



Peer review (fornylse) af alpha-cypermethrin. Vurdering af forbrugersikkerheden

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NOTAT

Til Fødevarestyrelsen

Vedr. Peer review (fornyelse) af alpha-cypermethrin. Vurdering af forbrugersikkerheden

Fra Fødevareinstituttet

28. marts 2019

J.nr 19/01074

bhje/annp

Forespørgsel

I forbindelse med EFSA's konklusionsrapport: Peer review of the pesticide risk assessment of the active substance, alpha-cypermethrin, 2018 er Fødevareinstituttet blevet spurgt:

Om de nævnte concerns eller mangler giver anledning til, at stoffet for så vidt angår forbrugersikkerheden, ikke bør gives fornyet godkendelse.

Konklusion

Alpha-cypermethrin er til fornyet godkendelse som insekticid med repræsentative brug i cerealer, raps, salat, kinakål, grønkål og på agurker og courgette i væksthus.

Der er ikke problemer med det kroniske indtag, idet den udgør 67% af ADI for de repræsentative brug. Derimod udgør det akutte indtag for agurker og courgetter henholdsvis 131% og 104% af ARfD og for grønkål og salat henholdsvis 2541% og 1248% af ARfD. Der er derimod ikke overskridelser af det akutte indtag for korn og raps.

Det vurderes, at da der er overskridelser af den akutte referencedosis for agurker, courgetter, grønkål og salat, kan disse afgrøder ikke længere være omfattet af de repræsentative brug.

Det vurderes, at alpha-cypermethrin kan blive godkendt med repræsentative brug i korn og raps, hvis

1. Evalueringen af de konfirmative data for metabolitterne 3-PBA og 4-OH-PBA viser, at disse ikke er genotoksiske,
2. Der fremsendes yderligere oplysninger om den relative toksicitet af de individuelle isomerer

Baggrund for konklusion vedr. vurdering af, om de nævnte concerns eller mangler giver anledning til, at alpha-cypermethrin for så vidt angår forbrugersikkerheden, ikke bør gives fornyet godkendelse.

ADI = 0,00125 mg/kg lgv/dag (tidligere 0,015 mg/kg lgv/dag)

ARfD= 0,00125 mg/kg lgv (tidligere 0,04 mg/kg lgv/dag)

Repræsentative brug omfatter brug som insekticid på cerealier, raps, salat, bladkål og på agurker og courgette i væksthuse.

Risikovurderingen af indtaget kunne ikke gøres færdig, fordi restdefinitionen for risikovurdering i planter og animalske er provisorisk. Der afventes en vurdering af den relative toksicitet af de individuelle cypermethrin isomerer samt undersøgelser for om metabolitter, der indeholder 3-phenoxybenzoyl, herunder 3-PBA og 4-OH-PBA er genotoksiske. Metabolitter der indeholder 3-phenoxybenzoyl dannes også ved brug af lambda-cyhalothrin, og en vurdering af om disse metabolitter er genotoksiske afventer vurderingen af konfirmative data for lambda-cyhalothrin. Ligeledes mangler der restforsøg for agurker, grønkål, salat og byg.

Fra EFSA's opinion om fornyelse:

The residue definition for monitoring was limited to 'cypermethrin including other mixtures of constituent isomers (sum of isomers)' as a valid marker of the total residues in all crop groups

The residue definition for risk assessment was 'cypermethrin including other mixtures of constituent isomers (sum of isomers)'

Consumer risk assessment

- *No chronic intake concern was identified using the MRL proposals for the representative uses and for animal commodities (theoretical maximum daily intake (TMDI): 67% of ADI, Dutch child).*
- *An acute intake concern was however identified for cucumbers (IESTI: 131% of ARfD, Dutch child), courgettes (IESTI: 104% of ARfD, UK toddler), kales (IESTI: 2,541% of ARfD, Dutch child) and for lettuces (IESTI: 1,248% of ARfD, German child). Acute intakes of milk and milk products for vulnerable consumer groups are very close to the ARfD (> 99% of ARfD for infants), applying the provisional risk assessment residue definition.*

I EFSA's opinion for fornyelse angiver EFSA følgende datamangler:

- *Further assessment of the genotoxic potential of the metabolites 3-PBA and 4-OH-PBA (common with lambda-cyhalothrin) (relevant to all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).*

- *The relative toxicity of the individual cypermethrin isomers, in particular the enantiomer (1S cisaR) to be addressed, or an argumentation to be provided, on how a sufficiently sound consumer dietary risk assessment can be conducted considering the change in isomer ratio in animal commodities (relevant for cereals, oilseed rape and leafy brassica; submission date proposed by the applicant: unknown; see Sections 2 and 3).*
- *Sufficient residue trials on cucumbers compliant with the indoor GAP (relevant for the representative uses evaluated on cucumbers and courgettes; submission date proposed by the applicant: unknown; see Section 3).*
- *Two residue trials and four residue trials on kales and compliant, respectively, with the NEU and SEU outdoor GAPs to be extrapolated to the whole subgroup of leafy brassica (relevant for the representative use evaluated on leafy brassica; submission date proposed by the applicant unknown; see Section 3).*
- *Sufficient residue trials on lettuces and compliant, respectively, with the NEU and SEU GAPs (relevant for the representative use evaluated on lettuces; submission date proposed by the applicant: unknown; see Section 3).*
- *One residue trial on barley compliant with the SEU GAP (relevant for the representative uses evaluated on barley and oats; submission date proposed by the applicant: unknown;*

Referencer

EFSA 2018, Conclusion on the Peer review of the pesticide risk assessment of the active substance alpha-cypermethrin