

## Frequently asked questions about fipronil levels in foods of animal origin

Updated BfR FAQ of 15 August 2017

Within the context of the current fipronil situation, the German Federal Institute for Risk Assessment (BfR) has prepared a risk assessment on the intake of eggs and foods containing fipronil:

http://www.bfr.bund.de/cm/349 /initial-preliminary-assessment-of-the-health-risk-posed-by-longer-term-consumption-of-foods-contaminated-with-fipronil.pdf (Communication No. 021 of 11 August 2017)

http://www.bfr.bund.de/cm/349/health-assessment-of-fipronil-levels-in-chicken-meat-in-germany-based-on-the-first-analysis-results.pdf (Communication No. 020 of 11 August 2017)

http://www.bfr.bund.de/cm/349/health-assessment-of-the-first-analysis-results-on-fipronil-levels-in-foods-in-germany.pdf (Communication No. 17 of 8 August 2017)

http://www.bfr.bund.de/cm/349/health-assessment-of-individual-measurements-of-fipronil-levels-in-foods-of-animal-origin-in-belgium.pdf (Opinion No. 016 of 30 July 2017)

The BfR bases its assessment on the assumption that products containing fipronil have been used outside their authorised areas of application over a longer period of time. This assumption is necessary in order to conduct an assessment of the health risks. It is not connected with any statement on the extent to which fipronil actually has been used illegally.

Against this background, the BfR has summarised the most important frequently asked questions about the short and longer-term consumption of foods containing fipronil.

### What is fipronil?

Fipronil is a broad-spectrum insecticide used to combat insects such as ants, fleas, lice, ticks, cockroaches and mites. Use on food-producing animals (livestock) is not permitted.

#### What fundamental effects can fipronil have on human health?

Fipronil is acutely toxic in animal experiments when ingested orally, absorbed through the skin, or when inhaled. The substance is not a skin or eye irritant and does not cause any allergic skin reactions. Fipronil has a toxic effect on the nervous system in tests with rats, mice, dogs and rabbits, but these effects are reversible in adult animals. Depending on the dose, neurotoxicity is observed in the offspring of rats after the mother animals have ingested the substance. Toxic liver effects are also observed in rats and mice. According to the current state of scientific knowledge, fipronil is not classified as mutagenic or carcinogenic.

# How many eggs containing fipronil can a person eat in one meal or within one day without exceeding the health-based limit value (acute reference dose)?

By way of example, using the highest level measured to date in Belgium of 1.2 mg of fipronil per kg of eggs, purely mathematically a child with a body weight of 16.5 kg could eat 1.7 eggs (each with an individual weight of 70 g) and an adult with a body weight of 65 kg 7 eggs in one day (once only or within 24 hours) without exceeding the health-based limit value expressed as the acute reference dose (ARfD). A health hazard is unlikely as long as the estimated maximum intake level remains below the ARfD. Accordingly, a child with a body weight of 10 kg, which corresponds with an age of approximately one year, can eat 1egg per



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day (once only or within 24 hours) without exceeding the health-based limit value expressed as the acute reference dose (ARfD).

An exceedance of the ARfD does not automatically mean that a concrete health risk exists, it merely indicates that, according to currently available knowledge, a health risk for consumers is possible after eating chicken eggs containing fipronil. The safety factor between the highest dose in animal studies at which no significant health-damaging findings were observed and the acute reference dose for humans is 100 for fipronil. This means that the highest dose which did not result in any health impairments in animal experiments was divided by 100 in order to achieve an appropriate safety margin when transferred to humans. The health-based limit values also include vulnerable population groups such as expectant mothers and elderly persons.

### On what basis was fipronil assessed?

The health risk assessment of short-term intake (with one meal or within one day) of the fipronil levels measured in chicken eggs and chicken meat was made on the basis of an exceedance of the acute reference dose (ARfD). The ARfD was set at the value 0.009 mg/kg body weight during the EU approval procedure for active substances contained in plant protection products. The assessment of the health risks of longer-term consumption of foods containing fipronil was made on the basis of full utilisation of the acceptable daily intake (ADI) of 0.0002 mg/kg body weight. The assessments took into account chicken eggs and chicken meat, including processed foods prepared from them.

The initial preliminary estimation of the risk for consumers was made on the basis of the available data with a number of very conservative assumptions. Conservative means that the estimated intake level lies significantly above the values that actually can be expected. This applies both to the short as well as the longer-term intake of foods containing fipronil.

## What happens if the acute reference dose (ARfD) or acceptable daily intake level (ADI) is exceeded?

An exceedance of the ARfD does not automatically mean that a concrete health risk exists, it merely indicates that, according to currently available knowledge, a health risk for consumers is possible after short-term consumption of chicken eggs containing fipronil. The safety factor between the highest dose in animal studies at which no significant health-damaging findings were observed and the acute reference dose is 100 for fipronil.

