Updated assessment of the health risks posed by longer-term consumption of foods contaminated with fipronil

Updated BfR Communication No. 023/2017 of 21 August 2017[1]

Based on currently available information, the German Federal Institute for Risk Assessment (BfR) assumes that illegal applications of products containing fipronil have apparently been carried out over an extended period of time. For this reason, the longer term consumption of foods contaminated with fipronil is given due consideration when assessing the risks.

An average daily intake level was determined for this updated estimation. As the estimation of the risk to consumers was made on the basis of the available data with a number of very conservative assumptions, the expected actual exposure of consumers should lie well below the exposures estimated here.

Based on German and European consumption data (NVS II Model and EFSA PRIMo (Ver.2)), n the ADI value (0.0002 mg/kg body weight per day) is not exceeded for any of the observed consumer groups through the consumption of chicken eggs and chicken meat containing fipronil, including processed foods made from them. With regard to the current fipronil findings, utilisation rates of the ADI of 39% and 12% were estimated for children and adults, respectively, from the consumption data for the German population. ADI utilisation rates of up to 40% were established for the various European consumer groups.

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.

As the updated estimation of the risk to consumers posed by the consumption of chicken eggs and chicken meat containing fipronil, including processed foods made from them, showed no exceedance of the acceptable daily intake levels over an entire lifetime, a health hazard is unlikely.

1 Object of the assessment

The BfR has updated its assessment of the health risks posed by longer-term consumption of foods contaminated with fipronil in consideration of the fipronil levels officially measured in chicken eggs and chicken meat up to 17 August 2017.

Regarding the short-term intake of high fipronil levels and the related assessment of the acute health risks posed to consumers, reference is made to BfR opinions already published. There are no changes in this respect.

2 Results

The health risk assessment of the fipronil residues measured in chicken eggs and chicken meat was made on the basis of a utilisation rate of the acceptable daily intake (ADI) of 0.0002 mg/kg body weight derived in the course of the EU approval procedure of active substances contained in plant protection products. The consumption quantities used to estimate exposure take into account processed as well as unprocessed foods.

[1] This updated communication supersedes BfR Communication No. 21/2017 of 11 August 2017

Based on German consumption data (NVS II model), the ADI value is not exceeded for any of the observed consumer groups through the consumption of chicken eggs and chicken meat containing fipronil, including all foods made from them. Based on European consumption data (EFSA PRIMo, Ver.2) the ADI value is not exceeded either through the consumption of chicken eggs and chicken meat containing fipronil, including processed foods made from them.

As the updated estimation of the risk to consumers posed by the consumption of chicken eggs and chicken meat containing fipronil, including processed foods made from them, did not show any exceedance of the acceptable daily intake over the course of a lifetime, a health hazard is unlikely.

3 Justification

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

3.1 Toxicological assessment of the active substance fipronil

The following limit values for dietary exposure were derived for fipronil in the course of the EU approval procedure for active substances contained in plant protection products (EFSA, 2006[2]):

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 procedure for active substances, the toxicity of the metabolite fipronil sulfone was estimated to be comparable to that of fipronil and, for this reason, it was concluded that the limit value for fipronil should be used when assessing exposure to fipronil sulfone (EFSA, 2006).

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.

The ADI value derived by EFSA in 2006 derived in the course of the EU approval proceduresfor active substances contained in plant protection products was used to estimate dietary exposure in this risk assessment.

3.2 Estimation of the long-term intake level (NEDI)

Based on currently available knowledge, it has to be assumed that products containing fipronil have been used illegally for months in sheds containing pullets and laying hens for egg production. In addition to the usual scenario of short-term exposure, as reported in the

[2] 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

European Rapid Alert System for Foods and Feeds (RASFF), the possibility exists of contamination over a period of weeks or months. Accordingly, there is also a necessity to assess chronic health risks to consumers. To this end, an updated estimation of the average daily intake levels was made using conservative parameters and assumptions.

Consumption models and calculation of long-term exposure
The assessment of long-term exposure to fipronil in food was conducted on the basis of German consumption data (NVS II model[3]) for children and adults, as well as European consumption data (EFSA PRIMo, Ver.2[4]). Both of these models are currently used in the assessment of plant protection products. Further refinement of this estimation will be possible when additional data become available.

