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CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance metaldehyde[1]

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SUMMARY

Metaldehyde is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by Austria, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of metaldehyde in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 5 December 2008 (2008/934/EC)[5] concerning the non-inclusion of metaldehyde in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Lonza GmbH made a resubmission application for the inclusion of metaldehyde in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Austria, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 5 January 2010

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 7 January 2010. The EFSA collated and forwarded all comments received to the Commission on 22 February 2010

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the areas of mammalian toxicology and ecotoxicology and to deliver its conclusions on metaldehyde.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of metaldehyde as a molluscicide in cereals (rye, oat, wheat, barley, and triticale)

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1 On request from the European Commission, Question No EFSA-Q-2010-00678, issued on 11 October 2010.
2 Correspondence: praper@efsa.europa.eu
3 OJ L224, 21.08.2002, p.25
4 OJ L 246, 21.9.2007, p. 19
5 OJ L 333, 11.12.2008, p.11
6 OJ L 15, 18.01.2008, p.5

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and oilseed rape, as proposed by the applicant. Full details of the representative uses can be found in Appendix A.

No area of concern or data gap was identified in the physical chemical properties section.

No area of concern or data gap was identified in the mammalian toxicology section.

For residues there are no critical areas of concern and the risk assessment is finalised.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at the EU level, for the representative uses assessed, however it should be noted that the assessment is specific to the particular formulated product ‘Metarex’ only. It is therefore inappropriate to extrapolate the environmental exposure assessment presented to any other products containing metaldehyde. The potential for groundwater exposure by metaldehyde, from the representative uses of the formulated product ’Metarex’ in cereals and spring sown oilseed rape, above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all the pertinent FOCUS groundwater scenarios (up to 9). For the representative use of ‘Metarex’ on autumn sown (winter) oilseed rape, the modelling results for 5 out of the 6 FOCUS groundwater scenarios indicated a low potential for groundwater exposure above 0.1 µg/L. Under the geoclimatic conditions represented by the Piacenza scenario, contamination of groundwater by parent metaldehyde above 0.1 µg/L cannot be excluded.

A high acute and long-term risk was assessed for birds and mammals. A data gap was identified to provide new acute and long-term risk assessments for birds from all routes of exposure for all representative uses. Moreover, a data gap was identified to provide a new acute and long-term risk assessment for granivorous mammals for all representative uses. The risk to other non-target organisms was assessed as low.

KEY WORDS

Metaldehyde, peer review, risk assessment, pesticide, molluscicide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002[7], as amended by Commission Regulation (EC) No 1095/2007[8] lays down the detailed rules for the implementation of the third stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant(s) for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

Peer review conducted in accordance with Commission Regulation (EC) No 1490/2002

Metaldehyde is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, Austria, which was received by the EFSA on 7 February 2006 (Austria, 2006).

The peer review was initiated on 1 September 2006 by dispatching the DAR to Member States and the applicant Lonza GmbH for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of metaldehyde in Annex I to Council Directive 91/414/EEC.

Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of metaldehyde in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Lonza GmbH made a resubmission application for the inclusion of metaldehyde in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18, Austria, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 5 January 2010 (Austria, 2009).

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 7 January 2010. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 22 February 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments

[7] OJ L224, 21.08.2002, p.25
[8] OJ L246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 333, 11.12.2008, p.11

in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 24 March 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on metaldehyde within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 7 April 2010; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology and ecotoxicology, and that further information should be requested in the those sections.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in September 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a molluscicide on cereals (rye, oat, wheat, barley, and triticale) and oilseed rape, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2010) comprises the following documents:

- the comments received on the DAR and the Additional Report,
- the Reporting Tables (DAR and AR revision 1-1; 7 April 2010),
- the Evaluation Table (11 October 2010),
- the reports of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of September 2010 containing all individually submitted addenda (Austria, 2010)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Metaldehyde is the common name for the chemical *r*-2,*c*-4,*c*-6,*c*-8-tetramethyl-1,3,5,7-tetroxocane or 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane (IUPAC). No ISO common name is required.

The representative formulated product for the evaluation was 'Metarex', a ready to use bait (RB), which contains 50 g/kg metaldehyde.

The representative uses evaluated are spreading (manually or with fertiliser spreader) on cereals (rye, oat, wheat, barley and triticale) and oilseed rape to control slugs and snails. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of metaldehyde should not be less than 985 g/kg. Acetaldehyde was considered as a relevant impurity, with a maximum content of 1.5 g/kg in the manufactured active substance. There is currently no FAO specification for metaldehyde.

The main data regarding the identity of metaldehyde and its physical and chemical properties are given in Appendix A. The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of metaldehyde or the respective formulation.

Adequate analytical methods are available for the determination of metaldehyde in the technical material and in the representative formulation.

Residues of metaldehyde in plants can be analysed by GC-MSD (enforcement method) or GC-MS/MS. In products of animal origin no analytical method for metaldehyde is necessary since there are no MRLs proposed. Soil and water are analysed for metaldehyde using also GC-MSD or GC-MS/MS and air by GC-MSD. An analytical method for body fluids and tissues is not required since metaldehyde is not classified as toxic or very toxic.

2. Mammalian toxicity

Metaldehyde was discussed during the PRAPeR 79 mammalian toxicology experts' meeting in July 2010. It can be considered that the batches used for the toxicological studies cover the proposed levels of impurities in the technical specification. The impurity acetaldehyde has to be considered toxicologically relevant but is not of concern at the proposed level.

Harmful after a single oral dose in rats (**Xn, R22** *Harmful if swallowed*), metaldehyde has a low acute toxicity after dermal exposure, is not irritant to the skin or eyes, and is not a skin sensitiser. After repeated administration, the target organs were the testes and the prostate in dogs, and the liver in rats and mice. Neurological signs were observed at acute toxic doses in rats, dogs and rabbit; and some deaths also occurred in dogs at 30 mg/kg bw/d, leading to the proposed classification of **Xn, R48/22** *Harmful: danger of serious damage to health by prolonged exposure if swallowed*. The relevant short-term NOAELs are 21 mg/kg bw/day for the rat (3-month study) and 10 mg/kg bw/day for the dog (1-year study, with also a NOAEL for acute neurological findings of 30 mg/kg bw/day). For the mouse, only a LOAEL of 19 mg/kg bw/day is identified in the 3-month range-finding study, based on histopathological findings in the liver at 54 mg/kg bw/day.

Based on the available data, metaldehyde has no genotoxic or carcinogenic potential relevant to humans. The agreed long-term NOAELs are 2 mg/kg bw/day for the rat (2-year study) and 16 mg/kg bw/day for the mouse (78-week study). In the rat multigeneration study, metaldehyde did not affect the fertility or reproductive parameters. The parental NOAEL is 3.2 mg/kg bw/day, whereas the offspring NOAEL is 65 mg/kg bw/day and the reproductive NOAEL is 134 mg/kg bw/day. In the developmental studies with rats and rabbits, no fetotoxicity or teratogenicity was observed in either species. In neurotoxicity studies with rats, the acute NOAEL is 75 mg/kg bw and the 90-day NOAEL for systemic toxicity and neurological findings (loss of hind limb function, attributed to spinal cord injury, not histopathologically investigated) is 39 mg/kg bw/day.

The agreed **Acceptable Daily Intake** (ADI) is 0.02 mg/kg bw/day based on the 2-year rat study, the **Acceptable Operator Exposure Level** (AOEL) is 0.1 mg/kg bw/day based on the 52-week dog study, and the **Acute Reference Dose** (ARfD) is 0.3 mg/kg bw based on the acute neurological findings observed from the first week of the 52-week dog study. All reference values were derived with the use of a safety factor of 100. Considering the PHED model for granule application, including by default the use of gloves and protective clothing, the operator exposure estimates are below the AOEL for tractor-mounted equipment or hand-held equipment (belly grinder). Since the tractor-mounted equipment is broadcast application, lodging of granular bait in the foliage of oilseed rape cannot be excluded (see also section 3). The exposure of re-entry workers to these lodged granular baits has not been assessed, however it is unlikely that such an exposure would represent a concern. Due to the lack of data, the use of gloves might be considered. With regard to the bystander, the estimated systemic exposure is considered to be negligible.

3. Residues

In the DAR (Austria, 2006) metabolism studies on sugar beet (root vegetables), strawberries (fruits), lettuce (leafy crops) and rice (cereals) have been evaluated. In the Additional Report metabolism studies on wheat and oilseed rape were provided to support the representative uses on cereals (rye, oat, wheat, barley and triticale) and oilseed rape in order to confirm the results of the metabolism studies already submitted. The metabolism data demonstrate that metaldehyde is extensively metabolised with natural incorporation of its carbon atoms. No significant metabolites were present. Therefore the residue definition is metaldehyde for both risk assessment and monitoring.

Residues in rotational crops will not occur because the values for the degradation potential of metaldehyde in soil (DT_{90} = 8.5 – 22.1 days) and the DT_{90} for the release of metaldehyde from the ‘Metarex’ granular baits is 61.37 days. Less than 10 % of the applied active substance remains in soil after 100 days based on the PEC (soil) values of 0.933 mg/kg (day 0) and <0.001 mg/kg (day 100). Thus, no residues in edible portions of succeeding crops are expected, and confined rotational crop studies are therefore not considered necessary.

The need for animal metabolism data is not triggered, however a lactating goat study was provided. The goat metabolism study revealed that radioactive residues of metaldehyde (administered even at exaggerated doses) are exhaled via CO_2 (58.9% and 58.1% of the total applied dose in the low dose and high dose animal, respectively) and that remaining radioactivity is broken down and incorporated into natural products such as fatty acids, amino acids and carbohydrates.

