RAG Risk Assessment Group

PRIMARY RISK ASSESSMENT

Detection of fipronil in eggs in Belgium

Date of the signal	Date of the RA	Signal provider	Experts consultation	Method
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Signal	Beginning of June, an egg processing company in Sint Niklaas informed the Belgian food safety agency FAVV/AFSCA about a suspicion of fipronil (FIP) found in eggs. Fipronil is a broad spectrum insecticide/acaricide authorized for use in pets for the control of fleas, lice, ticks, cockroaches and mites and for use as a plant protection product (seed treatment). Fipronil is not authorized for use in food production animals. Fipronil entered the food chain via use of an illegal product containing fipronil (Dega-16) to decontaminate chicken farms from red lice, a frequently occurring and difficult to treat ectoparasite of laying hens. The product was sold to farms in the Netherlands, Belgium, Germany and France. From mid July 2017, eggs were blocked from sale or withdrawn from the market in the Netherlands. About 180 Dutch farms were temporarily shut down. In Belgium, fipronil was detected in eggs from 21 companies, in concentrations ranging from "not detected" to 0.92 mg FIP/kg egg. FAVV/AFSCA communicated the finding of fipronil in eggs through a RASFF notification on 20/07/2017 and posted a first assessment of the risk for public health on August 1st. Based on this risk assessment and the first results of testing, there was no evidence of a risk for public health. Because of the high attention in the media and divergent interpretations on the risk for public health, the RAG was requested to perform a risk assessment.

Description		Score	Description / arguments
1	Cause known?	Yes	Fipronil ($C_{12}H_4Cl_2F_6N_4OS$, Frontline®, ®, also abbreviated as FIP) is a broad-spectrum insecticide and acaricide that belongs to the phenylpyrazole chemical family. It has been on the market since 1993 and is commonly used in veterinary products against lice, ticks, fleas in pets. Fipronil is registered in Belgium as biocide against ants and cockroaches. Its putative mode of insecticidal action is based on interference with the transport of chloride ions through the gamma-aminobutyric acid (GABA)-regulated chloride ion channel, which results in uncontrolled central nervous system activity and subsequent death of the insect. Although fipronil is electively toxic to insects, some toxic manifestations recorded in mammals also appears to involve interference with the normal functioning of the GABA receptor. The toxicokinetics of fipronil is summarized in Annex 1. Because of the use of fipronil in the agricultural sector, **Maximum Residue Levels (MRL)** have been defined. For fipronil, the highest level tolerated in eggs is 0.005 mg FIP/kg. Measures (see further) are taken as soon as the MRL is exceeded.

			Based on the toxicological studies in experimental animals, the following **Health Based Guidance Values** have been established by the European Food Safety Authority (EFSA): 1) The **acceptable daily intake (ADI)** (the daily intake which, during the entire lifetime, is expected to be without appreciable risk to the health of the consumer) of fipronil in humans is 0.0002 mg FIP/kg bw/day (or 0.2 µg/kg bw/day). It is based on the No Observed Adverse Effect Level (NOAEL = highest experimental dose without adverse effect) in a rat carcinogenicity study (Annex 1) with an assessment factor (AF) of 100. 2) The **Acute Reference Dose (ARfD)** (estimate of the amount of a substance in food and/or drinking water that can be ingested in a period of 24h or less, without appreciable risk to the health of the consumer) for Fipronil is 0.009 mg FIP/kg bw (or 9 µg/kg bw). This value was derived from the NOAEL identified in a developmental neurotoxicity study in rats (Annex 1) with an AF of 100. The **threshold used in Europe** to decide if there is a health risk for the consumer is 0.72 mg FIP/kg egg. This threshold is based on the ARfD and the P 97,5 % consumption of eggs by children (8.7 kg) in Europe (EFSA PRIMo2 model).
2	Unexpected/unusual	Yes	Fipronil is not authorized for use in food production animals, but it can be used as seed treatment (e.g. for sunflower and maize).
	Severity	Moderate	According to WHO, fipronil is "moderately toxic" (Class II moderately hazardous pesticide). Fipronil is **acutely toxic** after oral, inhalation and dermal exposure. The proposed classification is T, R23/24/25 “Toxic by inhalation, in contact with skin and if swallowed” (CLP Regulation: Acute tox. Cat.3 H301, Acute tox. Cat.3 H311 and Acute tox. Cat.2 H330 for respectively oral, skin and inhalation exposure). Symptoms of acute toxicity after ingestion are generally benign and reversible. Since little information is available on effects of **repeated fipronil exposure in humans,** the risk assessment is based on results from studies in experimental animals. Target organs after repeated oral exposure are the central nervous system (all species), the liver (rat & dog) and the thyroid (rat). The recorded findings were clinical signs of neurological disturbance, increased liver weight and hepatocyte enlargement, as well as thyroid follicular hypetrophy/hyperplasia. Classification as T, R48/25 “Toxic, Danger of serious damage to health by prolonged exposure if swallowed” was proposed (CLP Regulation: STOT RE Cat. 1 H372: Causes damage to organs through prolonged or repeated exposure). Fipronil has no genotoxic potential and does not appear to cause reproductive or developmental toxicity (Annex 1). No human relevant evidence of carcinogenicity was recorded in **long-term** animal studies.