The German NVS II model contains conservatively estimated consumption quantities for chicken eggs as well as chicken meat, including processed foods made from them. Using recipe data and under consideration of processing influences, all foods containing chicken eggs and chicken meat consumed within one day were broken down with regard to their ingredients and included in the assessment on the basis of the raw, unprocessed basic products.

By way of example, a total daily consumption of 1.6 eggs results for a person who eats a boiled egg in the morning (corresponds to 1 egg), a portion of egg pasta at lunchtime (corresponds to 0.2 eggs) and a piece of tiramisu (corresponds to 0.4 eggs) in the evening.

For the calculation of the intake levels, the conservative assumption is made that all of the eggs in these different foods have the same level of fipronil contamination, even though they most likely have different sources of origin, which would mean lower average levels. In addition to this, the calculation back to the raw product includes the assumption that the fipronil transferred completely to the consumed food. The much lower levels of fipronil in egg white compared to egg yolk when used separately in foods were also not taken into account as an additional effect. This would in all probability further reduce actual exposure. Therefore, due to a lack of sufficient analysis and measuring data, a significant overestimation of the actual average intake level can be assumed.

Long-term exposure is calculated in the German NVS II model and in the EFSA PRIMo (Ver. 2) in line with the NEDI procedure (National Estimated Daily Intake), which complies with the international provisions of the World Health Organization (WHO) [1, 2]. Both models are based on the assumption that consumers are exposed to average levels in foods throughout their lives. To this end, average consumption quantities are correlated with average levels for every food and added together to calculate daily consumption.

Fipronil levels in chicken eggs
The BfR has analyzed results for fipronil levels in eggs from affected businesses in the Netherlands and Germany. The data set comprises 281 measured values from the Netherlands and 162 from Germany in eggs and whole egg (as of 17.08.2017) from different businesses and different sheds. All of the values measured for eggs from the affected businesses exceed the maximum residue level (0.005* mg/kg). A level above the maximum residue limit was measured in 14 of the 162 German egg samples. The measured values used here for Germany originate from official food monitoring.

[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

To assess long-term intake, the data were subjected to a statistical-descriptive evaluation:

Table 1: Fipronil levels in eggs from affected farms in Germany and the Netherlands (data for Germany on the basis of official monitoring)

	Updated status: 18 August 2017			**Status: 11 August 2017**		
	Total	**Ger**	**NL**	**Total**	**Ger***	**NL***
Amount	443	162	281	290	9	281
	Concentration (mg/kg egg)			**Concentration (mg/kg egg)**		
3rd quartile (75th percentile)	0.059	0.005	0.11	0.1075	0.041	0.11
Median (50th percentile)	0.022	0.005	0.041	0.041	0.021	0.041
Arithmetical mean	0.0579	0.0165	0.0841	0.0837	0.072	0.0841
1st quartile (25th percentile)	0.005	0.005	0.022	0.022	0.013	0.022

* From affected farms only

Due to the topicality of the fipronil findings, the BfR does not yet have any representative data on eggs which reflect the actual market situation and thereby the average levels. For this reason, use was made of the data measured in affected businesses as well as official monitoring data when calculating long-term intake. Where long-term exposure is concerned, this method involves a very conservative assumption, as it is highly unlikely that consumers will only have eaten eggs containing fipronil over a period of weeks and months.

The updated data basis for Germany on fipronil in chicken eggs would be sufficient to make a separate calculation relating to the country of origin. Due to the comparability with the first preliminary assessment of 11 August 2017, however, and the simultaneous availability of German and Dutch eggs on the market, the total data situation was again taken into account.

For the calculation of the long-term intake levels according to the NEDI procedure, the mean level in all foods should normally be used. Instead, in order to pay specific regard to consumers in the vicinity of the affected businesses, who could in all likelihood have eaten eggs from these businesses, the 3rd quartile (75th percentile) was used as the basis of a conservative assumption of the mean daily contamination level in eggs.

