

Related Request No 2017-SA-0178

The Director General

Maisons-Alfort, 18 August 2017

Scientific and technical support NOTE of the French Agency for Food, Environmental and Occupational Health & Safety

on "the maximum concentration of fipronil not to be exceeded in egg products and other processed products containing eggs, to ensure that consumer exposure remains below the acute toxicological reference value"

On 16 August 2017 ANSES received an urgent request from the Directorate General for Food (DGAL) to provide scientific and technical support (STS) on the maximum concentration of fipronil not to be exceeded in egg products and other processed products containing eggs, to ensure that consumer exposure remains below the acute toxicological reference value.

1. BACKGROUND AND PURPOSE OF THE REQUEST

On 20 July 2017, the Belgian authorities informed the European Commission via the European food and feed safety alert network (RASFF) that high levels of fipronil had been detected in eggs and poultry meat.

On 7 August 2017, ANSES received a formal request from the Ministries of Agriculture, Health and Consumer Affairs for STS on the risks to human health associated with the presence of fipronil in eggs intended for consumption.

On 12 August 2017, ANSES issued an STS note in which it concluded, among other things, that the maximum quantity of eggs that can be consumed on a single occasion without exposing the consumer to an acute risk, on the basis of the maximum concentration of fipronil reported so far in the contaminated eggs in Europe (1.2 mg/kg of egg), ranged from 1 egg per day for children aged 1 to 3 years, to 10 eggs per day for adults, including pregnant women¹.

Following this opinion, the DGAL made a new formal request to ANSES to answer the following question:

 Based on French consumption data, what is the maximum fipronil concentration not to be exceeded in processed consumer products containing eggs to ensure that consumer exposure remains below the acute toxicological reference value for fipronil?

In the absence of any analytical measurements of the concentration of fipronil in the manufactured products concerned and of any data on egg product composition in these products, ANSES decided to apply a worst-case scenario, considering only the major food categories identified in the Individual and

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¹ ANSES Note on a request for scientific and technical support (STS) regarding the health risk assessment concerning the presence of fipronil in eggs intended for consumption. 10 August 2017.

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National Study on Food Consumption (INCA2), conducted in 2006-2007, which is representative of food consumption in France².

2. ORGANISATION OF THE WORK

The question relating to this urgent request for STS was examined by ANSES's Risk Assessment Department (DER), within the Foodborne Risk Assessment Unit (UERALIM).

An expert in food technology from ANSES's Working Group on "Assessment of substances and procedures subject to authorisation in human food" (ESPA WG) was consulted to determine the food categories that may contain egg products.

The declarations of interests of the experts and in-house scientists involved in this expert appraisal are made public via the ANSES website (www.anses.fr).

A more detailed analysis may be conducted by ANSES once any missing data become available.

3. ANALYSIS AND CONCLUSIONS

The toxicological profile of fipronil and the assessment of the risks associated with consumption of contaminated eggs were addressed in ANSES's previous note and will not be covered here. In the previous note, it was reiterated that the acute reference dose (ARfD) is the maximum amount of active substance, expressed in mg/kg body weight/day, that can be ingested by the consumer for a short period, i.e. during a meal or a day, in food or drinking water, without an adverse effect on health. In the case of fipronil, this ARfD was established at 0.009 mg/kg body weight¹.

The food groups that may contain eggs or egg products are:

- Pasta
- Sweet or savoury biscuits and bars
- Condiments and sauces
- Dairy-based desserts, cream desserts and jellied milks
- Pastries and cakes
- · Pizza, quiches and savoury pastries
- Mixed dishes
- Sandwiches, snacks

The quantities of these foods consumed per day and per individual expressed in grams, and the body weights (bw in kg) of consumers, were extracted from the database of the INCA2 study². These data were used to estimate the daily consumption of these products for children aged 3 to 17 years and for adults (>17 years). The sum of the quantities of these foods consumed per day was calculated for each individual.

