
2d	3.23 (10 cm) 1.62 (20 cm)	3.45 (10 cm) 1.72 (20 cm)	Not applicable	Not applicable
4d	2.85 (10 cm) 1.42 (20 cm)	3.24 (10 cm) 1.62 (20 cm)	Not applicable	Not applicable
Long term 7d	2.36 (10 cm) 1.18 (20 cm)	2.96 (10 cm) 1.48 (20 cm)	Not applicable	Not applicable
28d	0.628 (10 cm) 0.314 (20 cm)	1.72 (10 cm) 0.861 (20 cm)	Not applicable	Not applicable
50d	0.157 (10 cm) 0.0785 (20 cm)	1.11 (10 cm) 0.557 (20 cm)	Not applicable	Not applicable
100d	0.00672 (10 cm) 0.00336 (20 cm)	0.581 (10 cm) 0.290 (20 cm)	Not applicable	Not applicable

IN-A2213

Method of calculation	Kinetics: first order DT_{50}: 4 days (average of normalised first order laboratory values; corrected to a moisture content of pF2 and, where necessary, a temperature of 20 °C) Soil depth: 10 cm, 20 cm

Application rate	Crop: potatoes % plant interception: none (granule incorporation at time of planting or drilling) Number of applications: 1 Application rate: 5.5 kg a.s./ha (with IN-A2213 assumed to form at a maximum of 51.0% of the applied dose)

$PEC_{(s)}$ (mg/kg)	Single application Actual (mg/kg)	Single application Time weighted average (mg/kg)	Multiple application Actual (mg/kg)	Multiple application Time weighted average (mg/kg)
Initial	1.38 (10 cm) 0.692 (20 cm)	- (10 cm) - (20 cm)	Not applicable	Not applicable
Short term 24h	1.16 (10 cm) 0.582 (20 cm)	1.27 (10 cm) 0.635 (20 cm)	Not applicable	Not applicable
2d	0.978 (10 cm) 0.489 (20 cm)	1.17 (10 cm) 0.584 (20 cm)	Not applicable	Not applicable
4d	0.692 (10 cm) 0.346 (20 cm)	0.998 (10 cm) 0.499 (20 cm)	Not applicable	Not applicable
Long term d	0.411 (10 cm) 0.206 (20 cm)	0.801 (10 cm) 0.401 (20 cm)	Not applicable	Not applicable
28d	0.0108 (10 cm) 0.00540 (20 cm)	0.283 (10 cm) 0.141 (20 cm)	Not applicable	Not applicable
50d	<0.001 (10 cm) <0.001 (20 cm)	0.160 (10 cm) 0.0798 (20 cm)	Not applicable	Not applicable
100d	<0.001 (10 cm) <0.001 (20 cm)	0.0798 (10 cm) 0.0399 (20 cm)	Not applicable	Not applicable

IN-D2708

Method of calculation	Kinetics: first order DT_{50}: 6 days (average of normalised first order laboratory values; corrected to a moisture content of pF2 and, where necessary, a temperature of 20 °C) Soil depth: 10 cm, 20 cm
Application rate	Crop: potatoes % plant interception: none (granule incorporation at time of planting or drilling) Number of applications: 1 Application rate: 5.5 kg a.s./ha (with IN-D2708 assumed to form at a maximum of 34.7% of the applied dose)

$PEC_{(s)}$ (mg/kg)	Single application Actual (mg/kg)	Single application Time weighted average (mg/kg)	Multiple application Actual (mg/kg)	Multiple application Time weighted average (mg/kg)
Initial	0.679 (10 cm) 0.340 (20 cm)	- (10 cm) - (20 cm)	Not applicable	Not applicable
Short term 4h	0.605 (10 cm) 0.303 (20 cm)	0.642 (10 cm) 0.321 (20 cm)	Not applicable	Not applicable
2d	0.539 (10 cm) 0.270 (20 cm)	0.607 (10 cm) 0.303 (20 cm)	Not applicable	Not applicable
4d	0.428 (10 cm) 0.214 (20 cm)	0.544 (10 cm) 0.272 (20 cm)	Not applicable	Not applicable
Long term 7d	0.303 (10 cm) 0.151 (20 cm)	0.466 (10 cm) 0.233 (20 cm)	Not applicable	Not applicable
28d	0.0267 (10 cm) 0.0134 (20 cm)	0.202 (10 cm) 0.101 (20 cm)	Not applicable	Not applicable
50d	0.00211 (10 cm) 0.00105 (20 cm)	0.117 (10 cm) 0.0586 (20 cm)	Not applicable	Not applicable
100d	<0.001 (10 cm) <0.001 (20 cm)	0.0588 (10 cm) 0.0294 (20 cm)	Not applicable	Not applicable