A slight exceedance of the ADI over a limited period of time also does not automatically involve a health impairment.

## What does the acute reference dose (ARfD) express?

The ARfD is defined as the quantity of a substance per kilogram of body weight which can be ingested with one meal or within one day without any recognisable risk to the consumer.

### What does the acceptable daily intake quantity (ADI) express?

The ADI indicates the quantity of a substance which consumers can ingest every day of their lives without any recognisable health risk.

## Are any health risks connected with the short-term consumption of foods containing fipronil?

With regard to one-off consumption of foods containing fipronil and based on the currently available information and German consumption data, an exceedance of the acute reference



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dose (ARfD) does not result for any of the consumer groups observed in Germany, including children.

On the basis of European consumption data for children, specifically for children from Great Britain, the ARfD is exceeded if the highest fipronil level measured in an egg in Belgium (1.2 mg/kg egg) is used as the basis for calculation (see the opinion on this <a href="http://www.bfr.bund.de/cm/349/health-assessment-of-individual-measurements-of-fipronil-levels-in-foods-of-animal-origin-in-belgium.pdf">http://www.bfr.bund.de/cm/349/health-assessment-of-individual-measurements-of-fipronil-levels-in-foods-of-animal-origin-in-belgium.pdf</a>). A health impairment would be possible under these circumstances.

# Are any health risks connected with the longer-term consumption of foods containing fipronil?

According to current scientific knowledge, an exceedance of the ADI value would not result for consumers, including children, through the longer-term consumption of foods containing fipronil. 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.

This preliminary assessment is based on the data currently available to the BfR according to which a health hazard is unlikely, even after longer-term intake of foods containing fipronil. This assessment will be updated continuously as the additional data which the BfR deems necessary is collected and circumstances change.

# Are any health risks connected with the consumption of chicken meat containing fipronil at the levels measured in Germany?

As far as can be ascertained at the moment, a product containing fipronil was used illegally in sheds in which pullets and laying hens were kept for egg production. The meat of laying hens can be used as boiling fowl, for example. Broilers and fattening chickens are kept in separate businesses. The BfR has received no indications of the use of fipronil in businesses of this kind.

The BfR made an assessment of what little data are currently available on fipronil levels in chicken meat on the basis of official analysis results from Germany. The data relate exclusively to pullets and laying hens from the few affected businesses in Germany. The BfR comes to the conclusion that, according to current scientific knowledge, the consumption of chicken meat is unlikely to pose an acute health risk to the observed consumer groups, including children. This health risk assessment was made on the basis of an exceedance of the acute reference dose (ARfD).

An initial preliminary estimation shows that a health hazard is also unlikely through the longer-term consumption of chicken meat containing fipronil. This health risk assessment was made on the basis of the utilisation rate of the ADI under consideration of an average daily consumption level.

### Are there any general consumption recommendations for eggs?

The German Nutrition Society (DGE) recommends up to 3 eggs a week, including processed eggs. These are orientation values for adults.

http://www.dge.de/ernaehrungspraxis/vollwertige-ernaehrung/ernaehrungskreis/

### Does the fipronil level of contaminated eggs change when they are processed?

According to the current state of knowledge, fipronil is not degraded by boiling or frying (up to 120°C for 20 minutes). For this reason, the same fipronil levels are currently being assumed for processed eggs as for unprocessed eggs.



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Eggs are used in the production of a number of foods. The proportion of eggs in these foods varies. A dilution of the fipronil concentration should be assumed in foods made with the addition of eggs.

What fipronil levels in eggs do not lead to an exceedance of the acute reference dose? Using the European Primo exposure model as the worst case, a fipronil concentration of 0.72 mg/kg in chicken eggs and 0.77 mg/kg in chicken meat (each as the sum of fipronil and its sulfone metabolite calculated as fipronil) can be regarded as the maximum concentrations at which no acute health risk exists for any of the examined consumer groups, according to the latest available information, because the ARfD is not exceeded.

### What maximum residue levels apply to fipronil in eggs and chicken meat?

A maximum residue level of 0.005 mg/kg applies to fipronil (sum of fipronil and its sulfone metabolite). This is the analytical limit of detection. If maximum residue levels are exceeded, foods may not be put on the market.

### What happens if the maximum residue levels are exceeded?

Foods may not be sold if the levels of fipronil exceed the applicable EU maximum residue levels. If it is established during checks that levels have been exceeded, the products are taken from the market. A short-term exceedance does not automatically mean that consumption of the food in question involves a health risk.

## More information on warnings and notices to the public

The federal states (laender) or Federal Office of Consumer Protection and Food Safety (BVL) publish public warnings and information in accordance with Art. 40 of the German Food and Feed Code at the website <a href="http://www.lebensmittelwarnung.de">http://www.lebensmittelwarnung.de</a>

### More information on the subject of fipronil at the BfR website

http://www.bfr.bund.de/en/a-z index/fipronil-201485.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.

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