

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

spirodiclofen

finalised: 13 June 2007

SUMMARY

Spirodiclofen is a new active substance for which in accordance with Article 6 (2) of Council Directive 91/414/EEC¹ the Netherlands received an application from Bayer CropScience for inclusion in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision 2002/593/EC².

Following the agreement between the EU-Commission and the EFSA for the EFSA to organise a peer review of those new active substances for which the decision on the completeness of the dossier had been published after June 2002, the designated rapporteur Member State, the Netherlands, made the report of its initial evaluation of the dossier on spirodiclofen, hereafter referred to as the draft assessment report (DAR), available on 21 April 2004.

The peer review was initiated on 18 May 2004 by dispatching the draft assessment report for consultation of the Member States and the applicant. 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 applicant upon request were evaluated in a series of scientific meetings with Member State experts in June – July 2005.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 4 December 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 an insecticide and acaricide as proposed by the applicant which comprises of spray application to control mites and sucking insects. Full details of the GAP can be found in the table “Summary of representative uses evaluated” which is in the attached end points list.

The representative formulated product for the evaluation was "Envidor SC 240", a suspension concentrate containing 240 g/L spirodiclofen.

¹ OJ No L 230, 19.8.1991, p.1 as last amended by OJ L 106, 24.4.2007, p.14

² OJ No L 192, 20.7.2002, p. 60

Adequate methods are available to monitor all compounds given in the respective residue definition. Residues in food of plant origin can be determined with a multi-method (The German S19 method has been validated). For the other matrices only single methods are available to determine the residues of spirodiclofen and its enol metabolite in soil, water and animal products and spirodiclofen in air. Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available except for the relevant impurities 3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4.5]dec-3-en-2-one (BAJ-2740-enol) and N,N-dimethylacetamide to ensure that quality control measurements of the plant protection product are possible.

Spirodiclofen is not acutely toxic via oral, dermal and inhalation routes. It is not a skin or eye irritant, but it is a skin sensitizer, therefore R43 “May cause sensitisation by skin contact” was proposed. The overall relevant short and long term NOAEL is 1.45 mg/kg bw/day (liver and adrenals effects). Spirodiclofen chronic administration results in liver tumors in mice, Leydig cell tumours and uterus adenocarcinomas in rats, with clear NOAELs demonstrated. The classification R40 “Limited evidence of a carcinogenic effect” was proposed. Spirodiclofen has no genotoxic, reproductive and developmental toxicity potential. The subchronic NOAEL for neurotoxicity is 70 mg/kg bw/day, while the chronic neurotoxicity NOAEL is 110 mg/kg bw/day. The established ADI is 0.015 mg/kg bw/day and the AOEL is 0.009 mg/kg bw/day (100 safety factor applied). The allocation of an acute reference dose was not considered necessary. For the operators estimated exposure is below the AOEL for mechanical spraying in grapes and manual upward spraying in pome fruits, stone fruits and citrus, with the use of PPE; the estimated exposure for workers and bystander is \geq AOEL in all scenarios considered.

The metabolism of spirodiclofen in fruit has been fully elucidated and proceeds through ester cleavage and hydrolysis steps. The parent compound was identified as the major constituent of the residue on fruit crops for various PHIs. The identified metabolites are present at very low levels but considered as toxic as the parent compound. Given the predominance of spirodiclofen in the terminal residue on fruits, the residue definition can be restricted to parent compound only, for both risk assessment and monitoring. Under processing, spirodiclofen is degraded only at temperatures of 100°C or higher to spirodiclofen-enol and hence under conditions representative for fruit processing (pH 4, 90°C) no generation of spirodiclofen-enol is expected.

Upon exposure of spirodiclofen to livestock one main component of the residue in food of animal origin was identified as spirodiclofen-enol and defined as the residue of concern in terms of consumer exposure. Based on the results of the ruminant feeding studies MRLs for food of animal origin could be derived.

The consumer risk assessment showed that the chronic exposure to spirodiclofen residues from fruit and spirodiclofen-enol residues from food of animal origin is well below the ADI of spirodiclofen. Because an ARfD is considered not necessary, the acute risk for the consumer does not need to be assessed.