[An absolute worst-case PEC_S value for any given metabolite can be calculated by assuming 100% conversion of parent to the metabolite and taking no account of the lower molecular mass of the metabolite as compared to the parent. Therefore, for a soil depth of 10 cm, a soil density of 1.5 g/cm^3 and an application of 5.5 kg oxamyl/ha, the maximum possible PEC_S value for any given metabolite of oxamyl is 3.67 mg/kg soil.]

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	
	pH 4 and pH 5 Oxamyl DT_{50} (pH 5, 25 °C): stable (>>31 day) IN-A2213 DT_{50} (pH 4, 20 °C): stable (1386 days) IN-D2708 DT_{50} (pH 4, 20 °C): stable (386 days) IN-N0079 DT_{50} (pH 4, 20 °C): stable (990 days) IN-T2921 DT_{50} (pH 4, 20 °C): stable (>1000 days)
	pH 7 Oxamyl DT_{50} (25 °C): 8 days (first order, r^2 = 0.985) [IN-A2213 = 93.2%, at day 30] IN-A2213 DT_{50} (20 °C): stable (770 days) IN-D2708 DT_{50} (20 °C): stable (981 days) IN-N0079 DT_{50} (20 °C): 136 days (first order, r^2 = 0.96) [IN-T2921 = 1.41%, at day 7; IN-D2708 = 14.17%, at day 30] IN-T2921 DT_{50} (20 °C): stable (>1000 days)
	pH 9 Oxamyl DT_{50} (25 °C): 3 hours (first order, r^2 = 0.898) [IN-A2213 = 83.3% after 7 hours and

	105.6% by day 15] IN-A2213 DT_{50} (20 °C): stable (462 days) IN-D2708 DT_{50} (20 °C): stable (8556 days) IN-N0079 DT_{50} (20 °C): 3 days (first order, r^2 = 0.97) [IN-T2921 = 18.76%, at day 12; IN-D2708 = 78.73%, at day 12] IN-T2921 DT_{50} (20 °C): stable (337 days)
Photolytic degradation of active substance and relevant metabolites	Oxamyl: DT_{50} (pH 5, 25 °C) = 7.4 days continuous irradiation (first order, r^2 = 0.961), with IN-A2213 as the major degradation product (75.3%, at day 16). IN-A2213 stable to further photolysis. [Irradiation with artificial light, stated to be equivalent to summer sunlight in Delaware, USA.] Quantum efficiency in water: 0.01870 (calculated using GCSOLAR photolysis model) Theoretical maximum DT_{50} in the top layer of aqueous systems (for 30° N, 40° N and 50° N and all seasons): ranging from 6.6 days at 30° N in summer to 27.0 days at 50° N in winter (GCSOLAR – first order values) IN-A2213: molar absorptivity (ε) at 290 nm: >10 L/mol·cm (45.2 at pH <2, 56.9 at pH 7, 1110 at pH >10) [photolytic stability demonstrated in oxamyl photolysis study] IN-D2708: molar absorptivity (ε) at 290 nm: <10 L/mol·cm (2.31 at pH <2, 1.01 at pH 7, 0.375 at pH >10) IN-N0079: molar absorptivity (ε) at 290 nm: <10 L/mol·cm (3.28 at pH <2, 5.30 at pH 7, 0.383 at pH >10) IN-T2921: molar absorptivity (ε) at 290 nm: <10 L/mol·cm (6.29 at pH <2, 6.03 at pH 7, 2.11 at pH >10)
Readily biodegradable (yes/no)	No [Mean cumulative CO_2 production by oxamyl test mixtures reached 11% of the theoretical maximum by day 23 and 19% by the end of the test on day 29.]