			While children may be especially sensitive to pesticides compared to adults, there is currently no data indicating that children might be specifically sensitive to fipronil.
4	Dissemination (Low/Medium/High)	Medium	Fipronil-contaminated eggs may have been sold for some time prior to its first detection in Belgium. Media reports suggest that the Dutch authorities were aware in November 2016 of the possible use of fipronil in poultry farms.
5	Risk of (inter)national spread	High	Poultry farms in different countries are involved (Belgium, the Netherlands, Germany, France) and contaminated eggs have been exported to several other European countries (UK, Sweden, Austria, Denmark, Spain, Italy…) and to Hong-Kong.
Preparedness and response			
6	Preparedness	High	The agency in charge of the food safety control in Belgium is the FAVV/AFSCA (Federaal Agentschap voor de veiligheid van de voedselketen/Agence fédérale pour la sécurité de la chaîne alimentaire). The agency was created in 2000 and has experience with responding to potential threats in the food chain. Food chain operators and laboratories are legally bound to notify the agency when products placed on the market do not meet the food safety prescriptions (i.e. presence of an illegal substance such as fipronil). The agency takes the necessary measures to protect the consumer (withdrawal of contaminated products from the market, …) and to inform the public and the stakeholders. Laboratory analyses on Belgian eggs have been performed in laboratories in Belgium, the Netherlands and in Germany. The WIV-ISP is involved in monitoring fipronil and metabolites in fruit and vegetables, and can extend testing to other food or samples if necessary.
7	Specific control measures (surveillance, control, communication)		The Belgian policy regarding measures taken during the present incident, is fully in line with the European guidelines communicated by the European Commission to all member states via the RASFF system on 31 July. Both Belgium and the Netherlands follow this approach. Starting from July 2017, the FAVV/AFSCA visited all the poultry farms where fipronil may have been used (based on information from the judicial investigation) and samples were taken and analyzed for fipronil. Each sample is made up of 18 eggs, collected from different places in the farm (one sample/farm). As a precautionary measure, while waiting for the results, 86 poultry farms were closed. Fipronil was found in concentrations ranging from "not detected" to 0.92 mg FIP/kg egg in 28 farms. All contaminated eggs above the MRL (0.005 mg/kg) were traced and withdrawn from the market. For 6 holdings, one in which the fipronil concentration measured was above the European risk level of 0.72 mg FIP/kg, a recall was organised on 08 August 2017. A RASFF (Rapid Alert System for Food and Feed, EU).

