

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

Updated BfR Communication No. 002/2018 of 18 January 2018¹

In accordance with the latest available information, the German Federal Institute for Risk Assessment (BfR) is assuming that illegal applications of products containing fipronil would appear to have been carried out over an extended period of time. For this reason, the longer term consumption of foods containing 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 continues to be 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)), the ADI (0.0002 milligrams (mg) per kilogram (kg) body weight and day) is not exceeded in the updated assessment for any of the observed consumer groups through the consumption of chicken eggs and chicken meat containing fipronil, including all foods prepared from them. With regard to the current fipronil situation, utilisation rates of the ADI of 6.2% and 2.4% were calculated for children and adults respectively from the consumption data for the German population. ADI utilisation rates of up to 7.8% 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 all 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 containing fipronil under consideration of the fipronil levels measured in chicken eggs and chicken meat by official food monitoring authorities and reported to the Federal Office of Consumer Protection and Food Safety (BVL) up to 3 September 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 per kg body weight derived in the course of the EU approval procedure of active

¹ ¹ This updated communication supersedes BfR Communication No. 023/2017 of 21 August 2017

substances contained in plant protection products. The consumption quantities used to estimate exposure take into account processed as well as unprocessed foods

Based on German consumption data (NVS II model), the ADI 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 is not exceeded either through the consumption of chicken eggs and chicken meat containing fipronil, including all 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 all 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, 2006²):

| 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 EU active substance testing, 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 derived by EFSA in 2006 in the course of the EU approval procedures for 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 quantity (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

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

egg production. In addition to the usual scenario of short-term exposure, as reported in the European Rapid Alert System for Foods and Feeds (RASFF), the possibility exists of contamination over a period of weeks to months. Accordingly, there is also a necessity to assess longer term (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 model³) for children and adults, as well as European consumption data (EFSA PRIMo, Ver.2⁴). Both of these models are currently used in the assessment of plant protection products.

The German NVS II model contains conservatively estimated consumption quantities for chicken eggs as well as chicken meat, including all foods made from them. Using recipe data and under consideration of processing influences, all consumed foods containing chicken eggs and chicken meat were broken down with regard to their ingredients and added together again 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 not taken into account as an additional effect either. This would in all probability further reduce actual exposure. An overestimation of the actual average intake level should therefore 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. The arithmetical mean fipronil concentrations are used for chicken meat and eggs.

Fipronil levels in chicken eggs

The BfR has 1,110 analysis results from official food monitoring in Germany on fipronil levels in eggs, 966 of which relate to eggs from businesses in Germany (as of 03 Sep. 2017). A level in excess of the maximum residue level of 0.005* mg per kg was measured in 24 samples.

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

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

Table 1: Fipronil levels in eggs on the basis of data from official food monitoring in Germany; as of 03 Sep. 2017

| | Updated status of 03 Sep. 2017 | | Status on 18 Aug. 2017 | |
|--|-----------------------------------|-------------------|---------------------------|-------------------|
| | Total | Origin Germany | Total | Origin Germany |
| Number | 1,110 | 966 | 443 | 162 |
| | Concentration (mg/kg egg) | | Concentration (mg/kg egg) | |
| 3 rd quartile (75 th percentile) | 0.005 | 0.005 | 0.059 | 0.005 |
| Median (50 th percentile) | 0.005 | 0.0025 | 0.022 | 0.005 |
| Arithmetical mean | 0.0053 | 0.0045 | 0.0579 | 0.0165 |
| 1 st quartile (25 th percentile) | 0.002 | 0.002 | 0.005 | 0.005 |

Due to the topicality of the fipronil findings, it has to be assumed that they do not reflect the actual market situation and that they overestimate the average fipronil levels in eggs. The use of the data for calculating long-term intake should therefore be regarded as very conservative as it is highly unlikely that consumers will only have eaten eggs containing fipronil over a period of weeks and months.

Fipronil levels in chicken meat

According to the latest knowledge available to 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 not exposed to fipronil to the knowledge of the BfR. This is confirmed by the available data measured in official food monitoring in Germany (as of 03 Sep. 2017). A total of 125 measured values were reported, 48 of which relate to laying/boiling hens and 77 to broilers, turkey and chicken (parts) not specified any closer. Exceedances of the maximum residue level of 0.005* mg per kg were only recorded in a few laying hen samples.

Table 2: Fipronil levels in the meat of poultry (laying/boiling hens, turkey, broilers and chicken (parts) not specified any closer) on the basis of the data produced by official food monitoring in Germany; as of 03 Sep. 2017

| | Laying/boiling hens, updated status of 03 Sep. 2017 | Total poultry meat, updated status of 03 Sep. 2017 | Laying/boiling hens, status on 18 Aug. 2017 |
|--|---|--|---|
| Number | 48 | 125 | 36 |
| | Conc. (mg/kg) | Conc. (mg/kg) | Conc. (mg/kg) |
| 3 rd quartile (75 th percentile) | 0.005 | 0.005 | 0.0125 |
| Median (50 th percentile) | 0.0031 | 0.0025 | 0.0045 |
| Arithmetical mean | 0.0092 | 0.0059 | 0.0181 |
| 1 st quartile (25 th percentile) | 0.0025 | 0.0025 | 0.0028 |

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). As the available data does not distinguish between the consumption of broiler and laying/boiling hen meat, it is assumed when calculating average daily fipronil intake that only the meat of laying hens was consumed. Based on this assumption, the actual daily intake quantity of fipronil via poultry meat should be regarded as overestimated.

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 also be taken into consideration in principle.

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 confirm 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 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 |
| | | | | | |

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|--------------|--------|------|----------------------------------|-------|----------------------------------|
| Poultry meat | 0.0092 | 11.5 | 0.00000655 | 26.3 | 0.000003 |
| Eggs | 0.0053 | 18.0 | 0.00000591 | 22.55 | 0.000002 |
| Total | - | - | 0.000013 (\pm 6.2% of ADI) | - | 0.000005 (\pm 2.4% of ADI) |

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 three consumer groups with the highest long-term intake quantities

| PRIMo Consumer Group | Total utilisation rate of the ADI (0.0002 mg/kg body weight and day) |
|-----------------------|--|
| 1. ES Children | 7.8% |
| 2. FR Infants | 6.6% |
| 3. WHO cluster diet E | 6.4% |

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 containing fipronil. Children aged 2-4 years, who utilise the ADI for fipronil by up to 6.2%, 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 containing fipronil. Children from Spain, who utilise the ADI up to 7.8%, were identified as the European consumer group with the highest average daily fipronil intake.

3.3 Health assessment

Once again, the updated estimation of the risk posed to consumers through the consumption of chicken eggs and chicken meat containing fipronil, including all 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 with moderate consumption was carried out using a number of very conservative assumptions, so that the actual mean consumer exposure that can be expected should lie well below the exposure levels estimated here.

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

Communication of 10 August 2017 – Fipronil in foods containing eggs: 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>

Communication of 11 August 2017 – Health assessment of fipronil levels in chicken meat in Germany based on the first analysis results of pullets and laying hens from the few businesses affected in Germany:

<http://www.bfr.bund.de/cm/343/gesundheitliche-bewertung-von-fipronilgehalten-in-huehnerfleisch-in-deutschland-basierend-auf-ersten-analysenergebnissen.pdf>

Updated FAQ of 15 August 2017:

http://www.bfr.bund.de/en/frequently_asked_questions_about_fipronil_levels_in_foods_of_animal_origin-201492.html

Opinion of 30 July 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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