EUROPEAN COMMISSION



HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 30 AUGUST 2017

(Section Novel Food and Toxicological Safety of the Food Chain)

CIRCABC Link: https://circabc.europa.eu/w/browse/b4cd5d32-6ca6-4f18-8a5d-f60758e77065

A.01 Exchange of views and discussion on illegal use of fipronil containing products in laying hen farms (RASFF 2017.1065).

1) Presentation of the situation in different Member States

The Member States that are most affected by the illegal use of fipronil updated the Commission and the other Member States on the measures and actions taken and results of testing and inspections.

Belgium explained how a notification by a food business operator of a non-compliant result on fipronil in eggs started the incident on 2 June 2016. Belgium specified how it had dealt with the enquiry to trace the source of the incident and the steps taken to protect the integrity of the food chain by preventing affected products entering the food chain and recalling all known affected products. Belgium identified and blocked all stables on affected poultry farms (in total 93 farms blocked, currently still 20 laying hen farms and 10 breeders and rearing farms blocked). Blocked farms were only released following a favourable analytical result demonstrating the absence of fipronil in eggs. Once all possibly illegally treated poultry farms had been checked by sampling and analysis, the Belgian authorities decided to confirm the absence of fipronil on all remaining non suspect laying hen farms through analysis of samples of eggs taken in each of these.

Meanwhile actions were taken focussed on the operators downstream of the laying hen farms. In the egg processing plants, information on affected laying hen farms was used to identify and trace affected batches of eggs and egg products, which were subsequently withdrawn and/or destroyed. In laying hen slaughterhouses, batches of laying hens were tested. The results confirmed that the meat of these animals was compliant. In food processing plants screening of products occurred and residue results considered in the light of egg incorporation rate and processing factors. In retail, the traceability exercise was complemented by 1500 on-the-spot checks by the competent authority and a random analytical screening of foodstuffs. All non-compliant materials were destroyed as category 1 material to avoid any possible reentry in the food chain of fipronil.

Belgium highlighted that already in an early stage a judicial investigation started. This implied that certain information could not be communicated.

The Netherlands explained that the information received in November 2016 as regards illegal use of fipronil in laying hen farms resulted in the launching of a criminal investigation. The information received mid-June from the Belgian authorities lead to inspection at the suspected service treatment company. As a result of these inspections, 281 farms with a total of 708 stables have been blocked. The blocking of farms was based on the presence of the names of these farms in the administration of the company at the origin of the illegal use. Blocked farms were and are only released on the basis of favourable analytical results showing the absence of fipronil. Tracking and tracing is done based on analytical results. The egg codes of all affected laying hen farms were communicated through the website of the competent authority. 144 farms (285 stables) remain blocked at the moment. The residue monitoring in retail demonstrates that the measures taken to free the food chain of fipronil are effective as the number of non-compliant eggs decreased substantially (from 25 % in the week of 24 July to 1 % in the week of 22 August).

One of the outstanding questions is which the best method is make the illegally treated stables fipronil free. The Netherlands pointed out that the residue monitoring confirmed the persistence of fipronil: the substance can still be detected in farms 6 months after treatment. Currently different clearing methods are applied and the residue testing of re-populated stables will show their efficacy.

Also in the Netherlands a judicial examination takes place limiting the release of certain information.

In **Germany**, 7 farms remain blocked at this moment. 122 food establishments were affected. Besides eggs and carcasses of laying hens, also high levels of fipronil were found in the feathers of these hens. Inspections combined with sampling and analysis was used for surveillance, withdrawal and recalls. Information to the public was provided via the website of the Federal Office of Consumer Protection and Food safety (BVL). A control plan covering composite products with more than 5 % egg content is in place. Fipronil was included in the national residue control plan for eggs and meat.

In **France**, one laying hen farm was detected positive. All produced eggs were destroyed and the animals present on the farm were culled and destroyed. As the farm was only starting to produce eggs, no contaminated eggs had been placed on the market. As regards contaminated eggs received from other Member States, eggs were withdrawn based on analytical results. The consumer was warned using posters and a communication on the website of the Ministry. Cleaning and disinfection procedures on all poultry farms were checked to confirm the use of allowed products. The illegal use of amitraz in empty stables was observed in several farms. Processed egg products and composite products were investigated based on traceability, analysis and / or calculation. A control and survey plan at retail level is in place to verify that there are no contaminated products on the market.