Fipronil levels in chicken meat

According to current knowledge of the BfR, the products containing fipronil were used illegally and exclusively in sheds in which animals (pullets and laying hens) are kept for the purpose of egg production. Broilers, which make up the majority of chicken meat consumption, were to the knowledge of the BfR not exposed to fipronil.

As of the morning of 18 August 2017, the BfR had several non-representative analysis results of fipronil levels in chicken meat from official monitoring. The data set comprises 36 measured values in chicken meat from 5 businesses in the state of Lower Saxony, one in Mecklenburg-Western Pomerania and two samples from retailers. The muscles of laying hens (boiling fowl) were mainly analysed, as well as those of 6 pullets. Levels were above the maximum residue level (0.005* mg/kg) in 17 out of 36 samples.

Table 2: Fipronil levels in the meat of pullets and laying hens from affected farms in Germany (data for Germany on the basis of official monitoring)

	Updated status: 18 August 2017	**Status: 11 August 2017**
	Concentration (mg/kg)	**Concentration (mg/kg)**
3rd quartile (75th percentile)	0.0125	0.033
Median (50th percentile)	0.0045	0.0075
Arithmetical mean	0.0181	0.0457
1st quartile (25th percentile)	0.0028	0.0026

* From affected farms only

Although laying hens are not the main source of chicken meat consumption, they can potentially be used as human food at the end of their laying period (e.g. as boiling fowl). Due to a lack of data on the distinction between the consumption of broiler and laying hen meat, it is assumed when calculating average daily fipronil intake that only the meat of laying hens was consumed. The fipronil levels in pullets and laying hens are also given equal status, even though the highest levels were detected in pullets, which are not yet used for human consumption at their age. Concerning actual daily intake via chicken meat, these assumptions also constitute a significant overestimation.

When determining fipronil levels in chicken meat, as with chicken eggs, consumers in the vicinity of the affected businesses were assumed to be the consumer group with the highest level of exposure. Due to the small number of measured values and high influence of the maximum measured fipronil level, however, the arithmetical mean (0.0181) mg/kg) lies above the 3rd quartile (0.0125 mg/kg) and is therefore used as a conservative basis for calculating average daily intake.

Exposure from other food sources
As fipronil is used in the EU as an active substance in plant protection products, biocide products and veterinary drugs, possible background contamination must in principle also be taken into consideration.

Based on German food monitoring data from the years 2009 to 2014 for fipronil (determined as the sum of fipronil and fipronil sulfone), in which a random sampling concept [3, 4] developed by the BfR for determining consumer exposure to plant protection product residues in foods was implemented, a utilisation rate of less than 0.1% of the ADI value (0.0002 mg/kg body weight per day) resulted for the German population [5]. These data show that under normal market conditions, fipronil is hardly to be found at all in food. In a total of over 14,000 samples examined within the test period, only one sample was above the analytical limit of detection. For the assessment of the average daily intake of fipronil via food in light of the current situation, only the possible intake of fipronil via chicken eggs and chicken meat, including processed foods made from them, is relevant.

Calculation of long-term intake quantities for consumers
Based on the parameters outlined above, the following long-term intake levels are obtained for German and European consumers. As background contamination with fipronil through other foods is negligible, the calculation was only made for chicken eggs and chicken meat:

Table 3: Updated NEDI calculation on the basis of the NVS II model

Food	**Fipronil content in mg/kg**	**Children (2-4 years, 16.15 kg body weight)**		**Adults (14-80 years, 76.37 kg body weight)**	
		Consumption equivalent[1] in g per day	**Intake in mg/kg body weight**	**Consumption equivalent[1] in g per day**	**Intake in mg/kg body weight**
Chicken meat	0.0181	11.5	0.0000129	25.9	0.0000063
Eggs	0.059	18.0	0.0000658	22.55	0.000017
Total	-	-	0.000079 **(≙ 39% of ADI value)**	-	0.000025 **(≙ 12% of ADI value)**

1: The consumption equivalent takes into account the total daily consumption of each raw product including all processed foods
ADI value for fipronil: 0.0002 mg/kg body weight per day

Table 4: Updated NEDI calculation on the basis of the EFSA PRIMo model, Ver.2 – List of the five consumer groups with the highest long-term intake levels

PRIMo consumer group	**Total utilisation rate of the ADI (0.0002 mg/kg body weight per day)**
1. UK Infants	40%
2. DE Children	38%
3. FR Infants	38%
4. ES Children	33%
5. WHO Cluster Diet E	26%

Based on the German NVS II consumption model, the ADI value (0.0002 mg/kg body weight per day) is not exceeded in any of the examined consumer groups through the consumption of chicken eggs and chicken meat contaminated with fipronil. Children aged 2-4 years, who utilise the ADI value up to 39%, were identified as the German consumer group with the highest average daily fipronil intake.

