

DOI 10.17590/20170802-140011

Health assessment of individual measurements of fipronil levels detected in foods of animal origin in Belgium

BfR Opinion No. 016/2017 of 30 July 2017

Fipronil is a broad-spectrum insecticide used against fleas, lice, ticks, cockroaches, mites and other insects.

The estimation of the German Federal Institute for Risk Assessment (BfR) was made on the basis of a notice in the Rapid Alert System for Foods and Feeds (RASFF) according to which increased levels of fipronil were detected in eggs and egg products in Belgium. The currently available results of the analysis of fipronil levels range from 0.0031 to 1.2 mg per kg in chicken eggs and from 0.0015 to 0.0156 mg per kg in chicken meat. The estimation is also based on the general risk assessment of the European Food Safety Authority (EFSA) of 7 February 2006.

<https://www.efsa.europa.eu/de/efsajournal/pub/65r>

The health risk assessment of the fipronil residues measured in chicken eggs and chicken meat was made on the basis of an exceedance of the Acute Reference Dose (ARfD). The ARfD was derived from developmental toxicity studies with rats and is 0.009 mg per kg body weight (bw). It is defined as the quantity of a substance per kilogram body weight that can be ingested with one meal or within one day without any recognisable risk to the consumer. In the case of fipronil, calculations were performed with the highest measured value of the levels of fipronil in eggs (1.2 mg fipronil per kg eggs) as the worst case. On the basis of this level and the health reference values, the BfR arrives at the conclusion that under consideration of European consumption data, the ARfD for children is exceeded by chicken eggs. This does not necessarily mean that the consumption of chicken eggs poses a concrete health risk, but it indicates that, in line with the current level of available knowledge, a health risk is possible for children with the required margin of safety after consuming these contaminated chicken eggs.

1 Object of the assessment

The member states were notified by Belgium about fipronil levels in certain foods of animal origin via the RASFF rapid alert system.

The available results of the analysis of fipronil levels (measured as the sum of fipronil and its sulfone metabolite MB46136) range from 0.0031 to 1.2 mg/kg in chicken eggs and from 0.0015 to 0.0156 mg/kg in chicken meat.

The BfR was requested to assess the health risk posed to consumers.

2 Results

The health risk assessment of the residues of fipronil measured in chicken eggs and chicken meat was made on the basis of an exceedance of the acute reference dose (ARfD) of 0.009 mg/kg bw, which was derived within the scope of the EU evaluation of active substances contained in plant protection products, because, at the current point in time, there is no indication of a lifelong intake of fipronil residues via chicken eggs or chicken meat. Pro-

cessed as well as unprocessed products were taken into account in the consumption amounts on which exposure was estimated.

Based on the German National Nutrition Study (NVS II model), there is no exceedance of the ARfD for any of the examined consumer groups through the consumption of chicken eggs or chicken meat contaminated with fipronil. The EFSA PRIMo (Ver.2) shows no exceedance of the ARfD for adults either through the consumption of chicken eggs or chicken meat contaminated with fipronil.

When the European consumption data for children (UK infants) are taken into consideration, however, the ARfD is exceeded by a factor of 1.6 for chicken eggs. This does not necessarily mean that a concrete health risk exists through the consumption of chicken eggs, but it indicates that, where children are concerned, a health risk is possible with the required margin of safety after eating contaminated chicken eggs. On the basis of the two available exposure models, a fipronil concentration of 0.72 mg/kg (sum of fipronil and the sulfone metabolite MB46136 calculated as fipronil) can be regarded as the maximum concentration in chicken eggs at which no acute health risk exists for any of the examined consumer groups, since in this case the ARfD is not exceeded.

3 Risk Assessment

This risk assessment was carried out in accordance with the rules for residues of the active substances of plant protection products.

3.1 Toxicological assessment of the active substance fipronil

The following limit values for dietary exposure to fipronil were derived within the scope of the EU procedure for the approval of active substances contained in plant protection products (EFSA, 2006¹):

Designation	Value	Study / Species	Safety Factor
ADI	0.0002 mg/kg bw	2-year oral / rat	100
ARfD	0.009 mg/kg bw	Developmental neurotoxicity oral / rat	100

During the EU approval of the active substance, the toxicity of the metabolite fipronil sulfone was estimated to be comparable to that of fipronil and for this reason, it was decided that the limit value for fipronil should be used to assess exposure to fipronil sulfone (EFSA, 2006).

The above-mentioned study on developmental neurotoxicity in rats, which was used to derive the ARfD, was not presented within the scope of EU procedure for the approval of active substances for biocides. An ARfD was not derived during the biocide assessment. The AEL_{acute} was derived for different exposure scenarios than the dietary exposures assessed here (Assessment Report, 2011²).

¹ EFSA (2006). Conclusion regarding the peer review of the pesticide risk assessment of the active substance fipronil; finalised: 3 March 2006 revised 12 April 2006. EFSA Scientific Report (2006) 65, 1-110

² Assessment Report (2011). Inclusion of active substances in Annex I or IA to Directive 98/8/EC: Fipronil, Product type PT18 (insecticides, acaricides and products to control other arthropods); finalised: 6th May 2011.

The limit values for dietary exposures as derived within the scope of the EU evaluation of the active substance in plant protection products are used in this risk assessment.

ADI stands for Acceptable Daily Intake and indicates the quantity of a substance which consumers can ingest every day of their lives without any recognisable health risk.

