Peer review (fornyelse) af cypermethrin. Vurdering af forbrugersikkerheden

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Publication date:
2019

Document Version
Publisher's PDF, also known as Version of record

NOTAT

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Fra Fødevareinstituttet

28. marts 2019
J.nr 19/01111
bhje/annp

Forespørgsel
I forbindelse med EFSA´s konklusionsrapport: Peer review of the pesticide risk assessment of the active substance, 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
Cypermethrin er til fornyet godkendelse som insekticid med repræsentative brug i korn, raps og kartofler

Der er ikke problemer med det kroniske indtag, idet den højst udgør 43% af ADI (NL child) for de repræsentative brug. Det akutte indtag udgjorde derimod 99,4% af ARfD for mælk og mælkeprodukter for en UK infant.

Det vurderes, at cypermethrin kan blive godkendt med repræsentative brug i korn, raps og kartofler, 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

Evt. bidrag fra pollen, biprodukter og fisk til det kroniske indtag forventes kun at være af lille omfang og forventes ikke at ændre det kroniske indtag nævneværdig.

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

ADI = 0,005 mg/kg lgv/dag
ARfD= 0,005 mg/kg lgv

Repræsentative brug omfatter brug som insekticid på korn, raps og kartofler.

Risikovurderingen af indtaget kunne ikke gøres færdig, fordi restdefinitionen for risikovurdering i planter og animalske produkter 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 data for restindhold i pollen og biprodukter til human konsum samt metabolismeundersøgelse i fisk.

Fra EFSA´s opinion om fornyelse
The residue definition for monitoring was '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 provisionally set to 'cypermethrin (sum of isomers)' pending finalisation of the assessment of the genotoxic potential of 3-PBA and review of the preliminary conclusions in toxicology on the whole group of related metabolites bearing the 3-phenoxybenzoyl moiety (besides 3-PBA also, e.g. PBAldehyde, 4-OH-PBA)once the confirmatory data on lambda-cyhalothrin

The animal residue definition risk assessment is therefore provisionally set as 'cypermethrin including other mixtures of constituent isomers (sum of isomers)' and using a relative potency factor of 4 to account for the potential increase in toxicity of the residues in animal commodities until further information on the relative toxicity of the individual isomers has become available. Again, finalisation of the assessment of the genotoxic potential of 3-PBA and review of the preliminary conclusions in toxicology on the whole group of related metabolites with the 3-phenoxybenzoyl moiety is awaited to conclude on the animal residue definition for risk assessment.

Consumer risk assessment
The chronic and acute consumer risk assessment conducted with the EFSA PRIMo rev. 2 did not result in an exceedance of ADI (41.3% NL child) and the ARfD (99.4% milk and milk products, UK infant) for the representative uses. Acute intakes of milk and milk products for vulnerable consumer groups are very close to the ARfD, applying the provisional risk assessment residue definition and provisional relative potency factor. EFSA therefore emphasises

the importance of reducing uncertainty in the current assessment by providing further information on the relative toxicity of individual isomers in cypermethrin. The consumer dietary risk assessment is moreover provisional considering the data gaps identified for additional residue trials in barley and wheat and the pending assessment of the metabolites, most notably 3-PBA.

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

- *Toxicity studies on 3-PBA and 4-OH-PBA submitted under confirmatory data on lambdacyhalothrin (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).*

- *A fish metabolism study upon dietary exposure (relevant for all representative uses evaluated;submission date proposed by the applicant: unknown; Sections 2 and 3).*

- *The relative toxicity of the individual isomers to be addressed or an argumentation be provided how a sufficiently sound consumer dietary risk assessment can be conducted considering the change in isomer ratio in animal commodities (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3)*

- *At least two additional trials on barley compliant with the SEU GAP (relevant for the representative uses in cereals in SEU; submission date proposed by the applicant: unknown; see Section 3)*

- *At least one independent, GAP-compliant supervised residue trial on wheat in SEU (relevant for the representative uses in cereals in SEU; submission date proposed by the applicant:unknown; see Section 3*

- *Data on residue levels in pollen and bee products for human consumption as set out in current data requirements in Reg. 283/2013 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3)*

Referencer

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