Risk assessment of basil with residues of carbofuran, buprofezin and oxycarboxin

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Request

The Danish Veterinary and Food Administration has requested the National Food Institute to perform a risk assessment of carbofuran with a content of 0.053 mg/kg, buprofezin with a content of 0.025 mg/kg and oxycarboxin with a content of 0.051 mg/kg. The MRL is 0.02* mg/kg for all substances.

Conclusion

Due to the lack of data to exclude *in vivo* genotoxic properties of the metabolite 3-hydroxy-carbofuran and since it is assumed that there is no threshold for potential genotoxic effects, a health concern cannot be excluded.

For buprofezin, aniline can be formed during heating of basil. Since aniline is classified for genotoxic effects for which it is assumed that there is no threshold, a health concern cannot be excluded.

Since no toxicological reference values have been established for oxycarboxin in the EU Pesticide database, a risk characterization cannot be carried out and a health concern cannot be excluded.

Risk assessment

Carbofuran

Carbofuran is not approved for use in the EU. According to the EFSA conclusion from 2009:

Carbofuran is rapidly and completely absorbed and excreted in the rat. It is very toxic by ingestion (LD_{50} =7 mg/kg bw) and by inhalation (LC_{50} =0.05 mg/L) and "The metabolites 3-hydroxy-carbofuran and 3-keto-carbofuran are very toxic and toxic (LD_{50} of 8 and 107 mg/kg bw, respectively), the hydroxy metabolite is genotoxic as well in vitro (Ames test and mouse lymphoma cells assay). The metabolites 3-hydroxy-carbofuran-phenol, 3-keto-carbofuran-phenol8 and carbofuran-phenol are harmful if swallowed".

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EFSA last assessed carbofuran in 2009. The provisionally value of ARfD from 2005 was discussed at a teleconference (04/09) on the basis of an addendum (2008) containing new data. At the meeting, a new ARfD of 0.00015 mg/kg bw/day was set based on a new acute neurotoxicity study (LOAEL = 0.03 mg/kg bw/day with a safety factor of 200).

DTU National Food Institute considers the ARfD of 0.00015 mg/kg bw determined by EFSA as valid and notes that the reference values includes a sufficient margin of safety with respect to the acute oral toxicity for carbofuran and its metabolites. However, for the metabolite *3-hydroxy-carbofuran*, which is included in the residue definition for risk assessment, there is still an outstanding issue regarding *in vivo* genotoxicity. The metabolite was shown to be genotoxic in *in vitro* assays. It is not clear from the EFSA conclusion report whether the metabolite is formed in the rat > 10% and therefore can be covered by the data from the active substance. DTU National Food Institute concludes that due to the lack of clarification of r potential *in vivo* genotoxic effects of this metabolite and hence assuming no threshold, the determined ARfD cannot be used for risk assessment.

The acute exposure was estimated to 0.039 µg/kg bw and 0.0065 µg/kg bw for children and adults, respectively, when EFSA PRIMo version 3.1 is used for the calculation. In EFSA PRIMo it is a ”DE Child” and a ”NL general” who are the critical consumers in the EU.

Conclusion: Due to the lack of data to exclude *in vivo* genotoxic properties of the metabolite 3-hydroxy-carbofuran and since it is assumed that there is no threshold for potential genotoxic effects, a health concern cannot be excluded.

Buprofezin

Buprofezin is not approved for use in edible crops in the EU, since aniline can be formed during heating.

The acute exposure is estimated to 0.018 µg/kg bw and 0.0031 µg/kg bw for children and adults, respectively, when EFSA PRIMo version 3.1 is used for the calculation. In EFSA´s PRIMo it is a ”DE Child” and a ”NL general” who are the critical consumers in the EU.

Basil can be cooked and aniline can be formed during heating. Aniline is a suspected genotoxic and carcinogenic substance. A threshold for genotoxic effects cannot be assumed.

Conclusion: Since aniline can be formed during heating, a health concern cannot be excluded.

Oxycarboxin

Oxycarboxin is not approved for use in the EU. There is no toxicological reference values in the EU Pesticide database and a risk characterization cannot be performed.

The acute exposure is estimated to 0.037 µg/kg bw and 0.0063 µg/kg bw for children and adults, respectively, when EFSA PRIMo version 3.1 is used for the calculation. In EFSA PRIMo it is a ”DE Child” and a ”NL general” who are the critical consumers in the EU.

Conclusion: Since there is no toxicological reference values established in the EU Pesticide database, a health concern cannot be excluded.

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