3.2 Estimation of the short-term intake quantity (IESTI)

The available results on the analysis of levels of fipronil (measured as the sum of fipronil and its sulfone metabolite MB46136) range from 0.0031 to 1.2 mg/kg in chicken eggs and from 0.0015 to 0.0156 mg/kg in chicken meat. Analysis results for the sum of fipronil and MB46136 as well as MB46136 on its own are reported for the critical chicken egg sample at a level of 1.2 mg/kg. Accordingly, the content is formed solely by the metabolite MB46136 in this sample. The same toxicological limit values for acute oral exposure apply to both components, however.

To evaluate the short-term exposure of consumers, the German NVS II model³ for children and adults is available along with the EFSA PRIMo model (Version 2)⁴, which contains the consumption data of other EU member states in addition to those from Germany. The consumption quantity takes into account processed as well as unprocessed products.

The results of the estimations are summarised in the following tables.

Maximum intake of fipronil residues for children aged 2 to 4 years on the basis of the NVS II model (individual body weight)

Food	Selected percentile	Consumed quantity equivalent (g/kg bw/day)	MR (mg/kg)	Variability factor	Case	Intake in mg/kg bw/d	Percentage of ARfD
Chicken eggs	97.5	5.37	1.2	1	1	0.00644	72
Chicken meat	97.5	10.51	0.0156	1	1	0.000164	2

Maximum intake of fipronil residues for adults aged 14 to 80 years on the basis of the NVS II model (individual body weight)

Food	Selected percentile	Consumed quantity equivalent (g/kg bw/day)	MR (mg/kg)	Variability factor	Case	Intake in mg/kg bw/d	Percentage of ARfD
Chicken eggs	97.5	1.9	1.2	1	1	0.00233	26
Chicken meat	97.5	7.7	0.0156	1	1	0.000120	1

Maximum intake of fipronil residues for children (UK infants; 8.7 kg bw) on the basis of the EFSA model

Food	Selected percentile	Consumed quantity equivalent (g/kg bw/day)	MR (mg/kg)	Variability factor	Case	Intake in mg/kg bw/d	Percentage of ARfD
Chicken eggs	97.5	108.0	1.2	1	1	0.0149	166
Chicken meat	97.5	181.4	0.0156	1	1	0.00018	2

³ <http://www.bfr.bund.de/cm/343/bfr-berechnungsmodell-zur-aufnahme-von-pflanzenschutzmittel-rueckstaenden-nvs2.zip>

⁴ http://www.efsa.europa.eu/en/mrls/docs/calculationacutechronic_2.xls

Maximum intake of fipronil residues for adults (UK vegetarians; 66.7 kg bw) on the basis of the EFSA model

Food	Selected percentile	Consumed quantity equivalent (g/kg bw/day)	MR (mg/kg)	Variability factor	Case	Intake in mg/kg bw/d	Percentage of ARfD
Chicken eggs	97.5	252.7	1.2	1	1	0.0045	51
Chicken meat	97.5	783.5	0.0156	1	1	0.00018	2

Based on the German NVS II model, there is no exceedance of the ARfD through the consumption of chicken eggs or chicken meat contaminated with fipronil for any of the consumer groups examined.

The EFSA PRIMo model (Ver.2) does not show any exceedance of the ARfD for adults from the United Kingdom through these matrices. When the European consumption data for children (UK infants) are taken into account, however, the ARfD is exceeded by more than 100% through the consumption of chicken eggs. The consumption of chicken meat, on the other hand, caused a degree of exposure amounting to 2% of the ARfD.

On the basis of the two available exposure models, a fipronil concentration of 0.72 mg/kg (sum of fipronil and the sulfone metabolite MB46136 calculated as fipronil) can be regarded as the maximum concentration in chicken eggs at which the exposure accounts for ≤100% of the ARfD.

3.3 Estimation of the long-term intake quantity (NEDI)

There is no indication at this present point in time of a lifelong intake of fipronil residues through the consumption of chicken eggs or chicken meat and for this reason, the increased permanent exposure of the German population is not a realistic scenario at the present time. The existing MRLs of 0.005 mg/kg for fipronil in chicken eggs and chicken meat only account for a small amount of the ADI (<8% for the German population and <5% for other European population groups) and therefore constitute sufficient protection with regard to the health risks through lifelong exposure. In addition to this, reference is made to the population-related risk assessment of the German population on the basis of the monitoring data for the period 2009-2014⁵, in which no health risk through lifelong exposure was identified for fipronil.

3.4 Health assessment

If the estimated intake is above the ARfD, this does not automatically mean that a concrete health risk exists through the consumption of chicken eggs, but it indicates that, according to the current available knowledge, where children are concerned, a health risk is possible with the required margin of safety after eating contaminated chicken eggs. In the other cases, a health impairment is practically excluded.

Under consideration of the ARfD for fipronil (0.009 mg/kg bw) derived by EFSA (2006), the estimation of acute exposure on the basis of European consumption data for chicken eggs in infants (UK) results in an exceedance of the ARfD. On the basis of these data, an acute health risk through contaminated chicken eggs is possible for this consumer group.

⁵ Sieke C., Michalski B. und Kuhl, T., Probabilistic dietary risk assessment of pesticide residues in foods for the German population based on food monitoring data from 2009 to 2014, Journal of Exposure Science and Environmental Epidemiology (2017) 00, 1–9

For fipronil, for which acute exposure estimation resulted in an exceedance of the limit value used for the calculation, neurological behaviour changes in the offspring and low body weights and reduced feed intake in the mother animals were observed as the effects which were used to derive the limit value. Moderate symptoms occurred as critical effects in the study that was used to derive the ARfD value.

More information on the subject of plant protection products at the BfR website

http://www.bfr.bund.de/en/a-z_index/plant_protection_products-130188.html



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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.

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