The proposed GAP is for the EU; however, residue trials are only available for northern Europe. Therefore a data gap was identified for residue trials for southern Europe. Sixteen trials are available for wheat, residues were at the LOQ of either 0.01 mg/kg or 0.05 mg/kg. For oilseed rape there are eleven acceptable trials 7 x 0.01, 1 x 0.14, 2 x 0.06 and 1 x 0.53. The positive results are from lodging of granular bait in the leaves, which in practice will be a rare occurrence for a crop like oilseed rape. The positive residues are in part a factor of the small plot size used in residue trials. Therefore in agricultural practice, with the bulk harvesting of oilseed rape, no significant residues will occur. There is also a large margin of safety to the ADI and ARfD. This cannot be considered the case for more open crops like lettuce where positive residues would be expected. In freezer storage stability studies metaldehyde was shown to be stable in wheat grain for 18 months and rape seed for 24 months.

For the consumer risk assessment intakes were less than 1% of the ADI, and $\leq$ 0.2 % of the ARfD.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, metaldehyde initially does not degrade, but after a lag phase of up to 19 days, it exhibited low persistence, forming no major (>10% applied radioactivity (AR)) metabolites[11]. No metabolite accounted for >5% AR, a trigger pertinent for groundwater exposure assessment following European Commission (2003) guidance. Mineralisation of the carbon radiolabels (all carbons uniformly labelled) to carbon dioxide accounted for 50 - 78 % AR after 22-60 days (termination times of the incubations). The formation of unextractable residues (not extracted using methanol) for these radiolabels accounted for 13 – 20 % AR after 60 days. In anaerobic soil incubations metaldehyde was essentially stable. Metaldehyde exhibited high to very high mobility in soil. There was no evidence of pH dependent adsorption.

The representative product assessed, ‘Metarex’, is formulated as a granular bait. Satisfactory data on the kinetic release rate of metaldehyde from this specific product was provided and used to appropriately parameterise the FOCUS models and calculate the soil predicted environmental concentrations (PEC, as presented in Appendix A). It is important to note that these PECs in soil, surface water, sediment and groundwater are specific to the release rate characteristics of the formulated ‘Metarex’ product only. Therefore, the PECs in this conclusion should not be extrapolated to other products, as these will exhibit different release kinetics. Data on release rates from each different formulated product will be required for the calculation of PECs specific for each product.

In laboratory incubations in dark aerobic natural sediment water systems (four systems investigated), metaldehyde exhibited low to very high persistence. In the 2 systems where metaldehyde exhibited low persistence (where conditions were more oxidising, as indicated by the negative sediment redox potentials measured for the pertinent systems), the major metabolite acetaldehyde was formed (max. ca. 22 % AR in water and 5% in sediment). In these systems acetaldehyde exhibited moderate persistence. In the two less oxidising systems metaldehyde exhibited very high persistence and no major metabolites were formed. The unextractable sediment fraction (not extracted using methanol or dichloromethane) was a sink for the carbon radiolabels (all carbons uniformly labelled), accounting for 0.6 – 19 % AR at study end (97-100 days). Mineralisation of these radiolabels accounted for 5-8 % AR in the lower oxidation state systems and 62-69% AR under the more oxidising systems, at the end of the studies. The necessary surface water and sediment exposure assessments (PEC) were carried out for metaldehyde using the FOCUS (FOCUS, 2001) steps 1 to 3[12] approach with step 3 approaches being in accordance with EFSA, 2004b. PEC surface water and sediment were calculated for acetaldehyde by taking the maximum PEC calculated at step 3 for metaldehyde and factoring them for the maximum formation measured (% AR) in the sediment water studies.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and the models PEARL 3.3.3 and PELMO 3.3.2[13] for the active substance metaldehyde. The potential for groundwater exposure by metaldehyde, from the representative uses assessed on cereals and spring sown oilseed rape, above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all pertinent FOCUS groundwater scenarios (up to 9). For the representative use assessed on autumn sown (winter) oilseed rape the modelling results for 5 out of the 6 FOCUS groundwater scenarios indicated a low potential for groundwater exposure by metaldehyde above 0.1 µg/L. Under the geoclimatic conditions represented by the Piacenza scenario contamination of groundwater above 0.1 µg/L by metaldehyde cannot be excluded. The annual average groundwater recharge concentration in soil water leaving the

[11] There are indications in the available data, that at higher exposure concentrations in soil (from *ca.* 6mg/kg and above) metaldehyde may be more persistent than indicated by the data cited here. An explanation for this might be an inhibition of microbially-mediated transformation processes.
[12] At step 3, simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7. As the product is not sprayed, the parameterisation at step 3 also followed the EFSA (2004b) opinion.
[13] Simulations complied with the EFSA (2004a) opinion and correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

top 1m soil column, calculated using the PELMO 3.3.2 model, for the representative use on winter oilseed rape at the Piacenza scenario was 0.1002µg metaldehyde/L.

The PECs in soil, surface water, sediment, and groundwater covering the representative uses assessed for the specific granular bait product 'Metarex' can be found in Appendix A.

5. Ecotoxicology

Metaldehyde was discussed in the PRAPeR TC 38 ecotoxicology experts' teleconference in July 2010.

Birds may be exposed to metaldehyde by ingesting 'Metarex' granular bait intentionally, by mistaking them for grit or seeds, or unintentionally during feeding in treated habitats. Exposure to the active substance may also result from the uptake of metaldehyde poisoned snails or slugs, feeding on contaminated earthworms, the ingestion of residues with plants or via drinking water from puddles in the field.

The acute risk assessment for birds was based on a geomean from acute toxicity studies on Japanese quail (*Coturnix japonica*), mallard duck (*Anas platyrhynchos*) and pheasant (*Phasianus colchicus*). The geomean was accepted following the new guidance document (EFSA, 2009). Due to dose-dependent food avoidance no reliable LC50 values could be obtained from the results of the dietary studies on Japanese quail and Peking duck (*Anas platyrhynchos domestica*). The short-term risk assessment was considered to be covered by the acute and long-term risk assessment.

Based on the guidance document (European Commission, 2002) the acute and long-term risk to herbivorous birds was assessed as low. However, a high acute and long-term risk was identified for granivorous birds ingesting 'Metarex' granular bait. The applicant provided a refined risk assessment including focal species, avoidance factor, PD and PT values, based on extensive field studies in Germany, France and Great Britain (bird scanning and carcass search in cereal and oilseed rape fields) and palatability studies (see below). The Member State experts considered the field study valid to identify focal bird species but they were not convinced that valid PT values could be derived from these studies (because foraging activity of the birds outside of the scanned area could not be detected, and no radio-tracking studies were available). In each of the two field studies in France (summer cereals and winter oilseed rape) a dead redstart (*Phoenicurus phoenicurus*) was found (residues of metaldehyde were detected in the carcass of both birds). Experts were concerned that carcass searches would only provide minimum numbers of incidents, and in particular smaller birds may have been overlooked during searches. Furthermore, concerns were raised that the carcass search areas were too small, given the low density of birds.

From the field studies, the RMS identified the more relevant focal species based on occurrence and potential for high exposure (by multiplying PT, PD and FIR). The experts agreed with the principle of the approach and considered the PD data provided to be valid. Based on the revised calculation provided after the expert meeting (based on PD and FIR), the RMS had concerns that the revised list of focal species may not cover all Member States.

In studies on the palatability of 'Metarex' granular bait to house sparrow (*Passer domesticus*), grey partridge (*Perdix perdix*) and pheasant (6 hours no choice after grit and food deprivation, 3-4 days choice) there was no clear avoidance of the bait for any of the tested species. All birds however survived and did not show any symptoms of intoxication. The RMS was of the opinion that quite strong avoidance was demonstrated in the avoidance and dietary studies. Member State experts however considered that although avoidance studies did provide some reassurance that avoidance would occur, the available data were not robust enough to derive a value for avoidance. It was noted by the experts that some birds did eat bait in the avoidance study, and that their motivation to eat bait may be even higher under stressed environmental conditions. The majority of experts agreed not to use the AV factor. TER values were recalculated by the RMS after PRAPeR TC 38 for the revised focal species and without use of AV or PT values. TERs were clearly below the Annex VI trigger, indicating a high acute and long-term risk to granivorous birds for the representative uses. The risk assessment was supported by calculation of the number of baits needed by the focal species to reach the acute LD50 and long-term NOEL, including an assessment factor. The focal species would need 0.4-10 baits to reach LD50/10 and this number of baits would only cover 0.15-0.6% of their daily food intake rate. To reach the long-term NOEL/5 focal species would only need 0.1-2.6 baits per day, equivalent to 0.04-0.16% of the daily food intake rate.

The risk to birds from unintentional ingestion of bait as grit was considered to be covered by the risk assessment for granivorous birds.

Slug-eating birds might ingest slugs that have fed on ‘Metarex’ bait. Field data on metaldehyde residues in three different size classes of slugs were provided from two oilseed rape field sites in Germany treated with ‘Metarex’. The highest weighted mean concentration and the overall weighted mean for small and medium sized slugs was used for the acute and long-term risk assessment respectively. Decline rates in slugs were also calculated for the long-term risk assessment. Relevant focal bird species known to have slugs included in their diet[14] were identified from the extensive field studies mentioned above, and the birds most likely to be exposed were identified, based on FIR/bw since no sound species-specific PD values could be derived from literature, and Member State experts did not agree to the use of PT values (see above). A MAF was not considered relevant as slugs usually feed only once at a ‘Metarex’ bait, which is only available immediately after the application.

First tier TER calculations indicated a high acute and long-term risk to all slug-eating focal bird species. A refined risk assessment based on PT and PD was provided. PT refinements based on the field studies were not accepted for the same reason as mentioned above. Although a PD of 0.44 (based on literature data) was accepted as a conservative estimate for the proportion of slugs in the diet of birds in general, this was insufficient to address the long-term risk to slug-eating birds.