			notification message with the level of fipronil measured in the eggs was posted on the 20 July 2017. The first information on the FAVV/AFSCA website was posted on 1rst of August , with regular updates. On the 4th of August, supermarket chains Albert Heijn, Colruyt, Delhaize, Lidl and Aldi removed some or all eggs from their stores as a precautionary measure. In addition to inspections and samplings of eggs in the businesses which were designated as suspected, the FAVV/AFSCA carried out in a second step monitoring of eggs in unsuspected businesses and of egg products in egg breaking plants. Fipronil was found at low concentrations in 7 farms. These farms have been blocked immediately and the eggs coming from these farms have been withdrawn from the market and destroyed. Within the monitoring, 13 analyses have also been carried out on egg products from the period June-July 2017 in egg breaking plants. Eleven results are compliant. In 2 samples, a very low concentration of Fipronil has been found. This concentration is below the European reference value and therefore presents no threat to public health. The egg products concerned were immediately withdrawn from the market and destroyed. Analysis on the possible presence of fipronil in laying hens ready for slaughtering was perfomed in the only two slaughterhouses for laying hens in Belgium (30 samples). No fipronil was detected in any of the samples. Since the life time of broiler chickens is shorter than laying hens, they are less likely exposed to red lice, and usually not treated with products (possibly containing fipronil). It is, therefore, reasonable to consider that they do not present a risk for public health. As of 15 August 2017, 28 farms are still shut down. Because this use of fipronil is illegal, a criminal investigation is ongoing.
Public health impact			
A	Public health impact in Belgium (Low/Medium/high)	Low	As of 15 August 2017, the concentrations of fipronil measured in eggs were below the European threshold of health risk for the consumer of 0.72 FIP mg/kg, except for one sample (from one farm), for which a level of 0.92 mg/kg was recorded. Since all the eggs from suspected farms were blocked (pending the results from testing for fipronil) on 18 July, the eggs with this high level of fipronil did not reach the consumer. As a precaution measure, a recall of eggs was published through a press release on 08 August (see measures taken above). At this stage and based on the infirmation available, the health risk is assessed for the highest reported level (0.92 mg/kg). For the acute exposure scenario, data on consumption of raw and cooked eggs in Belgium were used (Food consumption poll 2014-2015). For the repeated exposure scenario, the total daily consumption of eggs (raw, cooked and secundary products like cream desserts, pastry, biscuits, etc.) was taken

			into account (annex 2). The mean usual daily consumption of raw eggs in Belgium (18-64y) is estimated at 0.005 g egg/kg bw (P97.5: 0.02) for adults; 0.007 g egg/kg bw (P97.5: 0.03) for children 10-17y old and 0.01 g egg/kg bw (P97.5: 0.04) for children aged 3-9y. For cooked eggs, the values are 0.13 g egg/kg bw/day for adults (P97.5: 0.55), 0.18 g egg/kg bw/day for children 10-17y (P97.5: 0.72) and 0.30 g egg/kg bw/day for children 3-9y (P97.5: 1.20). The weight of an egg is estimated at 50g. At a concentration of 0.92 mg FIP/kg egg, all the calculated estimates are below the ARfD for all age groups. Taking into account a usual daily intake of eggs (and secundary products) that would all contain this high concentration of fipronil, the ADI would be exceeded for almost the entire population. However, this is a worst case scenario, very unlikely to have occurred, for different reasons: this concentration was measured in one sample only; according to FAVV/AFSCA these eggs did not reach the consumers; people buy eggs from different stores/suppliers, that would not all contain the same high concentration of fipronil. Conclusion: the fipronil egg contamination incident is unlikely to have acutely affected public health. A risk to human health on a long-term cannot be formally excluded but is very unlikely.
B	Recommendations (surveillance, control, communication)		Further control and management by FAVV/AFSCA. Communication to the public by FAVV/AFSCA, Ministry of Health and of Agriculture.
C	Actions		1) Perform a more in depth risk assessment, taking into account a probalistic evaluation based on the distribution of the measurements in eggs (number of samples taken, proportion contaminated eggs, distribution of the results (mean, percentiles, ...) (FAVV-AFSCA). 2) Reflection on the feasibility of a study on fipronil exposure in the Belgian population (e.g. on samples from blood donors), to measure the baseline before the current incident and compare with levels after (WIV-ISP).

ANNEX 1: TOXICOKINETICS AND TOXICITY OF FIPRONIL

Information on the toxicokinetics of fipronil is based on experimental studies in animals.

The absorption of fipronil in rats via the oral route is rapid and extensive. Following a single dose of 4 mg FIP/kg body weight (bw), more than 80% is absorbed. After uptake, fipronil is widely rapidly metabolised and distributed in the tissues, mainly in fatty tissues. Fipronil sulfone is the major metabolite.

After oral administration of 4 mg/kg bw, the mean calculated elimination half-lives of fipronil in blood is 183h for males and 245h for females. The slow elimination of fipronil and/or its metabolites appears to be due to a combination of its distribution into a deep compartment (fat) and a high degree of biliary recirculation.

