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## Health impairment through carbofuran in red chili unlikely

BfR Opinion No 015/2019 of 24 April 2019

A regional laboratory found residues of carbofuran when analyzing frozen “Red chili without stalks” for plant protection products. The Federal Ministry of Food and Agriculture (BMEL) thereupon asked the German Federal Institute for Risk Assessment (BfR) to make a health assessment for the sample. The result was that a risk to the health of consumers is unlikely according to the latest available scientific knowledge.

Carbofuran is a plant protection product which can be used against certain insects, mites, ticks and nematodes. On the basis of the amount of the carbofuran residues and estimated dietary intake of red chilies, an exceedance of the acute reference dose (ARfD) is not to be expected for children or adults. The ARfD describes the quantity of a substance per kilogram of body weight that consumers can ingest with their food in one meal or in several meals spread over one day without any recognisable effect on health. The ARfD is therefore a limit value for risk assessment in relation to short-term intake.

Other plant protection products were also detected in the 10 samples from the manufacturer (2308 grams in total), but their contribution is negligible in relation to carbofuran so that no health risk is to be expected from them either. As the number of samples is small, the results cannot be generalised for red chili.

		<b>BfR Risk Profile:</b> Carbofuran in red chilli without stalks (Opinion No.015/2019)			
<b>A Affected groups</b>	[General population] 				
<b>B Probability of a health impairment with daily consumption of red chillies without stalks containing carbofuran</b>	Practically excluded	<b>Unlikely</b>	Possible	Probable	Certain
<b>C Severity of the health impairment with daily consumption of red chillies without stalks containing carbofuran</b>	The severity of the impairment can vary [1]				
<b>D Reliability of available data</b>	High: The most important data are available and free of contradiction	Moderate: Some important data are missing or contradictory	Low: Numerous important data are missing or contradictory		
<b>E Controllability by the consumer</b>	Control not necessary	Controllable through precautionary measures	<b>Controllable through avoidance [2]</b>	Not controllable	

### Explanations

The risk profile is intended to visualise the risk outlined in the BfR Opinion. It is not intended for the purpose of comparing risks. The risk profile should only be read in conjunction with the corresponding opinion.

[1] – Line C

When assessing the health risk of the uptake of carbofuran, total exposure from all sources has to be taken into account. This includes other foods too.

[2] – Line E

In the view of the BfR. Carbofuran levels in relevant foods should be kept as low as possible.

## 1. Object of the assessment

The Federal Ministry of Food and Agriculture (BMEL) asked the BfR to make a health assessment of the residues of 0.061 milligrams (mg) per kilogram (kg) carbofuran (sum of carbofuran and 3-OH-carbofuran calculated as carbofuran) determined in frozen red chilies without stalks.

## 2. Result

According to the latest available scientific knowledge, a health risk to children or adults through carbofuran residues in red chili totalling 0.061 mg per kg is unlikely.

In addition to carbofuran, other active substances (see Table 3) were detected in the same sample of red chilies which, just like carbofuran, lead to an inhibition of acetylcholinesterase and can therefore have a cumulative effect. Acetylcholinesterase is an enzyme which helps to pass on nerve impulses to synapses. Compared to carbofuran, the acute toxicity of the other active substances detected is much lower. A health risk through these residues is not likely either.

## 3. Justification / Risk assessment

Carbofuran (IUPAC name: 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate) is a systemic, insecticidal, acaricidal (includes mites and ticks) and nematocidal (against nematodes) active substance from the group of benzofuranylic methylcarbamates. Per EU Commission Decision 2007/416/EC of 13.06.2007, it was not included in Annex I to Council Directive 91/414/EEC, meaning that no plant protection products containing this active substance can be authorised in the EU.

### 3.1 Toxicological assessment of the active substance

Carbofuran has been comprehensively examined toxicologically. Current assessments by the World Health Organization (WHO, 2008)<sup>i</sup> and European Food Safety Authority (EFSA, 2009)<sup>ii</sup> are available for carbofuran along with the toxicological limit values listed in Table 1 and Table 2.

**Table 1: WHO limit values for carbofuran (2008)**

Designation	Value	Study/Animal species	Safety factor
ADI	0.001 mg per kg body weight	Acute studies on adult and 11 day-old rats on the inhibition of acetylcholinesterase in the brain	25*
ARfD	0.001 mg per kg body weight	Acute studies on adult and 11 day-old rats on the inhibition of acetylcholinesterase in the brain	25*

\* A safety factor of 25 was used because the relevant effects depend on  $C_{max}$  in the opinion of the WHO (2008).

**Table 2: EFSA limit values for carbofuran (2009)**

Designation	Value	Study/Animal species	Safety factor
ADI	0.00015 mg per kg body weight	Acute studies on adult and 11 day-old rats on the inhibition of acetylcholinesterase in the brain	200*
ARfD	0.00015 mg per kg body weight	Acute studies on adult and 11 day-old rats on the inhibition of acetylcholinesterase in the brain	200*

\* A safety factor of 200 was used because the limit values were derived from a LOAEL (lowest observed adverse effect level) in the opinion of EFSA (2009).

The lower limit values derived by EFSA for carbofuran were used for the risk assessment.

### 3.2 Estimation of short-term uptake quantity

Carbofuran residues amounting to 0.061 mg per kg (sum of carbofuran and 3-OH-carbofuran calculated as carbofuran) were measured during the examination of red chili. The maximum residue level that currently applies for the active substance in red chili in the EU is 0.002\* mg per kg; this concentration was established on the basis of the analytical limit of quantification.