The applicant provided a weight of evidence approach to address the risk to slug-eating birds. The field surveys did not indicate any mortality of slug-eating birds. Based on the study on residues in slugs, it was evident that metaldehyde concentration in slugs had substantially decreased within 1-2 weeks. The attractiveness of dead slugs to birds was questioned by the applicant, as literature studies with dead and desiccated insects indicated that birds had a preference for live and freshly dead insects. Furthermore, slugs dying after exposure to metaldehyde were found to have excessive slime formation, which would make them less attractive to birds. From literature data a maximum number of 19 slugs were found in the stomach of a single carrion crow (*Corvus corone*). The possible exposure from 19 slugs, based on the measured residue levels in slugs, was 47 times lower that the LD50 dose for a carrion crow. The number of slugs to reach LD50/10 for the focal slug-eating bird species was in the range of 2.9 to 179 slugs (correlated with weight of birds). The number of slugs would correspond to ingesting all affected slugs in 1m2 for a robin (*Erithacus rubecula*) to reach LD50. The rook (*Corvus frugilegus*) would need to ingest all affected slugs in 32m2. The number of slugs to reach the NOEL/5 was calculated to be in the range of 2.4 to 144 for the suit of relevant focal species.

Member State experts were of the opinion that the evidence provided by the applicant was not sufficient to conclude on a low risk to birds from exposure to metaldehyde poisoned slugs. The concerns identified in relation to the use of the field studies to address the risk for granivorous birds also apply to the use of these same studies to address the risk to slug-eating birds (see above). Furthermore, Member State experts wondered if there may be exposure via other relevant feeding guilds for birds (e.g. arthropods exposed to metaldehyde) considering both the estimated high number of slugs needed to reach the LD50 for birds and the finding of 2 dead redstarts in the field. Consequently a data gap was identified for the applicant to provide a new risk assessment for birds that should consider acute and long-term risks. All relevant feeding guilds should be considered in order to explain the circumstances under which the death of birds observed in the field may have occurred. However, the RMS remained of the opinion that considering the large amount of field data

[14] Literature data (see references in Additional Report)

available, and taking into account the current methodologies for higher tier risk assessments, new data would not significantly change the risk profile for metaldehyde.

The risk to earthworm-eating birds was assessed as low, as was the risk to birds from the consumption of contaminated drinking water.

In a first tier risk assessment for small herbivorous mammals the risk was assessed as low for all representative uses. However for granivorous mammals the acute and long-term TER values were significantly below the Annex VI trigger. Refinement of the risk assessment was based on two avoidance studies (bank vole and wood mouse; 4h food deprivation; no choice first day and choice between bait and seed during 3 days) and field effect studies on mammals by trapping and radio-tracking in winter oilseed rape and winter cereal fields in Germany. Wood mouse (*Apodemus sylvaticus*) was considered a relevant focal species for all representative uses.

Member State experts supported the selection of wood mouse as focal species and the use of a mean PD values derived from literature for the long-term risk assessment. However, the experts considered it inappropriate to refine the acute risk assessment based on PD or PT data. Moreover, the experts considered that mammals in the field might not have a choice between several food types (as in the avoidance test), in particular on large areas of bare soil where the appearance of food items was expected to be rare. For this reason an AV factor should not be used in the TER calculation.

Member State experts had concerns regarding the PT values derived from the field studies. The type of radio-tracking was not considered adequate to obtain sound data on foraging activity (i.e. no continuous tracking, just fixes). Consequently the experts agreed not to use the PT, because no data on foraging activity inside and outside the crop are available.

Field trapping studies indicated some mortality, but the data were considered to be inconclusive regarding population effects on mammals, and the studies were not representative for uses in South Europe. The Member State experts concluded that the evidence provided from the field studies was not sufficient to conclude that the risk to mammals would be low.

The risk to slug-eating mammals was assessed as low, since such species were not considered likely to enter bare fields, e.g. shrews (*Sorex spec.*) and hedgehogs (*Erinaceus europaeus*). Furthermore, studies indicated that hedgehogs could consume 200 contaminated slugs (exact exposure level unknown) without showing adverse effects. Member State experts concluded that wood mouse was considered to be a more relevant focal species in the bare field, although it has never been reported that wood mice eat slugs. Therefore it is assumed that the risk via secondary poisoning was low.

The risk to earthworm-eating mammals was assessed as low, as was the risk to mammals from the consumption of contaminated drinking water.

Overall, based on the data available a high acute and long-term risk was assessed for granivorous mammals, and a data gap was identified for further data to be provided. Exposure from other feeding guilds should be considered, if there would be an indication from the risk assessment on birds that such feeding guilds may pose a risk.

Metaldehyde was assessed as harmful to aquatic organisms (including gastropods) based on the data available. No toxicity studies on the formulation were provided as direct exposure to the aquatic environment was not expected. Based on FOCUSsw step 3 PEC values the risk to aquatic organisms was assessed as low for all scenarios for all representative uses. The risk from the metabolite acetaldehyde was additionally assessed as low. The potential for bioaccumulation was identified as low.

The risk to bees, non-target arthropods, earthworms, non-target micro- and macro-organisms, biological methods of sewage treatment and non-target terrestrial plants was assessed as low for all representative uses.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Metaldehyde	Following an initial lag phase of up to 19 days where degradation is negligible, the substance has low persistence biphasic with negligible initial decline DT_{90} 8.5 to 22 days (20°C, pF2 soil moisture)	The risk to soil-living organisms was assessed as low

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Metaldehyde	high to very high mobility K_{Foc} 38-149 mL/g	Yes at 1 out of 9 FOCUS scenarios at 0.1002µg/L.	Yes	Yes	Yes

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Metaldehyde	Metaldehyde is harmful to aquatic organisms. The risk from all representative uses was assessed as low.
Acetaldehyde	The risk from all representative uses was assessed as low.

6.4. Air

Compound (name and/or code)	Toxicology
Metaldehyde	No valid data available. No data required in view of the representative use and the physico-chemical properties.

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

- Residue trials to support the representative uses in southern Europe (relevant for the all representative uses in southern Europe; submission date proposed by the applicant: unknown; see section 3).

- A new risk assessment for birds that should consider acute and long-term risks. All relevant feeding guilds should be considered in order to explain the circumstances under which the death of birds observed in the field may have occurred (relevant for all representative uses evaluated; submission date proposed by the applicant: none; see section 5).

- A new risk assessment for granivorous mammals that should consider acute and long-term risks. Exposure from other feeding guilds should be considered (e.g. omnivorous mammals), if there would be an indication from the risk assessment for birds that such guilds may pose a risk (relevant for all representative uses evaluated; submission date proposed by the applicant: none; see section 5).

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- The use of PPE (gloves and coverall) is included by default in the operator exposure model used for the application of 'Metarex'. The use of gloves might be considered for workers in view of possible exposure to bait lodged in the foliage of oilseed rape.

ISSUES THAT COULD NOT BE FINALISED

- The consumer risk assessment cannot be finalised for the representative uses in southern Europe.

CRITICAL AREAS OF CONCERN

- A high acute and long-term risk was identified for birds and mammals.

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[15] For further guidance documents see http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council (EC) or http://www.oecd.org/document/59/0,3343,en_2649_34383_1916347_1_1_1_1,00.html (OECD)

APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

List of Endpoints

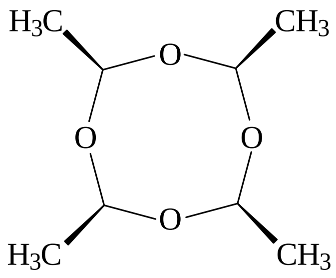
Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Metaldehyde (no ISO common name required)
Function (*e.g.* fungicide)	Molluscicide

Rapporteur Member State	Austria
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*r*-2,*c*-4,*c*-6,*c*-8-tetramethyl-1,3,5,7-tetroxocane 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane
Chemical name (CA) ‡	2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane
CIPAC No ‡	62
CAS No ‡	108-62-3 (tetramer) 9002-91-9 (homopolymer)
EC No (EINECS or ELINCS) ‡	203-600-2
FAO Specification (including year of publication) ‡	No specification is available at the moment of evaluation
Minimum purity of the active substance as manufactured ‡	985 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	acetaldehyde max. 1.5 g/kg
Molecular formula ‡	$C_8H_{16}O_4$ (tetramer)
Molecular mass ‡	176.2 g/mol (tetramer)

Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	(99.5% (w/w)) metaldehyde starts to sublime at 191 °C
Boiling point (state purity) ‡	not applicable
Temperature of decomposition (state purity)	(99.5% (w/w)) metaldehyde starts to sublime at 191 °C
Appearance (state purity) ‡	Purified product(99.5% (w/w)) White crystalline powder
	Technical product (99.3% (w/w) White powder
Vapour pressure (state temperature, state purity) ‡	6.6 ± 0.3 Pa at 25 °C (99.3% (w/w)) 4.4 ± 0.2 Pa at 20 °C
Henry's law constant ‡	3.5 Pa.m³.mol^{-1} at 20 °C values used for calculation: water solubility:0.222 g/L at 20 °C vapour pressure: 4.4 Pa at 20 °C
Solubility in water (state temperature, state purity and pH) ‡	at 19.9 - 23.0 °C (99.3% (w/w)) 0.222 g/L at pH 6.5 (unbuffered) at 20.0 ± 0.2 °C (99.3% (w/w)) 0.188 g/L at pH 7.2 0.196 g/L at pH 5 0.186 g/L at pH 9
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility all in g/L (99.5% (w/w)) at 20.3 - 22.4 °C hexane 52.1 x 10^{-3} methanol 1.73 toluene 0.53 tetrahydrofurane 1.56 at 20.0 ± 0.5 °C ethyl acetoacetate 0.754 at 20.0 °C 1,2-dichloroethane 3.08 acetone 1.46