Italy intends to launch a control plan on processed products in addition to an already on-going program on eggs. The program focuses on fipronil and amitraz and covers cage as well as free range production systems. 10 non-compliant results were detected on eggs sampled at farm level and 2 on eggs sampled at retail level. As all sampled eggs at retail level have not yet been analysed, this last figure cannot be considered final. 10 farms remain blocked at the moment.

In **Poland**, all results on eggs from farms were so far compliant but investigations are still ongoing. In addition, Poland performed sampling on eggs and poultry meat at retail level. All samples so far are compliant, but over 300 analyses are still pending.

In **Hungary**, 3 batches of egg were found non-compliant: two originating from farms in Hungary and one in Romania. The two affected Hungarian farms were immediately blocked and all individual stables were sampled. Hungary follows the same approach as Belgium and the Netherlands. Since 25 August, Hungary has started a monitoring program on poultry meat. This has so far not revealed any non-compliant results.

The **Czech Republic** performs investigations on possibly treated farms (based on information of non-compliant in egg products in which eggs from farms in the Czech Republic were used besides eggs from other origins). For the time being no findings of fipronil in eggs farms in the Czech Republic have been found. In addition the Czech Republic runs a monitoring program on eggs, egg products and poultry meat from affected countries. So far, all results were compliant.

Romania checked the products used for cleaning and disinfection in 94 poultry farms so far and found no illegal products. Romania has already started the investigations on the farms from which eggs were found by Italy to be non-compliant and will follow-up on the non-compliant result of eggs from another farm in Romania as signalled by Hungary during the meeting.

Luxembourg investigated two farms on which there was suspicion of illegal treatment with fipronil containing product following information provided by the Belgian authorities. Sampling demonstrated the absence of fipronil in these two farms. A control plan on eggs from all laying hen farms in Luxembourg confirmed that no fipronil was used on farms in Luxembourg. Luxembourg assures follow-up on information received regarding withdrawal and recall of affected products.

Greece has no affected farms, but found a non-compliant egg product on which it assures tracking and tracing.

The difficulties encountered by the competent authorities in the Member States were mainly linked to the confidentiality of the judicial investigations that hinders transparent communication, to the divergences in approach as regards processed products, to the use of the appropriate communication channels, to the management of the everyday increasing information in alert systems, to the methods to clean contaminated poultry farms and to the initial lack of analytical capacity.

2) AAC/ AAC-FF/RASFF

A presentation reminding the context and obligations linked to the three notification/alert networks (RASFF, AAC, AAC/FF) is performed by the Commission. Legal provisions are clear and there is no reason to think that confusion in posting events in these networks could occur. It is reminded that a presentation was given in May 2016 to the three network assembled together to explain the operational differences. The Commission encourage the Member States to make sure that the point of contacts for RASFF and AAC (dealing with simple non-compliance) are merged; this is far less desirable for the Food Fraud contact points as they are very specialised services dealing directly with police forces. The Commission declare that no confusion between the three networks have been detected during the Fipronil case as less than 10 messages were exchanged by the Food Fraud network and more than 400 by the RASFF network. However, this is in the agenda of the Commission since mid-2016 to merge the IT tools supporting the three networks in the context of the new Official Control Regulation (IMSOC).

3) Management of the contamination incident

Messages put forward by the Commission via the RASFF for the management of the incident.

In view of a high level of human health protection and to ensure a co-ordinated approach amongst Member States, the Commission services have put forward, via the RASFF, measures to be taken:

- On 31 July 2017, information on applicable maximum residue levels, measures to be taken as regards illegally treated farms
 - Farms treated by suspect company to be blocked and representative sample of eggs/chicken meat to be taken to check compliance with MRLs (0.005 mg/kg), sum of fipronil and sulfone metabolite, lower limit of analytical determination)
 - In case of non-compliance, farms to be continued to be blocked and eggs/chicken meat (end of life laying hens) to be withdrawn from the market
 - In case level of fipronil in eggs > 0,72 mg/kg and in chicken meat > 0,77 mg/kg (exceedance of ARfD making use of EFSA Primo model) there is a need for a consumer recall
 - Farms only to be released of eggs/chicken meat produced on these farms are compliant with MRLs (0.005 mg/kg)
- On 7 August 2017, a message was distributed that it is necessary that all Member States are vigilant as regards the products used for the control of red mite in poultry establishments to ensure that no treatments with unauthorised substances take place

- On 7 August 2017, a proportionate approach providing a high level of human health protection as regards processed composite products was put forward
- On 16 August 2017, a reminder was sent that all distribution of contaminated eggs/egg products/chicken meat has to be timely notified to RASFF in order to ensure a timely notification to the competent authorities of the country of destination (member States and third countries).