The available data demonstrate that spirodiclofen degrades in soil to the major (> 10% applied radioactivity (AR)) metabolites BAJ 2740-enol, BAJ 2740-ketohydroxy, BAJ 2740-dihydroxy and 2,4-dichlorobenzoic acid. Aerobic degradation of spirodiclofen in soil proceeds via hydrolytic and enzymatic/microbial pathways. Mineralization was significant (22-5-93.1% AR by day 120 with the dihydrofuranone-label and 69.1% AR with the cyclohexyl-label), and non extractable residues accounted for maximum 14.4 and 19.6% AR. In soil spirodiclofen, BAJ 2740-dihydroxy and 2,4-dichlorobenzoic acid exhibited low to moderate persistence, BAJ 2740-ketohydroxy exhibited very low to moderate persistence and BAJ 2740-enol can be classified as low persistent. The possibility that anaerobic conditions are encountered after application is unlikely as the proposed applications to orchard crops and grapes will occur during the spring (only for grapes) or summer months.

Adsorption coefficients of the major metabolites BAJ 2740-enol, BAJ 2740-dihydroxy and 2,4-dichlorobenzoic acid indicated that they are very high mobile, whereas the parent spirodiclofen is strongly adsorbed to soil particles and BAJ 2740-ketohydroxy can be classified as low mobile. There was no evidence of pH dependant adsorption. The low potential of spirodiclofen for leaching was confirmed in the aged column leaching study (<0.1% AR in leachate), but BAJ 2740-enol and 2,4-dichlorobenzoic acid were detected in the leachate at 17.4 and 19.0% AR, respectively.

FOCUS-PEARL modelling for all crops and EU-scenarios, based on average DT_{50} , Koc and $1/n$ values from laboratory studies, predicted 80th percentile of annual average concentrations in groundwater of < 0.001 µg/L for parent spirodiclofen, BAJ 2740-ketohydroxy, ≤ 0.001 µg/L for the metabolites BAJ 2740-enol and BAJ 2740-dihydroxy and up to 0.012 µg/L for 2,4-dichlorobenzoic acid.

In shallow natural waters, the major dissipation route of spirodiclofen will be hydrolysis, microbial degradation and partitioning to the sediment ($DT_{50system}$ 2.3-4.2 days). Photolysis will not contribute to the dissipation of spirodiclofen in the aquatic environment. In sediment, spirodiclofen dissipates rapidly with DT_{50} values of 2.5-4.4 days. Only low levels of non-extracted residues are formed. BAJ 2740-enol is the major sediment/water metabolite (max. 84% and 30% AR in water and sediment, respectively), dissipating from the water of one system with a DT_{50} of 186 days, but stable in the water of the second system. In the sediment of both systems, the levels of BAJ 2740-enol continued to increase throughout the study. The lifetime of this metabolite in natural aquatic system is likely to be controlled by photochemical degradation (DT_{50} in Rhine water 7.6 hours) rather than biological and chemical degradation. The pathway of anaerobic water/sediment degradation of spirodiclofen is similar, but rates of dissipation are lower (9.8 and 10 days in sediment and overall system, respectively).

The available aquatic exposure assessment is appropriate for addressing the spray drift route of entry to surface water for spirodiclofen and BAJ 2740-enol. Member states should therefore carry out a surface water exposure and consequent aquatic risk assessment from the runoff and drainage routes of exposure at the national level.

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

The risk to birds and mammals was assessed as low for the representative uses evaluated. The aquatic risk assessment was based on spray drift as the only route of entry into surface water. The acute TER values for aquatic organisms were markedly above the trigger values but the long-term TER values for fish, daphnids and sediment dwelling insects were below the Annex VI trigger of 10. Risk-mitigation measures such as no-spray buffer zones of up to 30m (early use in orchards), 15m (late use in orchards) and 10m (late use in vine) are required to mitigate the long-term risk to aquatic organisms. The acute risk to adult bees is low but larval stages are susceptible. Temporary adverse effects on bee brood development with recovery after 4 weeks were observed in field tests. Therefore it is suggested that the product should not be applied during flowering of the crop and to label the product accordingly. The standard laboratory tests suggested a high potential risk to predatory mites. Field tests with *T. pyri* showed that recovery within one year after the application is possible and the risk to non-target arthropods is considered as sufficiently addressed for the representative uses. Effects of >25% on soil nitrification were observed in tests with spiroticlofen and its major soil metabolites. The effects caused by the metabolites occurred on day 14 but were <25 % at day 28 and also the effects of spiroticlofen were <25% after day 56. Since the tested concentrations were a factor of 2 to 66 times higher than the initial PEC_{soil} values and the effects were of temporary nature it is assumed that the observed effects would not cause a high risk to soil functioning at the application rates suggested in the representative uses.

The risk to earthworms, other soil non-target macro organisms, non-target plants and biological methods of sewage treatment were assessed as low for the representative uses.

Key words: Spiroticlofen, peer review, risk assessment, pesticide, insecticide and acaricide.