In goats, after oral dietary administration of ^{14}C-fipronil for 7 consecutive days (0.05, 2.0 and 10 ppm, corresponding to 0.0015, 0.067 and 0.327 mg/kg bw/d) between 15 and 19% of the ingested dose of fipronil was absorbed in the body. Absorbed radioactivity was extensively excreted, mainly in the faeces (about 65%).

Experimental evidence indicates that if fipronil is absorbed orally in laying hens, a significant fraction of the pesticide is distributed to the eggs (mainly yolk). In a study in laying hens, fipronil was administered orally at daily doses of 0.05, 2 or 10 ppm (corresponding to 0.004, 0.174 and 0.872 mg/kg bw/d), for 28 days. Twenty four hours after administration of the final dose, 15-18% of the administered radiolabeled fipronil was found in eggs and 1-5% in tissues. The greatest total tissue residues after administration of the highest dose (10 ppm) were found in peritoneal fat (56 ppm). The levels in eggs were also high (30 ppm in yolks) after this dose. The levels were lower in skin (17 ppm) and much lower in liver, egg white, and muscle.

Symptoms of acute toxicity in humans after ingestion include sweating, nausea, vomiting, headache, abdominal pain, dizziness, agitation, weakness, and tonic-clonic seizures. These clinical signs are generally reversible and resolve spontaneously. Based on data from the antipoison center in France, no neurotoxic effects were reported in case of accidental ingestion of fipronil. In a prospective study from Sri-Lanka, reporting on 7 patients after self-poisoning with fipronil, non-sustained generalized tonic-clonic seizures were seen in two patients (peak measured plasma fipronil concentrations 1600 and 3744 microg/L). Plasma concentration was still high at discharge 3-4 days post-ingestion when the patients had recovered.

The **long-term effects of fipronil** were studied in a 2-year oral carcinogenicity study in rats (M: 0, 0.02, 0.06, 1.3 and 12.7 mg/kg bw/day; F: 0, 0.03, 0.08, 1.6 and 16.8 mg/kg bw/day) and a 18-month oral study in mice (M: 0, 0.01, 0.06, 1.2 and 3.4mg/kg bw/day; F: 0, 0.01, 0.06, 1.2 and 3.6 mg/kg bw/day). In the rat, effects were observed in the liver, thyroid and kidneys at the high dose. Dose-related incidence of convulsive episodes was also observed, except at the low dose. The NOAEL was 0.02 mg FIP/kg bw/day, based on the observation of convulsive episodes in animals at doses of ≥0.06 mg/kg bw/day and the death of 1 male at 0.06 mg/kg bw/day. The thyroid tumors observed at the high dose were induced by the increased clearance of T4 via the bile, rather than a direct effect on the gland. These tumors are rat-specific and not relevant to humans. In the mouse, the NOAEL was 0.06 mg FIP/kg bw/day, based on decreased body weight gain and liver toxicity. No human relevant evidence of carcinogenicity was recorded in this study.

Fipronil does not appear to cause **reproductive toxicity** based on an experimental study in rats. In an oral (dietary) two-generation reproductive toxicity study in rats (M: 0, 0.25, 2.5 and 26 mg/kg bw/day, F: 0, 0.27, 2.7 and 28 mg/kg bw/day), adverse effects on the offspring or on the reproductive parameters were only observed at maternal toxic doses. The NOAEL for maternal toxicity was 0.25 mg FIP/kg bw/day and the NOAEL for the offspring and reproduction toxicity 2.5 mg FIP/kg bw/day.

Fipronil does not appear to cause **developmental toxicity**, based on experimental studies conducted via the oral route (gavage) in 2 species. In the rat, the NOAEL for maternal toxicity was 4 mg FIP/kg bw/day and for developmental toxicity >20 mg FIP/kg bw/day. In rabbits, the NOAEL for maternal toxicity was 0.2 mg FIP/kg bw/day and for developmental toxicity >1 mg FIP/kg bw/day.