Actions towards Third Countries

The Committee was informed that the Commission has sent an information note to third countries on 10 August which will be updated if there are significant developments. Furthermore an "Argumentaire" and a "Thematical Hymn Sheet" has been sent to all EU delegations in Third Countries.

With regard to specific questions by individual third countries, the European Commission replies after consulting Member States' competent authorities.

Restrictive measures applied and requests for information by Third Countries

Ukraine has established an import ban of eggs, egg products and poultry meat from Belgium, Netherlands, Germany and France as from 21 August

Oman has an import ban for eggs from the EU and Hong Kong has put in place a systematic testing of eggs from EU for the presence of fipronil.

Brazil has prohibited the import of egg products from one establishment in Belgium and one establishment in Netherlands

Kurdistan has prohibited the import of eggs from Belgium Netherlands and Germany. Several Third Countries, such as USA, Brazil, Japan, Malaysia, Russia have put forward questions or requested more detailed information, which has been provided and no restrictive measures have been (yet) put in place by these countries.

Findings of illegal use of fipronil in laying hen farms in Third countries

Following the findings in EU controls have been performed on the possible illegal use of fipronil in laying hen farms in South Korea and Taiwan. Illegal use of fipronil and other unauthorised substances have been observed in several farms in these countries. Also China has announced on 25 August to control the possible illegal use of fipronil on domestic laying hen farms.

4) Further management of the contamination incident

Measurement uncertainty

Maximum residue levels have been established by Regulation (EC) 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin for fipronil (sum of fipronil + sulfone metabolite expressed as fipronil) of 0.005 mg/kg in chicken eggs and 0.005 mg/kg in chicken meat (0.005 mg/kg being the lower limit of analytical determination).

The measurement uncertainty is applicable to the analytical result (result as analysed). For pesticide residue analysis, the measurement uncertainty is 50 % unless a lower measurement uncertainty is reported in the analytical report (measurement uncertainty reflecting expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %).

This means e.g. that an analytical result of 0.007 mg/kg with a reported measurement uncertainty of 20 % (+/- 0.0014) is not compliant. Food business operators should be aware of this when applying the measurement uncertainty to the analytical results from their self-checking and therefore apply a prudent approach.

Processing factors

The Committee agreed to the following processing factors to be applied It was stressed that these processing factors have been established for the management of this contamination incident and cannot necessarily be applied as such tin other situations.

- average fat content egg: 10 %

- average fat content egg yolk: 32.6 %

- proportion egg yolk in whole egg: 32 %

- proportion egg white in whole egg: 68 %

- data indicate that 90-95 % of fipronil is concentrated in egg yolk and 5-10 % in egg white. For the calculation on egg yolk, 100 % is assumed

Product	(Processing) factor	Calculated MRL applicable	Comments
Whole egg	1	0.005 mg/kg	
Whole egg liquid	1	0.005 mg/kg	
Egg yolk liquid	3.125	0.016 mg/kg	proportion egg yolk in whole egg: 32 %, 100 % concentration of fipronil in egg yolk is assumed
Egg white liquid		< LOQ (possible range of LOQ of 0.002 to 0.005 mg/kg)	analytical limit of determination applies (fipronil concentrates in egg yolk) without taking into account measurement uncertainty (taking into account that maximum 10 % of the fipronil in the whole egg is present in liquid egg white, the level of fipronil in liquid egg white which corresponds to the level of 0.005 mg/kg of fipronil in whole eggs is 0.00074 mg/kg, i.e. below the LOQ)
Whole egg powder	4.28	0.021 mg/kg	Drying factor compared to whole egg liquid
Egg yolk powder	2.26	0.037 mg/kg	Drying factor compared to egg yolk liquid
Egg white powder	7,17	7.17 x LOQ analysis liquid egg white (*)	(*) see below
		0.005 mg/kg	Level to be applied in case there is no information on/evidence of the compliance of the liquid egg white used for the production of the egg white powder.