Degradation in water/sediment	- DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system	Water phase: DT_{50} / DT_{90} values were not calculated. Whole system: [Two different methods used for oxamyl.] Oxamyl DT_{50} = 0.4-1.0 days, oxamyl DT_{90} = 2.8-7.8 days (non-linear multi-compartment fit, n = 2, r^2 = 0.920-0.993) Oxamyl DT_{50} = 0.7-1.1 days, oxamyl DT_{90} = 2.4-3.6 days (non-linear first order fit, n = 2, r^2 = 0.972-0.990) IN-A2213 DT_{50} = 11.4-16.3 days, IN-A2213 DT_{90} = 37.9-54.1 days (linear first order fit, n = 2, r^2 = 0.891-0.930) IN-D2708 DT_{50} = 12.2-169 days, IN-D2708 DT_{90} = 40.5-562 days (linear first order fit, n = 2, r^2 = 0.858-0.957) IN-N0079 DT_{50} = 4.3-13.2 days, IN-N0079 DT_{90} = 14.3-43.9 days (linear first order fit, n = 2, r^2 = 0.712-0.999) IN-T2921 DT_{50} = 2.3-34.5 days, IN-T2921 DT_{90} = 7.8-115 days (linear first order fit, n = 2, r^2: not applicable – only two data points for each fit) [Due to limited partitioning into sediment, whole-system rates essentially represent the degradation rates in the water phase. It was not possible to determine degradation rates for the sediment phase.]

Mineralisation	CO_2 = 27.9-60.9% (at 100 days, study end, n = 2)
Non-extractable residues	Non-extractable residues = 9-18% (at 100 days, study end, n = 2)
Distribution in water / sediment systems (active substance)	Water phase: Oxamyl = 95.8-97.2% (day 0), 36.8-43.1% (day 1) and not detected by day 30 (n = 2 systems) Sediment phase: Oxamyl = <0.1-0.3% (day 1, n = 2), 1.2% (day 61, n = 1) and otherwise not detected [Dosing method – application to water, no mixing]

Distribution in water / sediment systems (metabolites)	IN-A2213: Stream system – maximum level = 48.8% in water (day 2), 4.4% in sediment (day 2) Pond system – maximum level = 25.3% in water (day 2), 2.1% in sediment (day 1) IN-D2708: Stream system – maximum level = 66.8% in water (day 30), 10.4% in sediment (day 30) Pond system – maximum level = 64.2% in water (day 30), 12.1% in sediment (day 61) IN-N0079: Stream system – maximum level = 11.3% in water (day 7), 0.7% in sediment (day 7) Pond system – maximum level = 52.9% in water (day 2), 3.7% in sediment (day 7) IN-T2921: Stream system – maximum level = 8.6% in water (day 14), 0.4% in sediment (day 14) Pond system – maximum level = 11.4% in water (day 14), 0.4% in sediment (day 14) IN-L2953: Stream system – maximum level = 1.8% in water (day 100), 0.2% in sediment (day 7, day 14) Pond system – maximum level = 3.8% in water (day 7), 0.1% in sediment (day 7, day 14, day 100) PROD1 (unidentified degradate): Stream system – maximum level = 0.3% in sediment (day 7), not detected in water Pond system – maximum level = 0.8% in sediment (day 14), not detected in water [Dosing method – application to water, no mixing]

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

Method of calculation	FOCUS surface water modelling tools (officially released versions): Step 1 and Step 2 calculations performed for oxamyl, IN-A2213 and IN-D2708 (FOCUS Steps 1-2 calculator – version 1.1) Step 3 calculations for oxamyl (FOCUS SWASH version 1.1 – Drift calculator version 1.1, MACRO version 4.4.2, PRZM version 1.1.1, and TOXSWA version 1.1.1) Calculations based on average first order DT_{50} values for soil (determined from the aerobic laboratory studies with viable soil, corrected to pF2 moisture and 20 °C), maximum water/sediment whole-system DT_{50} values (first order) and averaged sorption data (K_{foc}, 1/n).
Application rate	Soil incorporation (granules) at time of planting or drilling potatoes) Number of applications: 1 per season Application rate: 5.5 kg a.s./ha (with IN-A2213 assumed to form in soil and water/sediment at maximum respective levels of 51.0% and 53.2% of the applied dose, and IN-D2708 assumed to form in soil and water/sediment at maximum respective levels of 34.7% and 77.2% of the applied dose)
Main routes of entry	Drainage and runoff (using FOCUS assumptions for Steps 1-2 and relevant FOCUS scenarios for Step 3) 0% spray drift

Maximum and 21-day TWA PEC_{SW} values from Step 1 and Step 2 for oxamyl, IN-A2213 and IN-D2708

Simulation	Compound	Maximum PEC_{SW} (µg/L)	21-day TWA PEC_{SW} (µg/L)
Step 1	oxamyl	1800	138
	IN-A2213	685	453
	IN-D2708	335	321
Step 2 (northern Europe, March-May)	oxamyl	206	16.1
	IN-A2213	68.5	45.3
	IN-D2708	42.2	40.5
Step 2 (southern Europe, March-May)	oxamyl	412	32.2
	IN-A2213	137	90.6
	IN-D2708	84.5	80.9
Step 2 (southern Europe, June-September)	oxamyl	309	24.1
	IN-A2213	103	68.0
	IN-D2708	63.4	60.7

TWA = time-weighted average
Application timings for Step 2 were based on the potato cropping dates defined for the FOCUS Step 3 scenarios.

