



Risk assessment and risk management with regard to the presence of fipronil in eggs, egg products, poultry meat and processed products

ATTENTION:

With regard to the fipronil incident, the FASFC exceptionally asks the operators who are active in Belgium, to inform the FASFC in case of a withdrawal from the market (including the trademarks, the trade descriptions, the information on the labelling, the lot numbers and expiration dates) via the mail address: PCCB@favv.be (cf. p3-4, 'Withdrawal from the market').

What is fipronil - Use ?

Fipronil is an insecticide. In Europe, its use is allowed in arable farming for treating seeds of several plant species.

The use of fipronil as a biocide is authorized in Belgium to combat ants and cockroaches indoors and around habitations

Fipronil is also used in veterinary medicine as a treatment against fleas, lice and ticks in pets (e.g. doses in spot-on/pipettes used for dogs weighing 10 to 60 kg are respectively 67 mg and 402 mg of fipronil).

It is forbidden to use fipronil as a veterinary drug **in animals intended for human consumption**.

In order to be commercialized and used all these products need an authorization.

Toxicological data

In the framework of the approval procedure of fipronil as a pesticide in Europe, the EFSA (European Food Safety Agency) conducted a complete risk assessment in 2006. This risk assessment was based on several types of toxicity studies (acute toxicity, chronic toxicity, reproductive toxicity, neurotoxicity, genotoxicity, carcinogenicity).

Based on the results of these scientific studies, and in applying a safety factor 100 so as to consider the fact that the studies were conducted in animals (factor 10) and the variability in the human population (factor 10), the EFSA has identified **2 toxicological thresholds** for humans:

- ADI (acceptable daily intake) which corresponds to the dose a human may ingest on a daily basis over his lifetime without an appreciable health risk = 0.0002 mg/kg body weight of the exposed individual. For an adult (66.7 kg*) this corresponds to 0.013 mg of fipronil per person and for a young child (8.7 kg*) to 0.0017 mg of fipronil.

- ARfD (acute reference dose) is the dose above which a health effect might be observed when ingested during a short period of time (daily or meal) = 0.009 mg/kg body weight of the exposed individual. For an adult (66.7 kg*) this corresponds to 0.6 mg of fipronil per person and for a young child (8.7 kg*) to 0.078 mg of fipronil.

*: Values of the body weight of adults and children in Europe applied in the EU-PRIMo model.



Maximum Residue Levels (MRL)

In the context of using fipronil as a pesticide for plants, MRL (Maximum Residue Levels) have been fixed not only in plant products but also in animal products since food-producing animals might be exposed to fipronil residues in feed.

The MRL fixed by the European Commission (**regulation (EU) N° 1127/2014 of the Commission**) for fipronil in eggs and poultry meat is 0.005 mg/kg. This MRL concerns the sum of fipronil and his sulfone metabolite even if it is expressed as fipronil.

These MRL shall not be confused with toxicological limits as the legal and adequate use of the pesticide in authorized products and the exposure level of the animals through feed are also taken into account.

Besides, in the case of fipronil, the MRL of 0.005 mg/kg is fixed based on the limit of detection of the analysis method. By way of comparison, the MRL fixed for fipronil in onions is 0.02 mg/kg.

Approach of the risk assessment applied by the FASFC

Since the contamination of eggs with fipronil is limited in time, it does not equal the definition of a chronic risk where the consumer is exposed to the danger over a long period (several years).

In compliance with the recommendations of the European Commission, the FASFC has applied the acute reference dose as toxicological reference threshold to be taken into account to assess the risk for the European consumer. Based on the toxicological threshold, the FASFC calculated the maximum concentration of fipronil in eggs and meat that would not lead to an exceedance of this threshold for the person consuming these products. The consumed quantities of eggs and poultry meat used in this calculation are the consumption data from the PRIMo-model (Pesticide Residue Intake Model, developed by the EFSA) and more precisely the consumption data of European large consumers (worst case, consumption higher than an average consumption).