(*) Food business operators producing egg white powder must ensure that the liquid egg used for the production of egg white powder is compliant with EU legislation, i.e. the level of fipronil in egg white liquid is below LOQ, with LOQ ranging from 0.002 up to 0.005 mg/kg. As the concentration factor is 7.17, using compliant liquid egg for producing egg with powder could result in levels of fipronil in egg white powder in the range of 0.015 mg/kg up to 0.036 mg/kg, depending of the LOQ of the analysis of the liquid egg white. So therefore, egg white powder with a level exceeding 0.005 mg/kg can be placed on the market on the condition that the level of fipronil in the egg white powder does not exceed 7.17 times the LOQ of the analysis of the liquid egg white from which the egg white powder is produced.

Processed products

The Commission put forward its views on the approach to be taken on processed composite foods in view of ensuring a high level of human health protection (message distributed via the RASFF on 7 August 2017).

- All farms where the suspected company/companies have performed a treatment are identified and blocked and are only released if samples demonstrate compliance with the maximum residue limit. In case the sample indicates a non-compliance the farms remain blocked and the eggs/chicken meat (end of life laying hens) and egg products produced from these eggs (whole egg liquid, egg yolk liquid, egg white liquid, whole egg powder, egg yolk powder, egg white powder) are withdrawn from the market. These eggs/chicken meat and egg products have to be destroyed and cannot be used for production of food. In case the analytical result in the eggs/chicken meat is above the 0.72 mg/kg (possible acute health risks), the eggs/chicken meat have to be in addition recalled from the consumer and the products processed thereof traced and withdrawn from the market.
- In case of finding of a level of fipronil in a processed food above the legal limit of 0.005 mg/kg (taken into account the changes in concentration due to drying, dilution, processing or relative proportion of the ingredient (egg/chicken meat) in the processed food), the contaminated lot of processed food has to be taken from the market.
- In addition, it is important to stress that, according to EU legislation, every food business operator has the obligation to ensure that the ingredients/raw materials used for the production of food are compliant with EU legislation. Therefore the food business operator must ensure that the eggs/egg products/chicken meat used for the production of food is compliant with the EU MRL on fipronil. It is considered that as from 1 August the contamination of eggs/chicken meat (end of life laying hens) was widely known by food business operators.

It was noted that divergent approaches are applied by Member States

The Commission representative committed to come forward with a document which clarifies in more detail the approach as put forward by the Commission services. Member states are invited to provide their comments and based on the comments received, an assessment shall be made if there is a possibility/basis to have a common guidance at EU level for an approach on processed products and the Committee shall be informed thereof.

b) Control of red mite in poultry

Overview of authorised substances/ treatments for the control of red mite in farms.

The Commission updated the participants on the control of red mite by biocidal products and veterinary medicinal products.

As regards the biocidal treatment of poultry houses, the Commission clarified the legal situation as regards biocidal active substances. The Commission asked the Member States to send by 15 September 2017 a reply to the Commission on three questions on biocides. With the provided information an overview can be established of allowed biocidal products in the Member States to control red mite in poultry stables and the allowed uses of products containing the biocidal active substances cypermethrin, alpha-cypermethrin, fipronil, pyriproxifen and thiamethoxam against insects in poultry stables.

Currently two active substances are allowed for red mite treatment of poultry: phoxim (through national authorisations in 12 Member States and Iceland) and fluralaner (since 18 August 2017 centrally authorised for use in all Member States). Member States were reminded to the principles of veterinary treatment: if one or more allowed substances are authorised at national level for a specific condition, treatment has to be done with one of these substances. In case no product is authorised for the specific condition, treatment has to be restricted to the use of allowed substances following the cascade system (Article 11 of Directive 2001/82/EC). For treatment of red mite in laying hens, this would mean that cascade use was only possible in a Member State that had no national authorisation for phoxim. However, as fipronil is not classified as an "allowed substance" for food producing animals, it could never have been a treatment option for food producing animals.

A Member State enquired on the possibility to use the 'cascade system' laid down in Dir. 2001/82/EC to defend the use of alternatives to phoxim, in case a veterinarian would claim a lack of effectiveness. The Commission indicated that it was not aware of the receipt of a pharmacovigilance report mentioning lack of expected efficacy (possibly indicating development of resistance) for this substance. Scientific literature indicates a high efficacy for phoxim for the treatment of red mite in laying hens and a claimed lack of effectiveness can be due to inappropriate use (diluted beyond concentration of effectiveness in an attempt to cover more surface) or to use in stables, which have not undergone a proper cleaning prior to the spraying of the product (as this prevents the product to reach the red mites).