With regard to children aged 1 to 3 years, the consumption data came from the Nutri-Bébé-SFAE survey. The food groups selected for children aged 1 to 3 years are:

- Biscuits, cakes, croissant-like pastries
- Pasta
- Bread, sandwich loaves, biscuits
- Mixed dishes
- Dairy-based desserts, cream desserts

Table 1 shows the distribution of consumption.

² ANSES, 2009. INCA2 available online at https://www.anses.fr/en/content/detailed-results-inca-2-study

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Table 1: Consumption of foods that may contain eggs or egg products for children aged 1 to 3 years, 3 to 17 years and adults (>17 years).

Consumption	Age	5 th percentile	Median (50 th percentile)	97.5 th percentile	99 th percentile
Quantity in g/individual/day	1 to 3 years	16	136	391	444
	3 to 17 years	170	460	997	1231
	> 17 years	200	495	1182	1370
Quantity in g/kg body weight/day	1 to 3 years	1.42	10.76	35.48	39.15
	3 to 17 years	3.64	13.72	31.75	37.59
	> 17 years	3.01	7.36	16.68	20.98

Using French data on the consumption of foods that may contain eggs or egg products, in a theoretical scenario, it is possible to calculate the concentration of fipronil in these foods not to be exceeded to ensure that exposure remains below the acute toxicological reference value (ARfD of 0.009 mg fipronil/kg body weight). According to this scenario, a concentration of fipronil lower than 0.28 mg/kg of food would not cause exposure greater than the ARfD for 97.5% of consumers between the ages of 3-17 years. To protect more than 99% of consumers between the ages of 3 and 17, this concentration must be below 0.24 mg/kg of food. To protect more than 99% of children aged 1 to 3 years, the concentration must not exceed 0.23 mg of fipronil/kg of food.

In a scenario where an individual consumes foods that may contain eggs or egg products contaminated with fipronil with a concentration equal to 0.23 mg/kg of food, a child weighing 10 kg would have to consume quantities in excess of 391 g to be exposed to a dose greater than the ARfD.

Table 2 gives the quantities of consumed foods not to be exceeded according to body weight.

Table 2: Quantity of food that can be consumed without reaching the acute toxicological reference value (ARfD) of 0.009 mg/kg body weight

Body weight in kg	Maximum concentration (mg/kg of food*)	Quantity of food not to be exceeded per day, in grams	
10	0.23	391	
20	0.23	783	
30	0.23	1,174	
40	0.23	1,565	
50	0.23	1,957	
60	0.23	2,348	
70	0.23	2,739	
80	0.23	3,130	

^{*} food that may contain eggs or egg products

These are worst-case scenarios because they assume that the foods are consumed on the same day and are all contaminated with fipronil. These concentration limits are higher than the one proposed in a

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note prepared by the AFSCA³. This difference can be explained by the AFSCA's choice of a scenario in which the calculation is based on consumption of 500 g of processed product that may contain eggs or egg products per day and for a young child weighing 8.7 kg, which corresponds to 57.47 g/kg body weight/day. The INCA2 data show that this extreme scenario is not plausible for a French consumer.

4. CONCLUSION

On the basis of the available data and taking into account the work that was able to be done in the time available for the response, the maximum fipronil concentration not to be exceeded in egg products and other processed products containing eggs, to ensure that consumer exposure remains below the acute toxicological reference value, was determined based on a worst-case scenario.

With regard to processed products containing eggs, at this stage, the Agency recommends a limit not to be exceeded of 0.23 mg of fipronil per kg of food. For eggs and egg products, ANSES reiterates the limit already determined in its note of 10 August 2017⁴, namely 0.43 mg/kg of egg.

Dr Roger Genet

³ Federal Agency for the Safety of the Food Chain (Belgium). Risk assessment and risk management with regard to the presence of fipronil in eggs, egg products, poultry meat and processed products. http://www.afsca.be/businesssectors/foodstuffs/incidents/fipronil/_documents/NoteFipronil_17.08.17_ENG_v1.1.pdf

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KEYWORDS

Fipronil, eggs, contamination Fipronil, œufs, contamination