According to this data, an adult consumes ± 5 eggs per day (253 g eggs/day or 3.78 g eggs/kg body weight) and a young child ± 2 eggs per day (108 g eggs/day or 12.41 g eggs/kg body weight). The consumption of poultry meat is 181 g meat per day for a young child and 783 g per day for an adult.

The calculation performed has demonstrated that below a concentration of 2.38 mg/kg eggs (0.009 mg fipronil/kg body weight $\times 1000 / 3.78$ g eggs/kg body weight) or 0.77 mg/kg poultry meat for adults and 0.72 mg/kg eggs (= 0.009 mg Fipronil/kg body weight $\times 1000 / 12.41$ g eggs/kg body weight) or 0.8 mg/kg poultry meat for children, the consumer was not exposed to a quantity of fipronil that exceeds the toxicological threshold.

For processed products, considering the number of different products on the market, a “worst-case scenario”-approach (extreme case) is used. The calculation is based on a daily consumption of 500 g processed product by a young child. According to this approach, a concentration of fipronil lower than 0.15 mg/kg processed product does not lead to an exposure of the consumer to an amount of Fipronil above the toxicological threshold (0.15 mg fipronil/kg processed product $\times 0.5$ kg processed product = 0.075 mg fipronil, which is lower than the ARfD for a young child (8.7 kg) of 0.078 mg fipronil).

It should be recalled that a study on the food consumption carried out in 2014 by the Scientific Institute for Public Health in Belgium established that **the consumption of eggs by the Belgian population was**



lower than the European consumption data. This constitutes an additional guarantee of the low risk for the Belgian consumer. Based on the Belgian consumption data, the concentration of fipronil in eggs that should not be exceeded in order not to expose the consumer to a quantity of fipronil higher than the toxicological threshold, is 1.81 mg fipronil per kg eggs (value more than 2 times higher than the value of 0.72 mg/kg applied by the FASFC).

Risk management

Based on the recommendations of the European Commission

The most important management measure is to prevent the use and/or the placing on the market of contaminated eggs, egg products and poultry meat. Operators must therefore ensure that their eggs, egg products and poultry meat which are placed on the market or used as a raw material/ingredient in the production of foodstuffs comply with MRL for fipronil. Operators may under no circumstances place on the market, use or process eggs, egg products and poultry meat with a fipronil concentration above the MRL. Any overrun of the MRL must result in a withdrawal from the market. Any overrun of safety thresholds must be notified to the FASFC in the framework of the compulsory notification.