Maximum and 21-day TWA PEC_{SW} values from Step 3 for oxamyl

Simulation	Maximum PEC_{SW} (µg/L)	21-day TWA PEC_{SW} (µg/L)
1 (D3-ditch)	0.003	0.003
2 (D4-pond)	0.029	0.015
3 (D4- stream)	0.377	0.198
4 (D6-ditch-crop1)	0.169	0.039
5 (D6-ditch-crop2)	0.088	0.023
6 (R1-pond)	0.066	0.010
7 (R1-stream)	11.697	0.247
8 (R2-stream)	10.286	0.356
9 (R3-stream)	126.043	2.633

TWA = time-weighted average
The possibility of two potato crops per year was considered for D6. The two crops were simulated independently, since oxamyl would not be applied to the same field twice in one year.

(Initial PEC_{SW} values for metabolites IN-N0079 and IN-T2921 were calculated based on the maximum Step 2 PEC_{SW} value for oxamyl (412 µg/L – southern Europe, March-May). The calculations took account of the lower molecular mass of the metabolites as compared to the parent (219.26 g/mole for oxamyl, 98.10 g/mole for IN-N0079 and 116.12 g/mole for IN-T2921) and assumed immediate conversion of oxamyl to the metabolite concerned, using the maximum detected level of the substances in the water phase of the water/sediment systems (52.9% for IN-N0079 and 11.4% for IN-T2921). This procedure resulted in initial PEC_{SW} values of 97.5 µg/L for IN-N0079 and 24.9 µg/L for IN-T2921.)

PEC (sediment)

Method of calculation	FOCUS surface water modelling tools (officially released versions): Step 1 and Step 2 calculations performed for oxamyl, IN-A2213 and IN-D2708 (FOCUS Steps 1-2 calculator – version 1.1) Step 3 calculations for oxamyl (FOCUS SWASH version 1.1 – Drift calculator version 1.1, MACRO version 4.4.2, PRZM version 1.1.1, and TOXSWA version 1.1.1) Entry routes: drainage and runoff to surface water bodies (using FOCUS assumptions for Steps 1-2 and relevant FOCUS scenarios for Step 3) 0% spray drift Calculations based on average first order DT_{50}

	values for soil (determined from the aerobic laboratory studies with viable soil, corrected to pF2 moisture and 20 °C), maximum water/sediment whole-system DT_{50} values (first order) and averaged sorption data (K_{foc}, 1/n).
Application rate	Soil incorporation (granules) at time of planting or drilling potatoes) Number of applications: 1 per season Application rate: 5.5 kg a.s./ha (with IN-A2213 assumed to form in soil and water/sediment at maximum respective levels of 51.0% and 53.2% of the applied dose, and IN-D2708 assumed to form in soil and water/sediment at maximum respective levels of 34.7% and 77.2% of the applied dose)

Maximum and 21-day TWA PEC_{SED} values from Step 1 and Step 2 for oxamyl, IN-A2213 and IN-D2708

Simulation	Compound	Maximum PEC_{SED} (µg/kg)	21-day TWA PEC_{SED} (µg/kg)
Step 1	oxamyl	287	22.0
	IN-A2213	48.0	31.7
	IN-D2708	33.5	32.1
Step 2 (northern Europe, March-May)	oxamyl	33.0	2.58
	IN-A2213	4.80	3.17
	IN-D2708	4.22	4.05
Step 2 (southern Europe, March-May)	oxamyl	66.0	5.15
	IN-A2213	9.59	6.34
	IN-D2708	8.45	8.09
Step 2 (southern Europe, June-September)	oxamyl	49.5	3.86
	IN-A2213	7.19	4.76
	IN-D2708	6.34	6.07

TWA = time-weighted average
Values expressed on a dry weight basis.
Application timings for Step 2 were based on the potato cropping dates defined for the FOCUS Step 3 scenarios.