Surface tension ‡ (state concentration and temperature, state purity)	at 19.5 ± 0.5 °C (99.5% (w/w)) σ = 71.9 mN/m (0.204 g/L aqueous unbuffered solution)
Partition co-efficient ‡ (state temperature, pH and purity)	at 19.9 - 20.1 °C (99.3% (w/w)) log $P_{O/W}$ = 0.12 at pH 6.7 Effect of pH (4 to 10) not required, because metaldehyde is neither an acid nor a base
Dissociation constant (state purity) ‡	metaldehyde does not dissociate in water
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	c = 1.02 x 10^{-3} mol/L (0.18 g/L) (99.1% (w/w)) No significant absorption in neutral, acidic and alkaline medium occurs at any wavelength.
Flammability ‡ (state purity)	Highly flammable TGAI (99.5% (w/w))
Autoflammability	No self ignition up to 400 °C TGAI (99.5% (w/w))
Explosive properties ‡ (state purity)	No explosive properties TGAI (99.5% (w/w))
	St(H)2: strong dust explosion, indicator 2
Oxidising properties ‡ (state purity)	No oxidizing properties Statement

Summary of representative uses evaluated (Metaldehyde)*

Crop and/ or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)	**Remarks:**
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL (l) min – max	water L/ha min – max	kg as/ha (l) min – max		
Cereals (rye, oat, wheat, barley and triticale)	EU	Metarex	F	Slugs, Snails	RB	50 g/kg	Spreading (manually or fertiliser spreader)	00 – 29	max 2	min 14 d	not applicable	not applicable	0.35	n.a.	[1] [2]
Oilseed rape	EU	Metarex	F	Slugs, Snails	RB	50 g/kg	Spreading (manually or	00 – 30	max 2	min 14 d	not applicable	not applicab	0.35	n.a.	[1] [2]

Crop and/ or situation	**Member State or Country**	**Product name**	**F G or I**	**Pests or Group of pests controlled**	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Remarks:**
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL (l) min – max	water L/ha min – max	kg as/ha (l) min – max	(m)	
							fertiliser spreader)					le			

[1] A high risk was identified for birds and mammals

[2] The consumer risk assessment cannot be finalised for the representative uses in the South of Europe

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks:
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL (l) min – max	water L/ha min – max	kg as/ha (l) min – max		

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha

Crop and/ or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)	**Remarks:**
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL (l) min – max	water L/ha min – max	kg as/ha (l) min – max		

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical as (analytical technique)	GC – FID
Impurities in technical as (analytical technique)	GC – FID (GC – MS for confirmation); Karl Fischer titration
Plant protection product (analytical technique)	GC-MSD GC – FID (confirmatory technique: GC – MS) Relevant impurity acetaldehyde: GC-FID (GC – MS for confirmation) LOQ: 0.007%

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	metaldehyde
Food of animal origin	No residue definition proposed
Soil	metaldehyde
Water surface	metaldehyde
drinking/ground	metaldehyde
Air	metaldehyde

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC – MSD (enforcement) 0.05 mg/kg wheat grain, rape seed, orange, sugar beet and broccoli GC-MS/MS 0.05 mg/kg lettuce GC-MS/MS 0.05 mg/kg wheat grain, rape seed, orange, sugar beet and broccoli

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No analytical method is required since no residue definition is proposed
Soil (analytical technique and LOQ)	GC – MSD 0.05 mg/kg GC – MS/MS 0.05 mg/kg
Water (analytical technique and LOQ)	Drinking and surface water: GC – MSD 0.1 µg/L GC – MS/MS 0.1 µg/L
Air (analytical technique and LOQ)	GC – MSD 0.44 µg/m^3
Body fluids and tissues (analytical technique and LOQ)	No analytical method is required since metaldehyde is not classified as toxic or very toxic

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

	RMS/peer review proposal
Active substance	R 11 Highly flammable

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid and essentially complete (>95 %) based on excretion via air (80% within 48h) and urine (2-5% within 7 days).
Distribution ‡	Widely distributed; most of radioactivity found in carcass and not in specific organs. 8-10% still present in the body after 7 days.
Potential for accumulation ‡	No evidence of accumulation after repeated administration.
Rate and extent of excretion ‡	After 7 days: expired air (85%); urine (2-5%); faeces (2-3%)
Metabolism in animals ‡	85% metabolised to acetaldehyde and expired as CO_2; 2-5% metabolised and excreted via polar degradates in the urine (no parent compound in urine); 2-3% in faeces not identified.
Toxicologically relevant compounds ‡ (animals and plants)	Metaldehyde
Toxicologically relevant compounds ‡ (environment)	Metaldehyde

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	283 mg/kg bw	**R 22**
Rat LD_{50} dermal ‡	> 5000 mg/kg bw	-
Rat LC_{50} inhalation ‡	No valid data available but no further data necessary due to the physico-chemical properties.	
Skin irritation ‡	Non-irritating	-
Eye irritation ‡	Slightly irritating	-
Skin sensitisation ‡	Not sensitizing to the skin (LLNA)	-

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Atrophy of testes and prostate, mortality (dog). Hepatocellular hypertrophy and hepatotoxicity (rat, mouse). Neurological signs (e.g. tremor, convulsions, ataxia, paresis) at acute toxic doses (rat, dog, rabbit).	
Relevant oral NOAEL ‡	3-mo rat: 21 mg/kg bw/d 3-mo mouse: LOAEL = 19 mg/kg bw/d 1-yr dog: 10 mg/kg bw/d 1-yr dog, acute NOAEL (neurological findings): 30 mg/kg bw/d	**R48/22**
Relevant dermal NOAEL ‡	> 1000 mg/kg bw/d (21 days, rabbit)	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Not genotoxic *in vitro* and *in vivo*	

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

Target/critical effect ‡	Liver: hepatocellular hypertrophy (rats, mice) Decreased body weight (gain) (rats)	
Relevant NOAEL ‡	2-yr rat: 2 mg/kg bw/d 78-wk mouse: 16 mg/kg bw/d	
Carcinogenicity ‡	Metaldehyde is unlikely to pose a carcinogenic risk to humans.	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: reduced body weight Reproductive: no adverse effects Offspring: reduced body weight / body weight gain	
Relevant parental NOAEL ‡	3.2 mg/kg bw/d	
Relevant reproductive NOAEL ‡	134 mg/kg bw/d	
Relevant offspring NOAEL ‡	65 mg/kg bw/d	

Developmental toxicity

Developmental target / critical effect ‡	Maternal: mortality and clinical signs, reduced bw gain (rat); none (rabbit) Developmental: no fetotoxicity or teratogenicity (rat, rabbit)	
Relevant maternal NOAEL ‡	Rat: 75 mg/kg bw/d Rabbit: 80 mg/kg bw/d	
Relevant developmental NOAEL ‡	Rat: 150 mg/kg bw/d Rabbit: 80 mg/kg bw/d	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Rat, NOAEL = 75 mg/kg bw Findings in neurological screening	
Repeated neurotoxicity ‡	90-d rat, NOAEL = 39 mg/kg bw/d for neurotoxicity (loss of hind limb function) and systemic toxicity (reduced body weight gain)	
Delayed neurotoxicity ‡	No data available – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Published data (limited validity) suggest direct toxicity of metaldehyde and not of its degradation product acetaldehyde
Studies performed on metabolites or impurities ‡	No data – not required

Medical data ‡ (Annex IIA, point 5.9)

	No detrimental effects on health in manufacturing personnel. Many poisonings are reported after accidental or suicidal intake with intoxications ranging from mild to lethal outcome. Clinical signs include gastrointestinal symptoms which may be followed by convulsions, somnolence, apnea, cyanosis, coma and death.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.02 mg/kg bw/d	2-yr, rat	100
AOEL ‡	0.1 mg/kg bw/d	52-wk, dog	100
ARfD ‡	0.3 mg/kg bw	52-wk, dog (acute neurotoxic effects)	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	METAREX (granular formulation, 5% metaldehyde) *In vitro* study with human skin Dermal absorption: 0.23 %

Exposure scenarios (Annex IIIA, point 7.2)

Operator	PHED model for granule application; calculations with PPE (gloves and protective clothing); no model estimates for application without PPE available Tractor mounted equipment (with PPE): 2,6 % of AOEL for 20 ha 6,4 % of AOEL for 50 ha Hand-held equipment (with PPE): 4 % of AOEL for 1 ha
Workers	No need for re-entry * No dislodgeable residues as 'Metarex' is intended for soil application at an early stage of plant growth in cereals and oilseed rape.
Bystanders	Considered negligible: nearly dust free granular formulation. Estimation by applicant for possible exposure via vapour of metaldehyde demonstrates negligible exposure.

* It is noted that the exposure to granules lodged in the leaves has not been assessed. However it is unlikely that such an exposure would represent a concern. Due to the lack of data, the use of gloves might be considered.