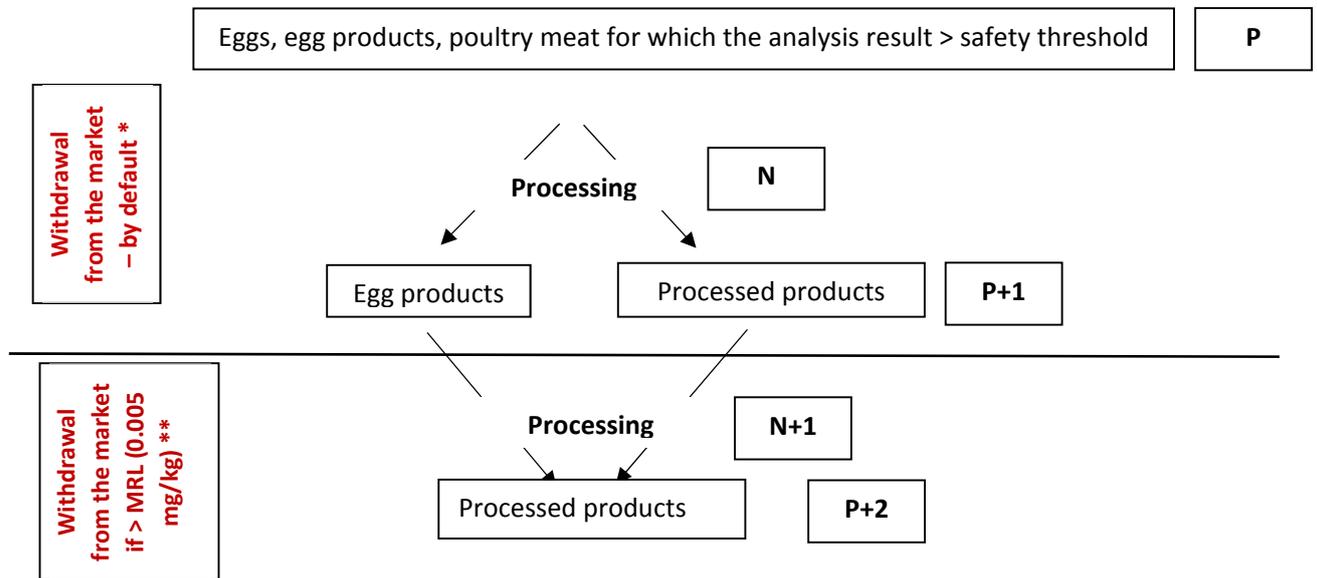
- A. **WITHDRAWAL FROM THE MARKET** (= withdrawal from the market, the product is removed from the shelves without a general recall from consumers):

Basic principle (when to carry out a withdrawal from the market?)

1. **Eggs, egg products, poultry meat and processed products: when the fipronil concentration is above the MRL (based on an analysis result or on the composition of the processed product concerned).**

Exception

2. **If eggs, egg products or poultry meat, for which the fipronil concentration is known and exceeds the safety threshold (0.72 mg fipronil/kg eggs or egg products and 0.77 mg fipronil/kg poultry meat), were used to produce egg products/processed products, a withdrawal from the market is carried out as outlined in the flow chart mentioned below.**



- * Unless the analysis result \leq MRL; a calculation based on the composition of the processed product cannot be used to avoid a withdrawal from the market, or in other words, only an analysis with a favorable result (\leq MRL) can be used to avoid a withdrawal from the market
- ** Unless the analysis result or the calculation based on the composition of the processed product \leq MRL

The standard measurement uncertainty of 50% (document SANTE/11945/2015) is only subtracted from the analysis result for the purpose to assess the (non-)compliance with the MRL. The measurement uncertainty is not applied to assess the compliance with the safety thresholds.

Attention: the analysis of fipronil must include the residue of fipronil and its sulfone metabolite, and the result must be expressed as fipronil.

Justification:

Eggs, egg products, poultry meat and processed products with a fipronil concentration above the MRL are considered as non-compliant with the European legislation and are therefore withdrawn from the market, although such concentration does not pose a risk to the consumer.

With regard to the fipronil incident, the FASFC exceptionally asks the operators who are active in Belgium, to inform the FASFC in case of a withdrawal from the market (including the trademarks, the trade descriptions, the information on the labelling, the lot numbers and expiration dates) via the mail address: PCCB@favv.be.



B. RECALL OF PRODUCT (= at the level of the consumer):

1. **When the measured values in eggs, egg products or poultry meat is above the safety threshold, namely:**
 - a. **0.72 mg fipronil per kg eggs and egg products;**
 - b. **0.77 mg fipronil per kg poultry meat.**
2. **When a risk assessment performed by the FASFC shows that the fipronil concentration is above the safety threshold in processed products (0.15 mg fipronil per kg processed product). The operator must notify to the FASFC all the cases where the processed product is likely to have such fipronil concentration (based on an analysis result or on the composition of the processed product concerned).**

Justification:

In order to ensure maximal protection of the consumers, the FASFC demands the recall of eggs and poultry meat with a fipronil concentration above 0.72 mg/kg eggs, 0.77 mg/kg poultry meat and 0.15 mg/kg processed product (the most restrictive values (worst case) obtained by the calculation mentioned above to obtain the safety thresholds).