Maximum and 21-day TWA PEC_{SED} values from Step 3 for oxamyl

Simulation	Maximum PEC_{SED} (µg/kg)	21-day TWA PEC_{SED} (µg/kg)
1 (D3-ditch)	0.001	0.001
2 (D4-pond)	0.004	0.002
3 (D4- stream)	0.050	0.029
4 (D6-ditch-crop1)	0.015	0.005
5 (D6-ditch-crop2)	0.007	0.002
6 (R1-pond)	0.006	0.002
7 (R1-stream)	0.761	0.042
8 (R2-stream)	0.828	0.060
9 (R3-stream)	6.402	0.483

TWA = time-weighted average
Values expressed on a dry weight basis.
The possibility of two potato crops per year was considered for D6. The two crops were simulated independently, since oxamyl would not be applied to the same field twice in one year.

PEC (groundwater) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	Modelling using FOCUS groundwater scenarios with FOCUS_PRZM_2.2.1 and FOCUS_PEARL_1.1.1. Crop: potatoes (all 9 FOCUS scenarios are relevant) Calculations based on average first order DT_{50} values for soil (determined from the aerobic laboratory studies with viable soil, corrected to pF2 moisture and 20 °C) and averaged Freundlich sorption data (K_{foc} or K_{fom}, 1/n). [DT_{50} = 5 days for oxamyl, 4 days for IN-A2213 and 6 days for IN-D2708; K_{foc} = 16 mL/g for oxamyl, 7 mL/g for IN-A2213 and 10 mL/g for IN-D2708; 1/n = 1.07 for oxamyl, 1.03 for IN-A2213 and 0.67 for IN-D2708] Degradation scheme: oxamyl → IN-A2213 → IN-D2708 (linear sequence of first order reactions, with average molar conversion fraction of 0.950 for the first step and 0.956 for the second step – obtained from ModelManager regression outputs for the degradation rate calculations)

Application rate	Time of application: planting dates for potatoes in FOCUS scenarios [15 January (Sevilla) to 15 May (Jokioinen)] Application regime: single application each year for 20 consecutive years Application rate: 5.5 kg oxamyl/ha Simulated time period: 26 years (warm-up period of 6 years, followed by 20 years of simulation)

$PEC_{(gw)}$

Maximum concentration	Maximum 80th percentile annual average concentrations at 1 m depth FOCUS_PRZM_2.2.1: Oxamyl = 0.86 µg/L (Piacenza scenario) IN-A2213 = 1.1 µg/L (Piacenza scenario) IN-D2708 = 1.4 µg/L (Piacenza scenario) FOCUS_PEARL_1.1.1: Oxamyl = 2.7 µg/L (Piacenza scenario) IN-A2213 = 5.4 µg/L (Piacenza scenario) IN-D2708 = 8.7 µg/L (Piacenza scenario)
Average annual concentration	Median 80th percentile annual average concentrations at 1 m depth (n = 9 scenarios) FOCUS_PRZM_2.2.1: Oxamyl = 0.0077 µg/L (Hamburg scenario) IN-A2213 = 0.023 µg/L (Hamburg scenario) IN-D2708 = 0.001 µg/L (Kremsmünster or Sevilla scenario) FOCUS_PEARL_1.1.1: Oxamyl = 0.095 µg/L (Châteaudun scenario) IN-A2213 = 0.28 µg/L (Hamburg scenario) IN-D2708 = 0.54 µg/L (Sevilla scenario)

80th percentile PEC_{GW} values at 1 m depth for oxamyl, IN-A2213 and IN-D2708

FOCUS scenario	FOCUS_PRZM_2.2.1 (µg/L)			FOCUS_PEARL_1.1.1 (µg/L)		
	Oxamyl	IN-A2213	IN-D2708	Oxamyl	IN-A2213	IN-D2708
Châteaudun	<0.001	0.0013	<0.001	0.095	0.31	0.44
Hamburg	0.0077	0.023	0.017	0.093	0.28	0.62
Jokioinen	0.044	0.19	0.018	0.11	0.24	0.24
Kremsmünster	0.0018	0.0052	0.001	0.060	0.18	0.67
Okehampton	0.020	0.057	0.045	0.14	0.44	0.85
Piacenza	0.86	1.1	1.4	2.7	5.4	8.7
Porto	0.001	0.0036	<0.001	0.035	0.17	0.0050
Sevilla	0.011	0.038	0.001	0.29	0.71	0.54
Thiva	<0.001	<0.001	<0.001	0.0030	0.0070	0.0020
Median	0.0077	0.023	0.001	0.095	0.28	0.54

New modelling required taking into account slow degradation under acidic soils.