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

	RMS/peer review proposal
Substance classified (name)	**Xn; R22** Harmful if swallowed **Xn; R48/22** Harmful: danger of serious damage to health by prolonged exposure if swallowed

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

Plant groups covered	cereals (wheat) and oilseeds (rape), fruits (strawberries), leafy crops (lettuce), root vegetables (sugar beet)
Rotational crops	No data required [Less than 10 % of the applied active substance remain in soil after 100 days based on the PEC (soil) values of 0.933 mg/kg (day 0) and 0.001 mg/kg (day 100)].
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	No data required [A log $P_{O/W}$ of 0.12 indicates that metaldehyde is not fat soluble. The intake on rape seed is below 10% of the ADI]
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Metaldehyde
Plant residue definition for risk assessment	Metaldehyde
Conversion factor (monitoring to risk assessment)	no

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

Animals covered	Lactating goat
Time needed to reach a plateau concentration in milk and eggs	Milk: 2 days
Animal residue definition for monitoring	Not necessary
Animal residue definition for risk assessment	Not necessary
Conversion factor (monitoring to risk assessment)	no
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	No (log P_{ow}= 0.12 at pH 6.7)

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

	Not applicable

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

	18 month (wheat grain), 24 month (rape seed)

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes* 1.58 mg/kg (beef cattle)	No	Yes* 0.82 mg/kg
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	no
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) The theoretical estimation of residues in the potential animal feed item rape forage is covered by the dose rates (1.02 mg/kg diet and 14.1 mg/kg diet, respectively) used in the livestock metabolism study provided. Livestock feeding studies are considered not necessary. Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not required	Not required	Not required
Liver	Not required	Not required	Not required
Kidney	Not required	Not required	Not required
Fat	Not required	Not required	Not required

Milk	Not required		
Eggs		Not required	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Wheat	Northern Region	8x < 0.01* 8x < 0.05*	Grain	0.01*	< 0.05*	< 0.03
		8x < 0.01* 8x < 0.05*	Straw	Not applicable	< 0.05*	< 0.03
Rape seed	Northern Region	7x < 0.01*, 1x 0.14**, 2x 0.06**, 1x 0.53**	Seed	0.01*	0.53	0.01
		0.09, 0.10, 0.14, 0.72 0.53	Forage***	not applicable	0.72	0.14

Data gap for the south of Europe

*…….Limit of quantification:

0.01mg/kg for trials conducted in 2008

0.05 mg/kg for trials conducted in 1998 and 1999

**….The positive residues found are from lodging in the leaf in practice this will not be significant. See the conclusion

***....Decline studies in rape seed conducted in 1998, 1999 and 2008 showed residues up to 0.72 mg/kg in rape forage (sampled at BBCH 30 - 85)

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

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

ADI	0.02 mg/kg bw/day			
TMDI (% ADI) according to EFSA model for chronic and acute risk assessment - rev. 2	< 1% of the ADI for all consumer groups			
ARfD	0.3 mg/kg bw			
NESTI (% ARfD) according to EFSA model for chronic and acute risk assessment - rev. 2	Adults			
	Commodity	HR mg/kg	IESTI mg/kg bw/d	%ARfD
	Wheat (Triticale)	0.05 *	0.00039	0.1%
	Rye	0.05 *	0.00024	< 0.1%
	Oats	0.05 *	0.00007	< 0.1%
	Barley	0.05 *	0.00036	0.1%
	No intake data for adults oilseed rape			
	Children			
	Commodity	HR mg/kg	IESTI mg/kg bw/d	%ARfD
	Wheat (Triticale)	0.05 *	0.00072	0.2%
	Rye	0.05 *	0.00031	0.1%
	Oats	0.05 *	0.00020	< 0.1%
	Barley	0.05 *	0.00009	< 0.1%
	Rapeseed	0.53	0.00059	0.2%

*… Limit of quantification

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not applicable				

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

Cereals (rye, oat, wheat, barley and triticale)	0.01* mg/kg
Oilseed rape	0.01* mg/kg

*… Limit of quantification

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

Fate and behaviour

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

Mineralization after 100 days ‡	50.2-77.7% after 22-60 d (end of studies), [14C]-Metaldehyde (n= 4) Max. 80.4 % at day 21, [14C]-Metaldehyde (n= 4)
Non-extractable residues after 100 days ‡	12.9–19.6 % after 60 d, [14C]-Metaldehyde (n= 4) Max. 26.4 % at day 29, [14C]-Metaldehyde (n= 4)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	none

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

Anaerobic degradation ‡

Mineralization after 100 days	9.7 % after 45 d anaerobic conditions, [14C]-Metaldehyde (n= 1)
Non-extractable residues after 100 days	4.9 % after 45 d anaerobic conditions, [14C]-Metaldehyde (n= 1) Max. 5.4 % at day 30 (anaerobic conditions), [14C]-Metaldehyde (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	none

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	none; photolysis is not a significant pathway of Metaldehyde dissipation/degradation

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	OC %	pH	t. °C / % MWHC	DT_{50} /DT_{90} Hockey-stick (d)	Duration of lag-phase (d)	DT_{50} pseudo SFO (d)	Chi² (%)
Silt loam	1.2	6.5	20 °C/pF 2	19.5/20.6	19.0	6.2	2.0
Sandy clay	4.2	7.0	20 °C/pF 2	11.6/21.0	7.5	6.3	9.6
Sandy clay	3.1	6.1	20 °C/pF 2	15.9/22.1	13.2	6.7	9.3
Sandy loam	1.0	7.3	20 °C/pF 2	6.6/8.5	5.8	2.6	7.8
Geometric mean/median						5.1	

Field studies ‡	no field studies required

pH dependence ‡ (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration ‡	not required

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	OC %	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation

Sandy loam	0.8	6.5	25 °C/75 % FC	Not enough data points for calculating adequate DT50 value – nearly stable under anaerobic conditions	-	-	-
Geometric mean/median				-	-		

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sand	0.29	7.4	-	-	0.432	149.0	0.910
Sandy loam	0.46	6.5	-	-	0.644	140.0	0.869
Silt loam	1.39	7.1	-	-	0.685	48.9	0.958
Clay loam	1.51	7.5	-	-	0.977	65.1	0.962
Humic sand	1.92	5.3	-	-	0.735	38.0	0.974
Sandy loam	1.57	7.7	-	-	0.633	40.0	1.023
Low humic content sand	1.45	7.5	-	-	0.591	78.0	0.675
Loam	0.76	7.8	-	-	0.807	56.0	0.961
Arithmetic mean/ median					0.688/ 0.665	77.0/ 60.6	0.92/ 0.96
pH dependence, Yes or No			no				

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

Column leaching ‡	No data, not required
Aged residues leaching ‡	No data, not required

Lysimeter/ field leaching studies ‡	No data, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 6.7 days Kinetics: pseudo-SFO Lag-phase: 19 d Field or Lab: representative worst case from lab studies
Application data	Crop: non specified Depth of soil layer: 5 cm (Application on soil surface) Soil bulk density: 1.5 g/cm^3 % plant interception: no crop interception Number of applications and application rate (kg ai/ha): Immediate release 2 x 0.35 kg a.s./ha Application interval: 14 d Start of degradation: 19 d after second application (33 d after first application)

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.933		0.933	
Short term 24h	0.933	0.933	0.933	0.933
2d	0.933	0.933	0.933	0.933

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
4d	0.933	0.933	0.933	0.933
Long term 7d	0.933	0.933	0.933	0.933
28d	0.368	0.847	0.368	0.847
50d	0.028	0.606	0.028	0.606
100d	0.000	0.347	0.000	0.347
Plateau concentration	-			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: stable at 25 °C
	pH 7: stable at 25 °C
	pH 9: stable at 25 °C
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50}: stable at 25 °C, pH 7
Quantum yield of direct phototransformation in water at Σ > 290 nm	$\Phi \approx 0$ mol · Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	substance not ready biodegradable

Degradation in water / sediment

Parent	Distribution (max. of 10.92 % in sediment after 7 days in S1, max. of 19.49 % in sediment after 7 days in S2, max. of 21.2 % in sediment after 14 days in system I, max. of 13.5 % in sediment after 29 days in system II)											
Water /	pH	pH	t. oC	DT50-	Chi²	Metho	DT50-	Chi²	Metho	DT50-	Chi²

sediment system	water phase	sed		DT90 whole sys.	(%)	d of calculation	DT90 water	(%)	d of calculation	DT90 sed	(%)
System 1 Bickenbach	8.4[a]–9[b]	7.9	20 ± 2	4.1/ 13.61	6.0	SFO	11.35/ 37.71	11.9	SFO	10.8/ 34.1	20.8
System 2 Unter Widdershei m	8.5[a] – 8.7[b]	7.8	20 ± 2	4.42/1 4.97	1.7	SFO	10.25/ 34.07	9.7	SFO	9.5/ 31.5	19.1
System I Calwich Abbey	7.8	8.0[a]-7.2[b]	20 ± 2	>1000 / >1000	1.1	FOM C	>1000 / >1000	1.3	DFOP	>1000 / >1000	na
System II Swiss Lake	5.1	7.4[a]-6.7[b]	20 ± 2	714 (1000)[c] / >1000	0.6	DFOP	473/ >1000	0.8	Hockey-stick	>1000 / >1000	na
Geometric mean/ median				65.25/ 119.5			86.3/ 242.2			86.1/ 189.3	

[a] beginning of test

[b] end of test

[c] the modelled DT_{50} value is 714 days. For the calculations the DT_{50} value of 1000 days (value in parentheses) was chosen derived from the slow phase rate constant (being >1000 days)

For FOCUS modelling, whole system DT_{50} value was set to the FOCUS default value of 1000 d. Water DT_{50} value was set to 65.25 d (geometric mean DT_{50} value of whole system).