These measures are completely in line with the recommendations of the European Commission in response to Belgium's notification of presence of fipronil in eggs through the RASFF system (Rapid Alert System for Food and Feed) (RASFF 2017-1065).

With regard to the compulsory notification to the FASFC, in this case the usual arrangements apply: the notification must be sent to the operator's Local Control Unit (Notif.XXX@favv.be).

References

EFSA Scientific Report (2006) 65, 1-110, Conclusion on the peer review of fipronil

Commission Regulation (EU) No 1127/2014 of 20 October 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for amitrole, dinocap, fipronil, flufenacet, pendimethalin, propyzamide, and pyridate in or on certain products

EFSA calculation model Pesticide Residue Model Intake 'Primo'

Document SANTE/11945/2015: Guidance document on analytical quality control and method validation procedures for pesticides residues analysis in food and feed

Annex

Explanatory table – Risk management



ANNEX

Definitions

Egg products: liquid eggs, egg yolk, egg white, egg powder, cooked eggs

Poultry meat: muscle, carcass, skin, offal

Raw materials: eggs, egg products and poultry meat

Processed products: other products made from the raw materials

Limits to be applied

Maximum Residue Level (MRL) egg/egg products/poultry meat/processed products: 0.005 mg/kg product

Maximum Residue Level (MRL) egg yolk: 0.016 mg/kg egg yolk

Maximum Residue Level (MRL) egg powder:

- MRL whole egg powder based on a dehydration factor of 4,28: 0,021 mg/kg powder
- MRL egg yolk powder based on a dehydration factor of 2,26: 0,036 mg/kg powder
- MRL egg white powder based on a dehydration factor of 8,23: 0,041 mg/kg powder

Safety threshold egg and egg products: 0.72 mg/kg eggs

Safety threshold poultry meat: 0.77 mg/kg poultry meat

Safety threshold processed products: 0.15 mg/kg processed product

Raw materials

Operators may under no circumstances place on the market, use or process eggs, egg products and poultry meat with a fipronil concentration above the MRL.

Raw materials	Analysis result ¹ ≤ MRL (0.005 mg/kg)	MRL (0.005 mg/kg) < Analysis result ¹ ≤ Safety threshold	Analysis result > Safety threshold
Eggs	No action	Withdrawal ² (safety threshold: 0.72 mg/kg)	Recall ³ (safety threshold: 0.72 mg/kg)
Egg products ⁴	No action	Withdrawal ² (safety threshold: 0.72 mg/kg)	Recall ³ (safety threshold: 0.72 mg/kg)
Poultry meat	No action	Withdrawal ² (safety threshold: 0.77 mg/kg)	Recall ³ (safety threshold: 0.77 mg/kg)

¹ : The measurement uncertainty of 50% is only subtracted from the analysis result for the purpose to assess the compliance with the MRL.

² : Withdrawal: withdrawal from the market, sales ban.

³ : Recall: recall of the products at the level of the consumer.

⁴ : Egg yolk: the specific MRL must be applied (0.016 mg/kg); egg powder: the processing factor must be taken into account (concentration related to dehydration).

Processed products

Processed products	Analysis result ¹ or on the basis of the composition of the processed product concerned ≤ MRL (0.005 mg/kg)	MRL (0.005 mg/kg) < Analysis result ¹ or on the basis of the composition of the processed product concerned ≤ Safety threshold (0.15 mg/kg)	Analysis result or on the basis of the composition of the processed product concerned > Safety threshold (0.15 mg/kg)
Processed products	No action	Withdrawal ²	Notification to the FASFC, which will carry out a risk assessment

¹ : The measurement uncertainty of 50% is only subtracted from the analysis result for the purpose to assess the compliance with the MRL.

² : Withdrawal: withdrawal from the market, sales ban.