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

Direct photolysis in air	Not determined – no data requested
Quantum yield of direct phototransformation	Not determined in air (0.01870 in water)
Photochemical oxidative degradation in air	DT_{50} = 5.68 hours (Atkinson method)
Volatilisation	from plant surfaces: not applicable (oxamyl is applied as a soil-incorporated granule)
	from soil: volatilisation loss of oxamyl estimated to be <0.0005% of the applied amount within 24 hours after treatment (Dow method)

PEC (air)

Method of calculation	Expert judgement based on vapour pressure, Henry's Law Constant, method of application, photochemical oxidative half-life in air and "Dow method" estimation of volatilisation loss from soil.

$PEC_{(a)}$

Maximum concentration	Negligible

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil: Oxamyl only (IN-A2213, IN-D2708, IN-N0079 and IN-T2921 adjudged not to be relevant in soil) Water: Oxamyl only (IN-A2213, IN-D2708, IN-N0079 and IN-T2921 adjudged not to be relevant in water) Air: No residue

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

Soil (indicate location and type of study)	Relevant European data not available
Surface water (indicate location and type of study)	Relevant European data not available
Ground water (indicate location and type of study)	UK (Anglia and Wales) – groundwater monitoring data from the UK Environment Agency database for 1992-1997 Wales: 26 samples analysed – oxamyl <0.1 µg/L in all cases Anglia: 169 samples analysed – oxamyl >0.1 µg/L in 3 cases (0.18, 0.329 and 0.541 µg/L)
Air (indicate location and type of study)	Not available

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	No classification necessary

Appendix 1.6: Effects on non-target Species

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

Acute toxicity to mammals	LD_{50} = 2.5 mg a.s./kg bw (Rat)
Reproductive toxicity to mammals	NOEC = 1.43 mg a.s./kg bw (Rat)
Acute toxicity to birds	LD_{50} = 3.16 mg a.s./kg bw (Mallard Duck)
	LD_{50} = 9.5 mg a.s./kg bw (BobWhite Quail)
Dietary toxicity to birds	LC_{50} = 340 mg a.s./kg diet (Mallard Duck)
	LC_{50} = 766 mg a.s./kg diet (BobWhite Quail)
Reproductive toxicity to birds	NOEC = 50 mg a.s./kg diet (Mallard Duck)
	NOEC = 10 mg a.s./kg diet (Bobwhite Quail)

Toxicity/exposure ratios for Birds and Mammals (Annex IIIA, points 10.1 and 10.3)

The risk to birds and mammals is assessed by the RMS according to the revised EPPO scheme for terrestrial vertebrates (02/9285 revised, September 2002).
The risk to birds was discussed in the EPCO 8 Expert meeting in June 2004 and the used approach was not accepted by this meeting. The data available at the moment of EPCO meeting 8 indicate a high acute risk to small birds from the ingestion of granules. A much more detailed risk assessment is needed and therefore a new data requirement was set at the EPCO meeting for a refined avoidance study using Vydate 10G and conducted with relevant birds for European agricultural landscapes under more realistic exposure conditions. Due to comments received on the DAR during the commenting period, 2 more data requirements were set at the evaluation meeting in March 2004. These data were made available to the RMS after the EPCO 8 meeting and are not evaluated by the RMS. The first data requirement concerns the submission of the full study report providing information on the number of granules available on the soil surface and the second concerns the submission of the full report of the study on the release of the active ingredient from the granule (DuPont-3025).

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

Test Substance	**Test organism**	**Exposure Period**	**Measurement endpoint**	**Endpoint value (mg a.s./L)**
Oxamyl	*Oncorhynchus mykiss*	96 hr	LC_{50}	3.13
Oxamyl 10GR	*Lepomis macrochirus*	96 hr	LC_{50}	3.6
Oxamyl	*Pimephales promelas*	28 day	NOEC	0.5
Oxamyl	*Daphnia magna*	48 hr	EC_{50}	0.319
Oxamyl	*Daphnia magna*	21 day	NOEC	0.0268
Oxamyl	*Selenastrum capricornutum*	72 hr	EC_{50}	0.931