Acetaldehyde	Distribution (max. in water 22.32 % after 30 days in S1; max. in sediment 4.7 % after 14 d in S1)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	Chi ^{2} (%)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
System 1 Bickenbach	8.4[a]–9[b]	7.9	20 ± 2	30.98/102.90	17.0	-	-	-	-	SFO

System 2 Unter Widdersheim	8.5^a – 8.7^b	7.8	20 ± 2	19.01/63.14	16.7	-	-	-	-	SFO
Geometric mean/median				24.3/80.6		-		-		

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
System 1 Bickenbach	8.4^a–9^b	7.9	61.57 % after 100 d	Max. 20.54 % after 30 d	19.05 % after 100 d
System 2 Unter Widdersheim	8.5^a – 8.7^b	7.8	68.8 % after 100 d	Max. 18.88 % after 62 d	10.63 % after 100 d
System I Calwich Abbey	7.8	8.0^a-7.2^b	4.8 % after 98 d	Max. 3.9 % after 14 d	3.3 % after 97 d
System II Swiss Lake	5.1	7.4^a-6.7^b	8.1 % after 98 d	Max. 0.7 % after 29 d	0.6 % after 97 d

[a] beginning of test

[b] end of test

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Version 1.1 Molecular weight (g/mol): 176.2 Water solubility (mg/L): 222 K_{OC} (L/kg): 60.4 DT_{50} soil (d): 5.1 d (Lab DT_{50}, geometric mean value) DT_{50} water/sediment system (d): 1000 d (representative worst case from sediment water

	studies) DT_{50} water (d): 65.25 (geometric mean of the total system) DT_{50} sediment (d): 1000 d Crop interception (%): no interception
Parameters used in FOCUSsw step 3 (if performed)	Version control no. of FOCUS software: SWASH 2.1, MACRO 4.4.2, PRZM 1.5.6, TOXSWA 2.5 Vapour pressure: 0 Pa (20°C) K_{OC}: 60.4 (mean value) 1/n: 0.960 (mean value) Plant uptake factor: 0 Activation energy Toxswa (J/mol): 65400 Exponent MACRO (1/k): 0.095 Q10 Factor: 2.58
Application rate	Crop: Winter cereals/Spring cereals Winter rape/Spring rape Crop interception: no interception Number of applications: Slow release effect simulated as 8 single applications Interval (d): 7 days Application rate(s): Appl. 1: 0.05 kg a.s./ha Appl. 2: 0.05 kg a.s./ha Appl. 3: 0.10 kg a.s./ha Appl. 4: 0.10 kg a.s./ha Appl. 5: 0.10 kg a.s./ha Appl. 6: 0.10 kg a.s./ha Appl. 7: 0.10 kg a.s./ha Appl. 8: 0.10 kg a.s./ha Application dates: According to PAT (Earliest application date: leaf emergence)

FOCUS STEP 1 not reported

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	28.817		17.405	
	24 h	28.512	28.665	17.393	17.399
	2 d	28.232	28.518	17.222	17.354
	4 d	27.680	28.237	16.885	17.204
	7 d	26.871	27.824	16.392	16.961
	14 d	25.076	26.894	15.297	16.400
	21 d	23.400	26.005	14.275	15.860
	28 d	21.837	25.156	13.321	15.343
	42 d	19.016	23.569	11.600	14.376
Southern EU	0 h	36.021		21.757	
	24 h	35.640	35.831	21.742	21.749
	2 d	35.290	35.648	21.528	21.692
	4 d	34.600	35.296	21.107	21.504
	7 d	33.589	34.780	20.490	21.201
	14 d	31.345	33.617	19.121	20.500
	21 d	29.250	32.507	17.844	19.825
	28 d	27.296	31.446	16.651	19.179
	42 d	23.770	29.461	14.500	17.970

FOCUS STEP 3 Winter cereals Scenario	Water body	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
		Actual	Actual
D1 (Lanna)	Ditch	46.230	41.239
D1 (Lanna)	Stream	28.885	25.073
D2 (Brimstone)	Ditch	25.706	11.460

FOCUS STEP 3 Winter cereals Scenario	Water body	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
		Actual	Actual
D2 (Brimstone)	Stream	16.091	6.376
D4 (Skousbo)	Pond	4.549	7.958
D4 (Skousbo)	Stream	6.215	2.958
D5 (La Jailiere)	Pond	1.296	1.955
D5 (La Jailiere)	Stream	1.628	0.667
R1 (Weiherbach)	Pond	0.327	0.510
R1 (Weiherbach)	Stream	10.065	1.169
R3 (Bologna)	Stream	15.277	2.121
R4 (Roujan)	Stream	4.237	0.577

D1 – D5: Northern European Drainage Scenarios

R1: Northern European Run-off Scenario

R3 – R4: Southern European Run-off Scenarios

FOCUS STEP 3 Spring cereals Scenario	Water body	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
		Actual	Actual
D1 (Lanna)	Ditch	1.102	1.188
D1 (Lanna)	Stream	1.256	0.447
D3 (Vreedepeel)	Ditch	0.000	0.000
D4 (Skousbo)	Pond	0.001	0.003
D4 (Skousbo)	Stream	0.001	0.002
D5 (La Jailiere)	Pond	0.003	0.006
D5 (La Jailiere)	Stream	0.003	0.003
R4 (Roujan)	Stream	10.113	1.504

D1 – D5: Northern European Drainage Scenarios

R4: Southern European Run-off Scenario

FOCUS STEP 3 Winter oilseed rape Scenario	Water body	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
		Actual	Actual
D2 (Brimstone)	Ditch	34.621	16.364
D2 (Brimstone)	Stream	21.677	9.668
D3 (Vreedepeel)	Ditch	0.002	0.007
D4 (Skousbo)	Pond	5.329	8.298
D4 (Skousbo)	Stream	8.498	3.433
D5 (La Jailiere)	Pond	2.113	3.666
D5 (La Jailiere)	Stream	3.188	1.390
R1 (Weiherbach)	Pond	0.326	0.386
R1 (Weiherbach)	Stream	22.325	2.626

D2 – D5: Northern European Drainage Scenarios

R1: Northern European Run-off Scenario

FOCUS STEP 3 Spring oilseed rape Scenario	Water body	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
		Actual	Actual
D1 (Lanna)	Ditch	4.895	4.501
D1 (Lanna)	Stream	5.147	2.288
D3 (Vreedepeel)	Ditch	0.000	0.000
D4 (Skousbo)	Pond	0.008	0.018
D4 (Skousbo)	Stream	0.009	0.011
D5 (La Jailiere)	Pond	0.003	0.007
D5 (La Jailiere)	Stream	0.004	0.003
R1 (Weiherbach)	Pond	1.073	1.329

FOCUS STEP 3 Spring oilseed rape Scenario	Water body	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
		Actual	Actual
R1 (Weiherbach)	Stream	88.743	12.112

D1 – D5: Northern European Drainage Scenarios

R1: Northern European Run-off Scenario

Metabolite Acetaldehyde Parameters used to calculate $PEC_{SW/SED}$	Molecular weight: 44.1 Water solubility (mg/L): 356800 (estimated by WSKOW v. 1.41 – EPI v. 3.11) Soil or water metabolite: water K_{oc} (L/kg): 1.5 (estimated by PCKOCWIN v. 1.66 – EPI v. 3.11) DT_{50} water/sediment system (d): 30.98 days (representative worst case from sediment water studies) Maximum occurrence observed for the metabolite (%): - Water/sediment studies: 22.3 % AR in water
Parameters used in FOCUSsw step 3 (if performed)	Not required
Application rate	Not required
Main routes of entry	Drainage, run-off

For PEC calculation of the possible degradation product Acetaldehyde, the maximum initial PEC values of Metaldehyde were corrected by the maximum occurrence found in the water / sediment studies.

Time after maximum peak [d]	PEC_{SW} (µg/L) Acetaldehyde		PEC_{SED} (µg/kg) Acetaldehyde	
	Actual	TWA	Actual	TWA
0	19.808	-	1.940	-

Time after maximum peak [d]	PEC_{SW} (µg/L) Acetaldehyde		PEC_{SED} (µg/kg) Acetaldehyde	
	Actual	TWA	Actual	TWA
1	19.368	19.588	1.896	1.92
2	18.94	19.372	1.856	1.896
4	18.112	18.948	1.772	1.856
7	16.936	18.336	1.66	1.796
14	14.48	17.004	1.42	1.664
21	12.38	15.804	1.212	1.548
28	10.588	14.72	1.036	1.44
42	7.74	12.844	0.76	1.256
50	6.472	11.92	0.632	1.168
100	2.116	7.908	0.208	0.776

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS models, with appropriate FOCUS groundwater scenarios, according to FOCUS guidance. Model used: PELMO 3.3.2, PEARL 3.3.3 Scenarios: FOCUS scenarios Crop: Winter/Spring cereals Winter/Summer oilseed rape Geometric mean parent DT_{50lab}: 5.1 days K_{OC}: parent, median= 60.4, 1/n= 0.96 Vapour pressure (Pa): 0
Application rate	2 x 350 g a.s./ha with 14 days application interval (slow release was not taken into account)

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

FOCUS PELMO 3.3.2	Scenario	Oil seed rape summer (Annual)	Oil seed rape winter (Annual)	Spring cereal (Annual)	Winter cereal (Annual)
		Metaldehyde (µg/L)			
	Chateaudun	n.d.	< 0.001	< 0.001	< 0.001
	Hamburg	n.d.	0.001	< 0.001	0.001
	Jokioinen	< 0.001	n.d.	< 0.001	< 0.001
	Kremsmünster	n.d.	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	0.004	< 0.001	0.003
	Piacenza	n.d.	**0.1002**	n.d.	0.013
	Porto	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	n.d.	n.d.	n.d.	< 0.001
	Thiva	n.d.	n.d.	n.d.	< 0.001

FOCUS PEARL 3.3.3	Scenario	Oil seed rape summer (Annual)	Oil seed rape winter (Annual)	Spring cereal (Annual)	Winter cereal (Annual)
		Metaldehyde (µg/L)			
	Chateaudun	n.d	< 0.001	< 0.001	< 0.001
	Hamburg	n.d	0.005	< 0.001	0.002
	Jokioinen	< 0.001	n.d	< 0.001	< 0.001
	Kremsmünster	n.d	0.002	< 0.001	< 0.001
	Okehampton	< 0.001	0.010	< 0.001	0.009
	Piacenza	n.d	0.068	n.d	0.003
	Porto	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	n.d	n.d	n.d	< 0.001
	Thiva	n.d	n.d	n.d	< 0.001

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	$\Phi \approx 0$
Photochemical oxidative degradation in air ‡	DT_{50} of 1.7 hours derived by the Atkinson model (12 hours day - 1.5 x 10^6 OH-radicals/cm^3)
Volatilisation ‡	from plant surfaces (BBA guideline): not relevant
	from soil surfaces (BBA guideline): potential of volatilization of metaldehyde in formulated form seems to be significantly reduced
Metabolites	None

PEC (air)

Method of calculation	Vapour pressure: 4.4 Pa (20°C) Henry's law constant: 3.5 Pa m^3/mol (20°C) Solubility in water: 222 mg/L Due to its physical/chemical properties metaldehyde can be classified as highly volatile. When formulated volatilisation of metaldehyde is expected to be significantly reduced. Due to its rapid photochemical oxidative degradation in air (DT_{50} 1.7 hours according Atkinson method) no significant residues of metaldehyde are expected in the atmosphere.