The sum of carbofuran and 3-OH-carbofuran calculated as carbofuran was defined as the relevant residue for risk assessment as well as monitoring.

No specific consumption data for the estimation of short-term uptake by consumers through the one-off consumption of fresh chilis is available in either the EFSA European PRIMo model (Version 3)<sup>iii</sup> or in the German NVS-II model<sup>iv</sup>. An estimation of the maximum tolerable portion size equivalent to 100% utilisation of the acute reference dose (ARfD) on the basis of the detected carbofuran level results in the following quantities, depending on body weight (assumption IESTI Case 1 – unit weight below 25 grams (g) each):

Children (2-4 years, 16.15 kg body weight):	up to 39 g per day
Adults (14–80 years, 76.37 kg body weight):	up to 187 g per day

As no consumption data has been reported for chili, use can only be made of the consumption data for bell peppers within the Capsicum product group. The maximum tolerable portion size of 187 g per day calculated for adults is of the same magnitude as the one-off large consumption quantity (“large portion”) for fresh bell peppers of 228.3 g per day (NVS-II model). As it is unlikely that an equivalent portion of fresh, hot chilis would be consumed, no exceedance of the ARfD for carbofuran (0.00015 mg per kg body weight) is to be expected for adults.

The maximum tolerable portion size for children is 39 g per day. Unlike the situation with adults, this quantity lies far below the one-off large consumption quantity (“large portion”) for fresh bell peppers of 143.5 g per day for children. There is no German data on the unit weight of an average chili pepper, but a unit weight of 9.6 g per fresh chili pepper is reported from the Netherlands in the IESTI model of the Joint Meeting on Pesticide Residues (JMPR)<sup>v</sup>. If this weight is used as the basis, children would have to eat a maximum portion of roughly 4 chilis within one day to reach the ARfD for carbofuran. Typical recipes for dishes containing chili, such as chili con carne, normally use only one chili per portion<sup>vi</sup>. It is therefore unlikely that the maximum tolerable portion size, and thereby an exceedance of the ARfD for carbofuran, would be reached with children either.

In addition to carbofuran, the active substances acephate, disulfoton, chlorpyrifos, methamidophos and profenofos were also detected in the sample to be assessed, all of which lead to inhibition of the acetylcholinesterase and can therefore have a cumulative effect. As there is no suitable consumption data for calculating cumulative uptake, the relative contribution to the Hazard Index (HI) was calculated using the levels detected. To do so, standardised consumption quantities and body weights of 1 kg respectively were used as the basis and the individual index contribution calculated for each substance:

**Table 3: Contribution of detected substances with acetylcholinesterase-inhibiting properties to cumulative total uptake**

Active substance	ARfD in mg per kg body weight (Source**)	Detected residue in mg per kg	Individual index contribution assuming 1 kg body weight and consumption quantity	Relative contribu- tion to HI in %
Carbofuran*	0.00015 (EFSA. 2009)	0.061	407	96.5
Acephate	0.1 (WHO. 2005)	0.039	0.39	<0.1
Chlorpyrifos	0.005 (EFSA. 2014)	0.024	4.8	1
Disulfoton	0.003 (WHO. 1996)	0.019	6.3	1.5
Methamidophos	0.003 (EFSA. 2005)	0.01	3.3	0.8
Profenofos	1 (WHO. 2007)	0.17	0.17	<0.1
Total	-	-	421.96	100

\* Sum of carbofuran and 3-OH carbofuran calculated as carbofuran

\*\* EFSA's toxicological limit value or lower value preferred. Where there was no EFSA limit value, the FAO/WHO limit value was used.

It can be seen on the basis of each ARfD that a total of 96.5% of the total toxicological load is caused by carbofuran. There is therefore no need for a more extensive cumulative assessment of the other acetylcholinesterase inhibitors contained, as their contribution is negligible compared to carbofuran.

**More information on the subject at the BfR website ...**

Opinion on foods with high capsaicin levels:

<https://www.bfr.bund.de/cm/349/too-hot-isnt-healthy-foods-with-very-high-capsaicin-concentrations-can-damage-health.pdf>

Frequently asked questions about plant protection product residues in food:

[https://www.bfr.bund.de/en/questions\\_and\\_answers\\_on\\_residues\\_of\\_plant\\_protection\\_products\\_in\\_food-60852.html](https://www.bfr.bund.de/en/questions_and_answers_on_residues_of_plant_protection_products_in_food-60852.html)



BfR "Opinions App"

#### 4 References

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- <sup>i</sup> WHO (2008) Pesticide residues in food – 2008 evaluations. Part II. Toxicological; pp. 81-104. World Health Organization, Geneva
- <sup>ii</sup> EFSA (2009) Conclusion on pesticide peer review regarding the risk assessment of the active substance carbofuran. EFSA Scientific Report (2009) 310, 1-132
- <sup>iii</sup> Use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3), Doi: 10.2903/j.efsa.2018.5147, EFSA Journal 2018;16(1):5147 [43 pp.],
- <sup>iv</sup> <http://www.bfr.bund.de/cm/343/bfr-berechnungsmodell-zur-aufnahme-von-pflanzenschutzmittel-rueckstaenden-nvs2.zip>
- <sup>v</sup> [http://www.fao.org/fileadmin/templates/agphome/documents/Pests\\_Pesticides/JMPR/Manual/Electronic\\_attachments\\_revised.zip](http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Manual/Electronic_attachments_revised.zip)
- <sup>vi</sup> <https://www.chefkoch.de/rezepte/116707122277296/Chili-con-Carne.html>

#### About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

*This text version is a translation of the original German text which is the only legally binding version.*