Several **neurotoxicity studies** have been conducted. In oral acute neurotoxicity studies in rats using doses of FIP ranging between 0.5 and 50 mg/kg bw, different signs of neurotoxicity were observed. A dose of 50 mg/kg bw caused mortality and various changes to nervous system function: clinical signs, functional observations and motor activity responses. At 25 mg/kg bw behavioural changes, reduced temperature,

decrease in landing footsplay and reduced locomotor activity was noted. At 7.5 mg/kg bw behavioural findings were limited to a decreased hind leg splay in males. At 5 mg/kg bw one slight functional effect on the nervous system was seen. The peak time effect was 7 hours post-dosing. The overall No Observed Effect Level (NOEL) for neurobehavioral and general toxicity was 2.5 mg FIP/kg bw.

In a 14-day oral (capsule) neurotoxicity study in dogs (0, 20 mg/kg bw/day), neurofunctional changes and loss of body weight were observed at 20 mg FIP/kg bw/day, but no histopathological changes were recorded in the nervous system.

In a 90-day dietary neurotoxicity study in rats (M: 0, 0.03, 0.3 and 8.9 mg/kg bw/day; F: 0, 0.04, 0.35 and 10.8 mg/kg bw/day), there was no evidence of neurological effect and the NOAEL for neurotoxicity was 8.9 mg FIP/kg bw/day.

In a rat dietary developmental neurotoxicity study (gestation day 6-lactation day 10; 0, 0.05, 0.91 and 15.2 mg/kg bw/d), the NOAEL for developmental neurotoxicity was 0.91 mg FIP/kg bw/day, based on neurobehavioral effects in offspring but without evidence of neuropathological changes. Reduced bw and food consumption was recorded in dams at 15 mg FIP/kg bw/day. The overall systemic NOAEL was 0.05 mg FIP/kg bw/day based on reduced bw in the offsprings during lactation.

ANNEX 2: EXPOSURE TO FIPRONIL

Estimated acute intake of fipronil (**µg FIP/kg bw/day**) at indivual level, based on the consumption of raw + cooked eggs on one day at a reported maximum level of fipronil of 0.92 mg/kg[1] in Belgian eggs. The Acute Reference Dose (ARfD) is 9 µg FIP/kg bw/day.

	Raw + cooked eggs
Children (3-9y)	
N of eggs (50g) needed to reach ARfD child 15 kg	2 eggs
FIP intake based on mean egg consumption	1.34
FIP intake based on P97.5 egg consumption	4.52
Children (10-17y)	
N of eggs (50g) needed to reach ARfD child 30 kg	5 eggs
Fipronil intake based on mean egg consumption	0.72
Fipronil intake based on P97.5 egg consumption	2.36
Adults (18-64y)	
N of eggs (50g) needed to reach ARfD adult 60 kg	11 eggs
FIP intake based on mean egg consumption	0.53
FIP based on P97.5 egg consumption	1.80

Estimated usual daily intake of fipronil (**µg FIP/kg bw/day**) for the Belgian population, assuming that all eggs consumed during the entire lifetime contained 0.92 mg/kg FIP, for raw + cooked eggs, and total consumption of eggs (raw, cooked, secondary products). The acceptable daily intake (ADI) of fipronil is 0.2 µg/kg bw/day.

	Raw + cooked eggs	Total
Children (3-9y)		
FIP intake based on mean egg consumption	0.31	0.58
FIP intake based on P97.5 egg consumption	1.21	1.59
Children (10-17y)		
Fipronil intake based on mean egg consumption	0.16	0.40
Fipronil intake based on P97.5 egg consumption	0.63	1.13
Adults (18-64y)		
Fipronil intake based on mean egg consumption	0.13	0.26
Fipronil intake based on P97.5 egg consumption	0.50	0.76

[1] this concentration has been measured in one sample, and the eggs were withdrawn from the market

ANNEX 3: DEFINITIONS

ADI	Acceptable daily intake: the daily intake which, during the entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time when a toxicological assessment is carried out.
ARfD	Acute Reference Dose: estimate of the amount of a substance in food and/or drinking water that can be ingested in a period of 24h or less, without appreciable risk to the health of the consumer on the basis of all the known facts at the time of evaluation.
MRL	Maximum Residue Level: highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly
NOAEL	An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of any adverse effect between the exposed population and its appropriate control.
NOEL	An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of any effect between the exposed population and its appropriate control.

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