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

methomyl

finalised: 23 June 2006

SUMMARY

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

United Kingdom being the designated rapporteur Member State submitted the DAR on methomyl in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 3 May 2004. Following a quality check on the DAR, the peer review was initiated on 28 June 2004 by dispatching the DAR for consultation of the Member States and the main applicant DuPont de Nemours. Makhteshim Agan ICC also submitted a dossier which the rapporteur Member State considered to be substantially incomplete. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting on 9 February 2005. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in September 2005.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 7 June 2006 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as insecticide comprise foliar spraying to control biting and sucking insects in cucumber, courgette, tomato and eggplants. Only the use as insecticide was evaluated. It should be noted that the use in grape was withdrawn during the EU peer review process.
The representative formulated product for the evaluation was "Methomyl 20 SL", a soluble concentrate (SL), registered in some Member States of the EU.

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

Adequate methods are available to monitor all compounds given in the respective residue definition. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Methomyl is highly toxic via the oral, ocular and inhalation routes of exposure, but it has a low toxicity via the dermal route. On the basis of the data package available the proposed classification is T+, R26 'Very toxic by inhalation' and R25 'Toxic if swallowed'. It is not an eye or skin irritant and does not cause skin sensitisation. The overall short term NOAEL is approximately 10 mg/kg bw/day. Reliable data on effects on cholinesterase activity were not always determined. Based on the available studies, the weight of the evidence indicates that methomyl does not pose a genotoxic, reproductive or developmental concern. There was no evidence of methomyl-induced carcinogenic activity in rats or mice. The NOAEL for acute neurotoxicity is 0.25 mg/kg bw. The ADI, AOEL and ARfD were set at 0.0025 mg/kg bw, based on the acute neurotoxicity NOAEL applying a SF of 100.
The operator, worker and bystander risk assessment should be regarded as inconclusive, since the rapporteur Member State recalculated operator, worker and bystander exposure with dermal absorption values slightly different from the ones agreed during the experts' meeting; however, the assessment is not expected to change significantly even with the use of values agreed during the experts' meeting. The operator exposure estimates exceed the AOEL in all scenarios considered.

The metabolism of methomyl in fruits is fully elucidated. Four metabolic pathways were identified generally leading to metabolites of no toxicological concern, as formed as a result of hydrolysis of the carbamate ester link and further degradation. However at least 2 metabolites were identified with intact carbamate structure (IN-HUZ57 and IN-G6520) and are considered as toxicologically relevant. In fruits, these metabolites are present at much lower levels than the parent compound and their contribution to the global toxicological burden is expected to be minor. Therefore, only the parent compound is proposed to be included in the residue definition for monitoring and risk assessment in fruit crops. For other commodities dealt with at member state level, the need for inclusion of these metabolites in the residue definition for risk assessment should be carefully considered as it appears that their ratio to the parent compound may be significant on leafy parts of plants, based on information obtained on grape foliage.
A sufficient amount of supervised residue trials were conducted in accordance with the supported representative uses, demonstrating that a MRL of 0.5 mg/kg would be needed for table and wine grapes, while residues in fruiting vegetables are consistently below the Limit Of Quantification (0.02 mg/kg) of the analysis method. In processed commodities (grape juice and wine), residues are lower than in raw grapes, this resulting from a preferential transfer to solid fractions during processing and from a partial degradation of methomyl to methomyl oxime. This degradation product has however no toxicological relevance.

On the basis of the supported representative uses dealt with under this peer review, no livestock exposure to methomyl residues is expected. Due to the low persistency of methomyl in soil, no residue of methomyl is expected in following crops.
Acute and chronic exposure assessments to methomyl residues were performed. A potential acute risk was identified for all considered population subgroups resulting from the consumption of treated table grapes.

Degradation of methomyl under dark aerobic conditions in soil does not produce any major metabolite. Taking into consideration also studies performed with thiodicarb (where methomyl appears as metabolite) methomyl is low or moderate persistent in soil under aerobic conditions. Unextractable residues accounted for up to 32.2 % AR after 30 d and CO_2 for 75.4 % AR after 92 d. No new soil metabolites were identified in the soil photolysis study. Acetonitrile was detected as the major volatile metabolite. The meeting of MS experts considered that the potential environmental contamination by acetonitrile derived from the use of methomyl will be insignificant with respect to other anthropogenic sources. Under normal environmental conditions microbial degradation in soil is likely to predominate over the photolytic one.
In the available field studies for thiodicarb, field degradation half lives of thiodicarb and methomyl were longer than the ones measured under laboratory conditions. The rapporteur Member State normalized the field dissipation rates for methomyl using the average soil temperatures over the period resulting in corrected half lives in the range of those observed in laboratory studies.
Since the half life originally used to calculate PEC in soil was derived from a study finally not considered adequate, new PEC soil were calculated and reported in an addendum. Worst case laboratory half life of 15.2 d was used. Two applications of 450 g/ha with an interval of 14 d were calculated as a worst case representative use. Interception of 60 % (corresponding to leaf development BBCH 50) was assumed for vines and 70 % (corresponding to BBCH 20 onwards for tomatoes) was assumed for vegetables. However, the proposed representative uses do not restrict the application to any particular growing stage. Therefore, EFSA calculated peak PEC soil for tomatoes considering leaf development stages (growing stages BBCH 10-19; 50 % interception) in the updated addendum.
Methomyl is very high mobile in soil. A column (3 soils) and an aged column (1 soil) leaching studies are available for methomyl. In the column leaching study methomyl in leachate represented 6.6 – 55 % AR. Methomyl oxime was observed up to 2.2 % AR in soil and 1.7 % AR in leachate. In the aged column study, the major radioactive component in the leachate (5 % AR) co-chromatographed with methomyl.
Neither hydrolysis nor photolysis are expected to contribute significantly to the degradation of methomyl in the aqueous environment. Methomyl is not ready biodegradable.
In water / sediment systems, methomyl partitions to the sediment to levels up to 11.4 % AR after one day. Degradation occurred with half lives between 2.5 to 4.8 days in the whole systems. Dissipation from the water phase was between 3.5 and 4.5 d. Unextractable residues in the sediment reached a maximum of 20.1 % AR after 14 d declining to 14.7 % AR at the end of the study (102 d). CO_2 reached a maximum of 32.1 – 72.3 % AR at the end of the studies. Acetonitrile appears as a major