Test Substance	Test organism	Exposure Period	Measurement endpoint	Endpoint value (mg a.s./L)
IN-A2213	*O. mykiss*	96 hr	LC_{50}	>132
IN-A2213	*D. magna*	48 hr	EC_{50}	>125
IN-A2213	*S. capricornutum*	72 hr	EC_{50}	>122
IN-D2708	*O. mykiss*	96 hr	LC_{50}	93.8
IN-D2708	*D. magna*	48 hr	EC_{50}	>134
IN-D2708	*D. magna*	21 day	NOEC	66.1
IN-D2708	*S. capricornutum*	72 hr	EC_{50}	13.7
IN-N0079	*O. mykiss*	96 hr	LC_{50}	22.4
IN-N0079	*D. magna*	48 hr	EC_{50}	>128
IN-N0079	*S. capricornutum*	72 hr	EC_{50}	8.71
IN-T2921	*O. mykiss*	96 hr	LC_{50}	>127
IN-T2921	*D. magna*	48 hr	EC_{50}	>123
IN-T2921	*S. capricornutum*	72 hr	EC_{50}	>113

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

Compound	Test Organism	Exposure Period	EC50 or LC50 (mg/l)	Surface Water Scenario	Max PECsw (µg/l)	TERs	Annex VI Trigger
Acute Toxicity							
Oxamyl	Daphnia magna	48h	0.319	Step 3: D3-ditch D4-Pond D4-Stream D6-Ditch (1st crop) D6-Ditch (2nd crop) R1-pond R1-stream R2-Stream R3 Stream	 0.003 0.029 0.377 0.169 0.088 0.066 11.697 10.286 126.043	 106333 11000 846 1888 3626 4833 **27** **31** **3**	100
IN-A2213	Daphnia magna	48h	>125	Step 1:	685	>182	100
IN-D2708	O. mykiss	96h	93.8	Step 1:	335	280	100

Compound	Test Organism	Exposure Period	EC50 or LC50 (mg/l)	Surface Water Scenario	Max PECsw (µg/l)	TERs	Annex VI Trigger
Chronic Toxicity							
Oxamyl	Daphnia magna	21d	0.0268	Step 3:			10
				D3-ditch	0.003	8933	
				D4-Pond	0.029	924	
				D4-Stream	0.377	71	
				D6-Ditch (1st crop)	0.169	158	
				D6-Ditch (2nd crop)	0.088	304	
				R1-pond	0.066	406	
				R1-stream	11.697	**2.26**	
				R2-Stream	10.286	**2.61**	
				R3 Stream	126.043	**0.21**	
IN-D2708	Daphnia magna	21d	66.1	Step 1:	335	197	10

Acceptable TER values were calculated for the metabolites IN-N0079 and IN-T2921 using the PEC_{sw} values reported in the Fate and Behaviour chapter in the list of endpoints (97.5µg/L and 24.9 respectively). Values of 230 and >4940 were obtained for IN-N0079 and IN-T2921 respectively (using acute effects endpoints of 22.4 mg/L for IN-N0079 and >123 mg/L for IN-T2921.

Bioconcentration

Bioconcentration factor (BCF)	Not required as Log Pow= -0.44
Annex VI Trigger for the bioconcentration factor:	Not applicable
Clearance time (CT_{50}) (CT_{90})	Not applicable
Level of residues (%) in organisms after the 14 day depuration phase	Not applicable

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

Oxamyl tech.	
Acute oral toxicity	0.38 µg a.s./bee
Acute contact toxicity	0.47 µg a.s./bee
Oxamyl 10SL	
Acute contact toxicity	0.26 µg a.s./bee
Acute contact toxicity	0.23 µg a.s./bee

Hazard quotients for honeybees (Annex IIIA, point 10.4)

Application rate (g as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
5.5	Potatoes	Oxamyl Tech. Oral Contact Oxamyl 10SL Oral Contact	 14474 11702 21154 23913	 >50 >50 >50 >50
Field or semi-field tests				
Not required as residues will not arise in plant tissue, therefore, no exposure to bees from oxamyl residues is expected. Although oxamyl has been shown to be toxic to honey bees in the laboratory, field exposure will be very limited because it is formulated as a granule and incorporated in to the soil immediately after application (potatoes). Oxamyl shows systemic activity, being translocated within the plant and so there is the possibility of exposure of foraging bees via the nectar of treated crops. Although potatoes may be actively foraged by bees, they are not a preferred food source because they only produce pollen (not nectar). Also, the time elapsed from planting to flowering is such that the Oxamyl 10 GR residues will have dissipated to a considerable extent. Accordingly, it is considered that there will not be a significant risk to honey bees from the recommended use of Oxamyl 10 GR. It can be concluded that Oxamyl 10 GR will not be a significant risk to honey bees when used according to Good Agricultural Practice."				