In response to another question on the withdrawal period for eggs for phoxim, the Commission replied that the withdrawal period would depend on the concentration and instructions for use and are determined during the authorisation procedure, which for phoxim was national.

The Commission clarified that once fluralaner will be available in all Member States, it will no longer be possible to refer to the cascade for using alternative products besides phoxim and fluralaner.

<u>Discussion on substances to be covered by monitoring, sampling, analysis and reporting of the results.</u>

From the presentations and interventions of the Member States it has become clear that many Member States have set up national monitoring exercises as a follow up to the identification of fipronil residues in poultry products in several Member States. In order to get an EU wide comprehensive view on the contamination of eggs and chicken meat, due to the illegal use of acaricides, an ad hoc data collection by the Member States is organised.

A discussion took place on the scope of this data collection and it was agreed that the focus would be put on the analysis of acaricides in eggs and poultry meat/fat. Sampling of fresh products from domestic production is recommended, in order to facilitate the follow up, when possible non-compliances would be identified.

The Commission presented a table of 12 substances that should in any case be included in this monitoring exercise, because misuses could be suspected. Furthermore a more extended list was presented, which consists out of acaricides that can be analysed by pesticides labs with a multi-residue method, substances described in the MSDVet Manual for the treatment of poultry against mites, substances not specifically approved but in literature reported to be widely used against red mites, substances banned for use on red mites in the EU and substances against ectoparasites for which MRLs have been established under the EU veterinary medicinal products legislation for food species. The Member States are encouraged to supplement for their national monitoring programmes the list of 12 substances, with substances from the extended list on the basis of a set of criteria which was discussed in the meeting.

The Commission referred to the sampling requirements laid down in <u>Directive</u> 2002/63/EC and <u>Decision 97/747/EC</u>.

The Member States were asked to submit the data to EFSA by 30 November 2017 under the SSD format and to also report all identified non-compliances to the Commission as soon as possible. Although the Member States agreed on the general principles and scope of the ad hoc data collection, certain Member States indicated to need more time to discuss the details of the programme with their experts. Therefore Member States are requested to send further comments on the ad hoc data collection to the Commission by 8 September 2017. Taking into account the received comments, the Commission will then circulated an updated version of the programme and its annexes.

A Member State enquired whether this data collection would be funded by the Commission. The Commission clarified that in view of the short term timelines, it is not possible to organise this, but that the Member States are encouraged to supplement their national control programmes with these additional analyses.

A Member State enquired whether minimum sample numbers, related to the national production, would be fixed. The Commission indicated that no mandatory sample numbers will be fixed but that the Member States are encouraged to take a sufficient number of samples to get a representative picture for their national laying hen farms.

As regards the scope a Member State pointed to the possible contamination of mushrooms grown on chicken manure. However, so far all analytical results of fipronil in mushroom samples are compliant.

5) Any other business

<u>Disposal of of fipronil contaminated Animal By Products (eggs, carcasses, feathers, manure, non-compliant food).</u>

The competent authority should make an assessment and take a decision based on the provision of Directive 96/23/EC.

Once the decision has been taken that it was "illegal treatment" in accordance with Article 2(b) of Directive 96/23/EC the material must be declared a Category 1 material as referred to in Article 8(c) of Regulation (EC) No 1069/2009.

Category 1 materials must be in accordance with Article 12 of the aforementioned Regulation No 1069/2009 disposed of as waste by incineration, co-incineration or in an authorised landfills. However, the competent authority may, in accordance with Article 12(f) of the above Regulation (EC) No 1069/2009, authorise in accordance with the procedures described in Article 36(a), the application of Category 1-manure to land where farmed animals have no access or are not fed with crops grown on such land.

Proficiency tests

On the website of the EURL for pesticides in food of animal origin, links can be found to two PTs for fipronil:

- PT organised by RIKILT, open to all labs
- PT organised by JRC, open to official control laboratories http://www.eurl-pesticides.eu/docs/public/home.asp?LabID=300&Lang=EN

Fact finding missions

The Committee was informed that it is foreseen that Directorate F of DG Health and Food Safety organises late September/early October 2017 fact finding missions in the most concerned Member States to gather information.