metabolite in some systems both in the sediment and as volatile metabolite. The meeting of MS experts considered that the potential environmental contamination by acetonitrile derived from the use of methomyl will be insignificant with respect to other anthropogenic sources.

$PEC_{SW\ /\ SED}$ values for parent methomyl were calculated based only in spray drift loadings and considering two categories. The first category is 'late grapes and listed tall vegetables' (i.e. tomatoes and grapes post-flowering) and the second category is 'listed low vegetables' (i.e. courgettes and aubergines). For cucumber it is necessary for Member States to consider which category cucumbers fit into under their growing regimes. The values were recalculated for a water phase half life of 4.5 d in the addendum.

The potential of ground water contamination by methomyl and its minor soil metabolite methomyl oxime was simulated by the applicant and recalculated by the rapporteur Member State for the representative uses in vines and tomatoes with FOCUS PRZM 2.2.1 and FOCUS PEARL 1.1.1 models for all relevant scenarios. None of the crop / scenario combination exceeded the 0.1 µg / L on the 80^{th} percentile annual average concentrations neither for methomyl nor for methomyl oxime.

Concentration of methomyl in the air compartment and transport through it is not expected to be significant.

Methomyl is intended to be used in cucumber/courgette, tomato/eggplant and grape (table & wine). The use in grapes is not longer supported by the applicant for the EU review process (i.e. with respect to Annex I inclusion). Nevertheless the risk from this originally intended use is reported in the section on ecotoxicology as far as the risk assessment is available.

Based on the assessment according to EPPO (1992) the short and long term risk to birds can be regarded as low. The first tier acute risk to insectivorous birds is considered to be high. The applicant should be asked to address the acute risk from methomyl on the same basis as was done by the PPR Panel for pirimicarb. Furthermore the applicant is requested to provide a first tier risk assessment based on SANCO/4145/2000 and the dietary and reproduction endpoints for birds in terms of mg a.s./kg bw/day and a revised risk assessment. Based on the assessment according to EPPO (1992) both the acute and the long term risk to herbivorous mammals in grapes have to be regarded as high. Based on a weight of evidence approach, this long term risk was considered to be addressed. The acute risk from methomyl should be refined by the applicant on the same basis as was done by the PPR Panel for pirimicarb. A low risk to insectivorous mammals was identified in cucumber/courgette and tomato/eggplant if calculated according to EPPO (1992).

The EFSA recalculated the first tier risk to birds and mammals according to SANCO/4145/2000. Based on this risk assessment the short term risk to birds can be regarded as low but a high acute and long term risk was identified as well as a high acute and long term risk to mammals for all representative uses evaluated. Therefore the applicant is requested to submit a refinement of the long term risk to birds and mammals if the risk is assessed according to the latest guidance document (SANCO/4145/2000). For the acute risk to birds and mammals see outstanding data gap discussed above. A risk for birds and mammals from consumption of contaminated drinking water was identified which the EFSA proposes to be addressed.

A high risk to aquatic organisms was identified for which risk mitigation measures such as a buffer zone of 50 metres for 'late grapes and listed tall vegetables' and a buffer zone of 30 metres for 'listed low vegetables' should be taken into account.
A high risk to bees was identified. Risk mitigation measures to avoid all contact with bees are considered necessary. No data to establish a withholding period is available.
A high risk to non-target arthropods was identified. The applicant is asked to refine the risk assessment for non-target arthropods for both the in-field and off-field areas. The risk can only be concluded once this data becomes available but risk mitigation measure will possibly be necessary.
The acute risk to earthworms is considered to be low. In addition also the long term risk to earthworms can be considered as low for the representative uses in cucumber/courgette and tomato/eggplant for growth stages from BBCH 20 onwards. A long term risk to earthworms in grapes and in fruiting vegetables before growth stage BBCH 20 was identified. It is proposed that the applicant should address this risk.
The risk to soil micro-organisms, other soil non-target macro-organisms, non-target plants and biological methods for sewage treatment is considered to be low.

Key words: methomyl, peer review, risk assessment, pesticide, insecticide