Based on the EFSA PRIMo model (Ver.2), the ADI value is not exceeded either in any of the examined consumer groups through the consumption of chicken eggs and chicken meat contaminated with fipronil. UK infants, who utilise the ADI value up to 40%, were identified as the European consumer group with the highest average daily fipronil intake.

3.3 Health assessment

The updated estimation of the risk posed to consumers through the consumption of chicken eggs and chicken meat containing fipronil, including processed foods made from them, did not result in an exceedance of the acceptable daily intake level in the course of a lifetime, so that a health hazard is unlikely.

The consumer risk assessment was carried out using a number of very conservative assumptions, so that the actual consumer exposure should lie well below the exposure levels estimated here.

3.4 Outlook

An updated assessment of the health risks posed by longer-term consumption of foods containing fipronil was carried out on the basis of the measurement results of fipronil levels in eggs and chicken meat available to the BfR on the morning of 18.08.2017. The assessment

shows that after expanding the data basis, lower average intake levels were determined for consumers compared to the first preliminary assessment. It is assumed that by means of further measurement results of fipronil levels of the same magnitude as those already presented, no relevant change of the risk assessment is to be expected.

Accordingly, a further update of the health risks posed by the longer-term consumption of foods containing fipronil will only be appropriate in the case of an increased occurrence of new elevated findings.

More information on the subject of fipronil in eggs at the BfR website

Communication of 10 August 2017 – Estimations of maximum acceptable daily intake:
http://www.bfr.bund.de/cm/349/fipronil-in-foods-containing-eggs-estimations-of-maximum-tolerable-daily-consumption.pdf

Communication of 8 August 2017 – Health assessment of the first analysis results on fipronil levels in foods in Germany:
http://www.bfr.bund.de/cm/349/health-assessment-of-the-first-analysis-results-on-fipronil-levels-in-foods-in-germany.pdf

FAQ of 11 August 2017:
http://www.bfr.bund.de/en/frequently_asked_questions_about_fipronil_levels_in_foods_of_animal_origin-201492.html

Opinion of 30 Juli 2017 – Health assessment of individual measurements of fipronil levels in foods of animal origin in Belgium:
http://www.bfr.bund.de/cm/349/health-assessment-of-individual-measurements-of-fipronil-levels-in-foods-of-animal-origin-in-belgium.pdf

4 References

1. Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food), *Guidelines for predicting dietary intake of pesticide residues (revised).* 1997. **WHO/FSF/FOS/97.7**: p. 41.
2. World Health Organization (WHO), *Food consumption and exposure assessment of chemicals - Report of a FAO/WHO Consultation, Geneva, Switzerland 10-14 February 1997.* 1997(WHO/FSF/FOS/97.5).
3. Sieke, C., O. Lindtner, and U. Banasiak, *Pflanzenschutzmittelrückstände, Nationales Monitoring, Abschätzung der Verbraucherexposition: Teil 1.* Deutsche Lebensmittel-Rundschau, 2008. **104 (2008) 6**: p. 271 – 279.
4. Sieke, C., O. Lindtner, and U. Banasiak, *Pflanzenschutzmittelrückstände, Nationales Monitoring, Abschätzung der Verbraucherexposition: Teil 2.* Deutsche Lebensmittel-Rundschau, 2008. **104 (2008) 7**: p. 336–342.
5. Sieke, C., B. Michalski, and T. Kuhl, *Probabilistic dietary risk assessment of pesticide residues in foods for the German population based on food monitoring data from 2009 to 2014.* J Expos Sci Environ Epidemiol, 2017.

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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