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

Species	Test Substance	Test	Measurement endpoint	Endpoint value
Aphidius rhopalosiphi	Oxamyl 10 SL[1]/ dose-response	Tier 1 (glass)	48 hr LR_{50}: 48 hr LR_{30}: 30% Effect on Reproduction:	0.03 g Oxamyl/ha 0.005 g Oxamyl/ha ≥0.01 g Oxamyl/ha
Typhlodromus pyri	Oxamyl 10 SL[1]/ dose-response	Tier 1 (glass)	7 d LR_{50}: 7-d LR_{30}: 30% Effect on Reproduction:	1.8 g Oxamyl/ha 1.0 g Oxamyl/ha ≥0.8 g Oxamyl/ha
Poecilus cupreus	Oxamyl 10 GR (3.85 mg Oxamyl/kg dry soil)	Tier 2 (LUFA 2.1 soil)	14-d Corrected Mortality: Reduction in Feeding Rate (relative to controls):	0% +141%

Species	Test Substance	Test	Measurement endpoint	Endpoint value
Aleochara bilineata	Oxamyl 10 GR (3.85 mg Oxamyl/kg dry soil)	Tier 2 (LUFA 2.1 soil)	7-d Mortality: 0 d aged soil 7 d aged soil 14 d aged soil 28 d aged soil Reduction in Reproduction (relative to controls): 0 d aged soil 7 d aged soil 14 d aged soil 28 d aged soil	 0% 2.5% 0% 0% 40.4% 31.8% 24.6% 13.4%
Pardosa spp.	Oxamyl 10 GR (3.85 mg Oxamyl/kg dry soil)	Tier 2 (LUFA 2.1 soil)	14-d Corrected Mortality: Reduction in Feeding Rate (relative to controls):	17.6% 0%

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

Test Substance Component	Duration of test (days)	LC_{50} (mg test substance/kg soil)	PEC_{soil} (mg Oxamyl/kg soil)		TER_a	
			10 cm	20 cm	10 cm	20 cm
Acute						
Oxamyl a.s.	14	112	3.67	1.83	30.5	61.2
IN-A2213	14	>1,000	1.38	0.69	>725	>1,450
IN-D2708	14	>1,000	0.68	0.34	>1,470	>2,940
IN-N0079[1]	14	640	3.67	1.83	174.4	349.7
IN-T2921[1]	14	>1,000	3.67	1.83	272.5	546.4
Oxamyl 10 GR	14	>100	3.67	1.83	>27	>55
Chronic (based on NOEC)						
Oxamyl 10 GR	56	>6.4	3.67	1.83	**>1.7**	**>3.5**
Oxamyl 10 GR	56	< 7.0	3.67	1.83	**<1.9**	**<3.8**
Field Study The study has been submitted to the RMS and was evaluated by the RMS in the addendum of October 2004 but not peer reviewed						

[1] Worst case estimation considering 100 % conversion and no molecular weight correction.

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

Nitrogen mineralization	Effect < 25% at 5 mg a.s./kg soil for oxamyl Effect < 25% at 49 mg:kg soil for IN-A2213 Effect < 25% at 36 mg/kg soil for IN-D2708 Effect < 25% at 30 mg/kg soil for IN-N0079 Effects < 25% at 35.3 mg/kg soil for IN-T2921 Effects < 25% at 27.5 kg a.s./ha for Oxamyl 10 GR
Carbon mineralization	Effect < 25% at 10 mg a.s./kg soil for oxamyl Effect < 25% at 49 mg:kg soil for IN-A2213 Effect < 25% at 36 mg/kg soil for IN-D2708 Effect < 25% at 30 mg/kg soil for IN-N0079 Effects < 25% at 35.3 mg/kg soil for IN-T2921 Effects < 25% at 27.5 kg a.s./ha for Oxamyl 10 GR

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	Classification:	Dangerous for the environment
	Label:	
	Symbol:	N
	Indication of danger:	Dangerous for the environment
	Risk phrase:	R50/53– Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	Safety phrases:	S61

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
bw	body weight
°C	degree Celsius (centigrade)
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
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)
GLP	good laboratory practice
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

MHC	moisture holding capacity
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
NOEL	no observed effect level
OC	organic carbon content
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
pH	pH-value
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
TWA	time weighted average
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year