$PEC_{(air)}$

Maximum concentration	No harmonized model for PEC_{air} calculation available, negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.	Soil: Metaldehyde Surface Water: Metaldehyde, Acetaldehyde Sediment: Metaldehyde

	Ground water: Metaldehyde Air: Metaldehyde

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

Soil (indicate location and type of study)	No data, not required
Surface water (indicate location and type of study)	No data, not required
Ground water (indicate location and type of study)	No data, not required
Air (indicate location and type of study)	No data, not required

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for R53 due to the non ready biodegradability of metaldehyde

Ecotoxicology

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds				
Japanese quail	Metaldehyde	Acute	LD_{50}: 170	-
Mallard duck	Metaldehyde	Acute	LD_{50}: 196	-
Pheasant	Metaldehyde	Acute	LD_{50}: 262	
	Preparation	Acute	No study available	-
Japanese quail	Metaldehyde	Short-term	strong food avoidance → no LD_{50} can be derived	3460
Peking duck	Metaldehyde	Short-term	strong food avoidance → no LD_{50} can be derived	3450
Bobwhite quail	Metaldehyde	Long-term	NOED: 55	500
Mallard duck	Metaldehyde	Long-term	NOED: 21	175
Additional higher tier studies				
Palatability of Metarex pellets for grey partridges, pheasants and wild caught house sparrows: No signs of intoxication were observed using a rather severe test design (after grit deprivation and food deprivation prior to exposure, 6 hour no-choice phase followed by 3-4 days choice phase where untreated food was available in excess, birds were housed in pairs in aviaries).				
Acceptance of Metarex pellets by Japanese quails: No signs of intoxication were observed after 16 hours food deprivation followed by an 8 hours choice exposure phase. Birds were housed in groups of 6/8 birds /aviary.				
3 Field effect studies in freshly drilled summer cereal, winter cereal and winter oilseed rape. In each study 30 study plots (10 in UK, 10 in DE and 10 in FR) were monitored after Metarex application. In total 90 fields in NE and SE were investigated. In an extensive carcass search and monitoring effort the species composition using respective fields was recorded and acute effects on birds of Metarex application were investigated. The only effects observed were two dead redstarts found on two occasions in France. These individuals had residues of Metaldehyde.				
Mammals				
Rat	Metaldehyde	Acute	LD_{50}: 283	-
Rat	Metaldehyde	Acute	LD_{50}: 654	
Mouse	Metaldehyde	Acute	LD_{50}: 427	

Rat	Helarion*	Acute	LD_{50}: 5000 (a.s. 250)	-
Rat	Metaldehyde	Long-term	NOAEL: 134	2000
Additional higher tier studies				
Palatability of Metarex pellets to wood mice and bank voles: No signs of intoxication were observed using a rather severe test design (first 6 hours of exposure: 3 Metarex test groups were exposed under different combinations of food deprivation prior to exposure and choice between slug pellets and untreated wheat seeds, the following three days mice were exposed daily for 6 hours to a choice of pellets and untreated wheat).				
Generic field studies were conducted in DE in winter cereals and winter oilseed rape to determine the extent to which shrews are using freshly drilled fields. No shrews were captured in the fields, only in off-crop habitat.				
Two effect studies wer conducted in DE in winter oilseed rape and winter cereal. The "Mark and recapture" technique was used to identify effects on the rodent population (excluding shrews) and radio-tagging was used to identify the extent to which fields are used as feeding habitats. The majority of mortalities were due to injuries, illnesses or predation. In one study 3 out of 17 and in the second study 2 out of 6 mortalities could be Metarex related (residues found in respective carcasses). No effect on population level could be found after Metarex application.				

* Helarion is a formulation comparable to Metarex

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

Cereals and rape seed, application rate: 2 x 350 g a.s./ha, minimum interval: 14 days

Tier 1 Birds (DAR)

Indicator species/Category	Exposure route	Time scale	Toxicity (mg/kg bw/d)	ETE (mg/kg bw/d)	TER	Annex VI Trigger
Granivorous bird	Metarex pellets	Acute	170	19 000	0.01	10
		Short-term [1]	-	19 000	-	10
		Long-term	21	19 000	0.001	5
Herbivorous bird	Plants	Acute	170	0.76	224	10
		Short-term [1]	-	0.76	-	10
		Long-term	21	0.76	28	5
Earthworm eating bird	Earthworms	Acute	170	1.1	154	10
		Short-term [1]	-	1.1	-	10
		Long-term	21	1.1	19	5

Indicator species/Category	Exposure route	Time scale	Toxicity (mg/kg bw/d)	ETE (mg/kg bw/d)	TER	Annex VI Trigger
Slug eating bird	Poisoned slugs	Acute	170	314	0.5	10
		Short-term [1]	-	132	-	10
		Long-term	21	132	0.2	5
Small bird (15 g)	Drinking water	Acute	170	0.33	515	10
		Short-term [1]	-	0.33	-	10
		Long-term	21	0.33	64	5

[1] Due to strong food avoidance no toxicity value in terms of daily dose could be derived from short-term dietary toxicity studies. For herbivorous birds, earthworm-eating birds and small birds drinking contaminated water the short-term risk is covered by the long-term risk assessment (TER values for long-term exposure are above the TER triggers for short term exposure, for long-term exposure estimates no dissipation of residues over time was assumed).

Tier 2 Birds (Additional Report)

Granivorous birds: Calculation of TERs for acute exposure of the focal species

Species	Residues [mg/kg pellets]	FIR/BW [g/kg bw]	Daily dose [mg ai/d/kg bw]	TER
Chaffinch	50 000	0.32	16000	0.013
Yellow hammer	50 000	0.3	15000	0.014
Tree sparrow	50 000	0.31	15500	0.013
Brambling	50 000	0.31	15500	0.013
Linnet	50 000	0.35	17500	0.012
Jackdaw	50 000	0.14	7000	0.029

Granivorous birds: Calculation of TERs for long-term exposure of focal species under consideration of refinement of PD

Species	Residues	FIR/BW [g/kg bw]	PD	Daily dose [mg ai/d/kg bw]	TER

Species	**Residues**	**FIR/BW [g/kg bw]**	**PD**	**Daily dose [mg ai/d/kg bw]**	**TER**
Chaffinch	39500	0.32	0.95	12008	0.002
Yellow hammer	39500	0.3	0.93	11020.5	0.002
Tree sparrow	39500	0.31	1	12245	0.002
brambling	39500	0.31	1	12245	0.002
Linnet	39500	0.35	1	13825	0.002
Jachdaw	39500	0.14	0.96	5308.8	0.004

Slug eating birds: No refined TER values were calculated for acute exposure. The applicant provided an approach of evidence as a refined risk assessment.

Slug eating birds: Calculation of toxicity exposure ratios (TER) for long-term exposure of focal species under consideration of refinement of PD (by RMS)

Crop	Region	Focal species	FIR/bw	RUD [mg ai/kg]	PD	f_{twa}	ETE [mg a.s./kg bw]	NOEL [mg a.s./kg bw]	TER
Summer cereal	NE	Carrion crow	0.6	321.5	0.44	0.39	33.1	21	0.6
		Rook	0.6	321.5	0.44	0.39	33.1	21	0.6
		Yellowhammer	1.6	321.5	0.44	0.39	88.3	21	0.2
	SE	Song thrush	1.2	321.5	0.44	0.39	66.2	21	0.3
		Robin	1.8	321.5	0.44	0.39	99.3	21	0.2
Winter OSR	NE	Carrion crow	0.6	321.5	0.44	0.39	33.1	21	0.6
		Magpie	0.9	321.5	0.44	0.39	49.7	21	0.4
		Pheasant	0.3	321.5	0.44	0.39	16.6	21	1.3
	SE	Robin	1.8	321.5	0.44	0.39	99.3	21	0.2
Winter cereal	NE	Carrion crow	0.6	321.5	0.44	0.39	33.1	21	0.6
		Magpie	0.9	321.5	0.44	0.39	49.7	21	0.4
	SE	Robin	1.8	321.5	0.44	0.39	99.3	21	0.2

RUD = residues per unit dose, PT = proportion of time spent in treated area, PD = composition of diet, f_{twa} = time weighted average factor, ETE = estimated theoretical exposure.

Tier 1 Mammals (DAR)

Indicator species/Category	Exposure route	Time scale	Toxicity (mg/kg bw/d)	ETE (mg/kg bw/d)	TER	Annex VI Trigger
Granivorous mammal	Metarex pellets	Acute	250	11 500	0.02	10
		Long-term	81	11 500	0.007	5
Small herbivorous	Plants	Acute	250	1.39	180	10

Indicator species/Category	Exposure route	Time scale	Toxicity (mg/kg bw/d)	ETE (mg/kg bw/d)	TER	Annex VI Trigger
mammal		Long-term	81	1.39	58	5
Earthworm eating mammal	Earthworms	Acute	250	1.4	179	10
		Long-term	81	1.4	58	5
Small slug eating mammal	Poisoned slugs	Acute	250	564	0.4	10
		Long-term	81	241	0.3	5
Small mammal (20 g)	Drinking water	Acute	250	0.21	1190	10
		Long-term	81	0.21	386	5

Tier 2 Mammals (Additional Report)

Granivorous mammal: Calculation of toxicity exposure ratio (TER) for acute exposure of focal species

Crop	**Region**	**Species**	**FIR/bw**	**RUD [mg a.s./kg pellets]** [a]	**Daily dose [mg a.s./kg bw/d]**	**TERa**
OSR/ cerals	NE/SE	Wood mouse	0.203	50000	10150	0.04

[a] Metaldehyde content in fresh pellets

Granivorous mammals: Calculation of toxicity exposure ratio (TER) for long-term exposure of focal species

Crop	**Region**	**Species**	**FIR/bw**	**RUD [mg a.s./kg pellets]** [a]	**PD**	**Daily dose [mg a.s./kg bw/d]**	**TERlt**
Summer OSR	NE/SE	Wood mouse	0.203	39500	0.19	1524	**0.09**

Crop	Region	Species	FIR/bw	RUD [a] [mg a.s./kg pellets]	PD	Daily dose [mg a.s./kg bw/d]	TERlt
Summer cereal	NE/SE	Wood mouse	0.203	39500	0.19	1524	**0.09**
Winter OSR	NE/SE	Wood mouse	0.203	39500	0.36	2887	**0.05**
Winter cereal	NE/SE	Wood mouse	0.203	39500	0.36	2887	**0.05**

[a] Metaldehyde content in pellets equivalent to 0.794 mg a.s./pellet, the value is derived from the study of Klein (2007, Doc. No. 644-001)

Slug eating mammals: No refined TER values were calculated for slug eating mammals. The applicant provided an approach of evidence as a refined risk assessment.

Multiple food sources: Calculation of toxicity exposure ratio (TER) for acute exposure of focal species

Season	Food type	RUD [mg/kg]	FIR/bw	PD	Daily dose [mg a.s./kg bw/d]	TER
Spring	Pellets	50000	0.20	0.3	3000	
	Earthworms	1.0	1.02	0.7	0.72	
				sum	**3000.7**	0.14
Autumn	Pellets	50000	0.20	0.62	6200	
	Earthworms	1.0	1.02	0.38	0.39	
				sum	**6200.4**	0.07

RUD = residues per unit dose, FIR/bw = food intake rate per body weight, PD = proportion of grain/seeds in diet, AV = avoidance factor, TER = toxicity exposure ratio

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity [mg/L]
Laboratory tests				
Fish				
Oncorhynchus mykiss	Metaldehyde	96 h (semi-static)	Mortality, LC_{50}	75 (n)
Oncorhynchus mykiss	Metaldehyde	21 d (semi-static)	Mortality, weight, length, NOEC	37.5 (n)
	Metarex	No study submitted, not required		
Pimephales promelas	Acetaldehyde	96 h (flow-through)	Mortality, LC_{50}	30.8 (mm)
Aquatic invertebrates				
Daphnia magna	Metaldehyde	48 h (static)	Immobility, EC_{50}	> 90 (mm)
Planorbarius corneus	Metaldehyde	48 h (static)	Immobility, EC_{50}	> 200
Daphnia magna	Metaldehyde	21 d (semi-static)	Mortality, reproduction, NOEC	90 (n)
-	Formulation	No study submitted, not required		
Gammarus pseudolimnaeus	Acetaldehyde	96 h (flow-through)	Mortality, LC_{50}	19.3 (n.r.)
Sediment dwelling organisms: No study submitted, not required				
Algae				
Desmodesmus subspicatus	Metaldehyde	72 h (static)	Growth rate, EC_{50} Yield, EC_{50}	> 200
Higher plant: No study submitted, not required				
Microcosm or mesocosm tests: No study submitted, not required				

(n)…toxicity value based on nominal concentrations, (mm)…toxicity value based on mean measured concentrations, (n.r.)…not reported whether the toxicity value is based on nominal or measured concentrations

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

FOCUS Step 3 (worst case for all uses and FOCUS scenarios: 0.089 mg ai/L, run off scenario R1 (stream) for spring oilseed rape)

Test substance	Organism	Toxicity value [mg/L]	Time scale	PEC_{max} [mg/L]	TER	Annex VI Trigger
Metaldehyde	Fish	75	Acute	0.089	843	100
Metaldehyde	Fish	37.5	Chronic	0.089	421	10
Metaldehyde	Invertebrates	> 90	Acute	0.089	> 1011	100
Metaldehyde	Invertebrates	90	Chronic	0.089	1011	10
Metaldehyde	Gastropods	> 200	Acute	0.089	> 2247	100
Metaldehyde	Algae	> 200	Acute/ chronic	0.089	> 2247	10
Metaldehyde	Higher plants	Not required				10
Metaldehyde	Sediment-dwelling organisms	Not required				10
Acetaldehyde	Fish	30.8	Acute	0.02	1540	100
Acetaldehyde	Invertebrates	19.3	Acute	0.02	965	100
Acetaldehyde	Algae	2 [a]	Acute/ chronic	0.02	100	10
Metarex	Not required since it is not expected that the formulated product (pellets) will reach surface waters (dust content < 0.003 %).					

[a] No toxicity data are available for algae, it was assumed that acetaldehyde is 100 times more toxic to algae than metaldehyde

Bioconcentration	
	Active substance
$logP_{O/W}$	0.12 (19.9 - 20.1 °C, pH: 6.7)
Bioconcentration factor (BCF)	11 (whole fish at steady state) *
Annex VI Trigger for the BCF	100
Clearance time (days) (CT_{50})	Depuration of total radioactivity was negligible during

Level and nature of residues (%) in organisms after the 14 day depuration phase	28 days depuration phase. Metaldehyde is metabolised to acetaldehyde which enters anabolic pathways via acetyl-CoA and hence ^{14}C-residues are incorporated into body carbon pools.

* based on total ^{14}C residues

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	> 87.5	> 113
Preparation	not relevant	not relevant
Field or semi-field tests		
not required		

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

granular application

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	not relevant	50
a.s.	oral	not relevant	50
Preparation	Contact	not relevant	50
Preparation	oral	not relevant	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha)

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri ‡	Metarex	Mortality	> 350 g a.s./ha
Aphidius rhopalosiphi ‡	Metarex	Mortality	> 350 g a.s./ha

granular application

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
Metarex	*Typhlodromus pyri*	> 350 g ai/ha	not relevant		2
Metarex	*Aphidius rhopalosiphi*	> 350 g ai/ha	not relevant		2

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1]	End point	% effect[2]	Trigger value
Pardosa sp.	adult	Metarex, soil, 14 d	7 kg/ha 14 kg/ha	mortality / food consump.	0 / 0 0 / - 1	50 %
Aleochara bilineata	adult	Metarex, soil, 28 d	7 kg/ha 14 kg/ha	offspring emergence	- 30 - 23	50 %

[1] initial residues, product Metarex (granules)

[2] negative percentages relate to positive effects

Field or semi-field tests
not required

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

Test organism	Test substance	Time scale	End point
Earthworms			

Test organism	Test substance	Time scale	End point
Eisenia fetida	Metaldehyde	Acute 14 days	LC_{50} > 1000 mg a.s./kg dw soil
Eisenia fetida	Metaldehyde		NOEC growth: 64 mg ai/kg dw soil NOEC repro.: 32 mg ai/kg dw soil
Other soil macro-organisms			
not required			
Soil micro-organisms			
Nitrogen mineralisation	Metaldehyde	28 days	17.4 % effect at day 28 at 6.22 mg a.s./kg d.w.soil (sandy loam) - 3.3 % effect at day 28 at 6.35 mg a.s./kg d.w.soil (loam)
Carbon mineralisation	Metaldehyde	28 days	- 17.7 % effect at day 28 at 6.22 mg a.s./kg d.w.soil (sandy loam) 4.6 % effect at day 28 at 6.35 mg a.s./kg d.w.soil (loam)
Field studies			
not required			

Toxicity/exposure ratios for soil organisms

granular application

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia fetida	Metaldehyde	Acute	0.933	> 1072	10
Eisenia fetida	Metaldehyde	Long-term	0.933	34	10

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

Preliminary screening data

Not relevant

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
not relevant						

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

not relevant

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

Test type/organism	End point
Activated sludge	EC50 (3 h) > 100 mg/L

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

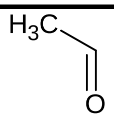
Compartment	
Soil	Metaldehyde
Water	Metaldehyde
Sediment	Metaldehyde
Groundwater	Metaldehyde

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

	RMS/peer review proposal
Active substance	R 52/53

	RMS/peer review proposal
Preparation	No proposal because no toxicity data for the formulation are available

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
acetaldehyde	acetaldehyde	

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ETE	estimated theoretical exposure
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography

GC-MSD	gas chromatography – mass selective detector
GC-MS/MS	gas chromatography with tandem mass spectrometry
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RB	ready to use bait formulation
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year