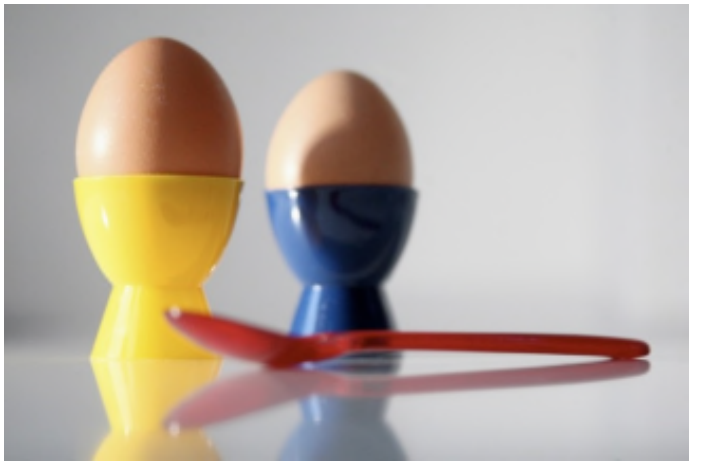
GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT

15 YEARS Science in the Service of Humanity

BfR Bundesinstitut für Risikobewertung

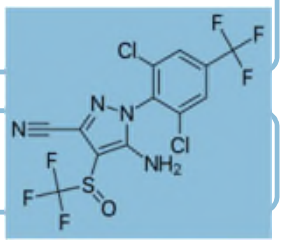
# Risk assessment of fipronil – a German perspective

*Andreas Hensel*

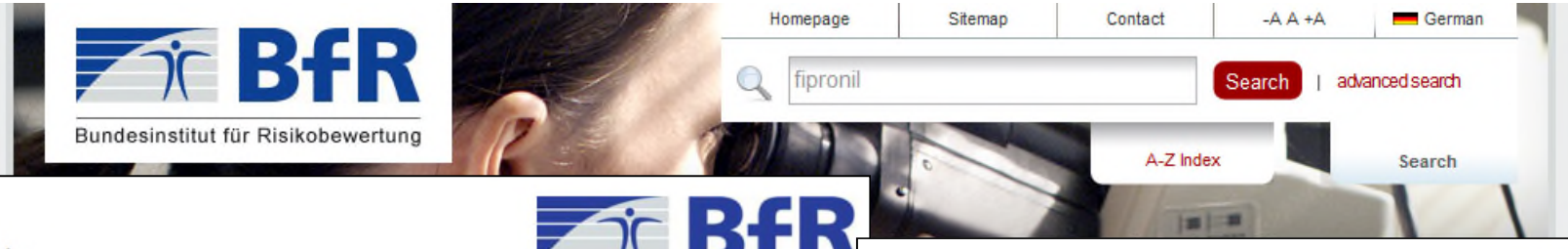


# Chronology of the fipronil incident in 2017 (selection)

| | |
|---|---|
| 20 Jul | • 1st RASFF notification Kat II ‘other message’; sample from May 2017, maximum concentration 1.2 mg/kg; Detection of "Dega 16" and "Copper Boost" |
| 26 Jul | • First request to BfR for a „short-term risk assessment“ (Federal Ministry of Food and Agriculture, BMEL) |
| 27 Jul | • Request for „Residues of fipronil in food of animal origin” (BMEL) |
| 30 Jul | • 1st BfR opinion on acute risk assessment in preparation online (BfR) |
| 3 Aug | • „Incident“ proclaimed (BMEL)<br>• 12 federal states affected |
| 3 Aug | • 1st Meeting „incident core team“ followed by different conference calls between Federal government and the Federal States |
| 8 Aug | • FAQs and, Updated Evaluation of chronic exposure‘ published (BfR) |
| 4 Sep | • „Incident“ terminated (BMEL) |



# Public communication on BfR-website

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**Fipronil in foods containing eggs: Estimations of maximum tolerable daily consumption**

BfR Communication No. 019/2017 of 10 August 2017

www.bfr.bund.de

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**Health assessment of the first analysis results on fipronil levels in foods in Germany**

Updated Communication No. 017/2017 of 8 August 2017

Press information: Contaminants

www.bfr.bund.de

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

Updated BfR FAQ of 15 August 2017

15.08.2017

www.bfr.bund.de

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DOI 10.17590/20170802-140011

**Health assessment of individual measurements of fipronil levels detected in foods of animal origin in Belgium**

BfR Opinion No. 016/2017 of 30 July 2017

German departmental research

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**Updated assessment of the health risks posed by longer-term consumption of foods contaminated with fipronil**

6) Communication: Health assessment of fip
in Germany based on the first analysis result
hens ...
11.08.2017

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**Health assessment of fipronil levels in chicken meat in Germany based on the first analysis results for pullets and laying hens from the few affected businesses in Germany**

BfR Communication No. 020/2017 of 11 August 2017

Up

Bisphenol A

# BfR Opinion No. 016/2017: Health assessment of individual measurements of fipronil levels detected in foods of animal origin in Belgium (30th July 2017)

**What fundamental effects can fipronil have?**

- 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

# BfR Opinion No. 016/2017: Health assessment of individual measurements of fipronil levels detected in foods of animal origin in Belgium (30th July 2017)

**Are any health risks connected with consumption of foods containing fipronil?**

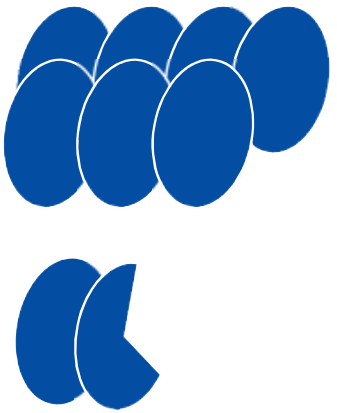
- With regard to consumption of foods containing fipronil within 24 h and based on the currently available information and German consumption data, an exceedance of the acute reference dose (ARfD) does not result for any of the consumer groups observed in Germany. A health risk for children through the acute intake of Fipronil containing eggs is possible

- 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.

- This preliminary assessment is based on principles for pesticide risk assessment and the data currently available to the BfR.

# Fipronil incident – Risk assessment of acute intake


- Content of Fipronil in chicken meat or eggs that does not lead to an exceedance of the ARfD for Fipronil for any of the concidered consumer groups
  - 0.72 mg/kg in Eggs
  - 0.77 mg/kg in Meat
- Amount of eggs with the maximal Fipronil content of 1.2 mg/kg that could be consumed per day without exceeding the ARfD
  - Adult (65 kg bw): 7 Eggs* per day
  - Child (16.15 kg bw): 1.7 Eggs* per day



***Fipronil content: 1.2 mg/kg; Weight: 70 g / egg**

# European starting points for risk assessment

**Acute Reference Dose (ARfD)**
after consultation with EFSA and WHO:
ARfD of 0,009 mg/kg body weight (EFSA)

**MRLs, residue definitions, ADI, ARfD**
based on EU Pesticides database:
http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

**Consumption Data and Models**
EFSA PRIMo Model
https://www.efsa.europa.eu/de/applications/pesticides/tools
additionally in Germany: NVS 2 Model (children and adults)

**Processing Factors**
to account for concentration/dilution effects during processing and distribution of fipronil within the food

# Contact to partner organizations

| Country | Time of contact | Information Exchange | active collaboration |
|---|---|---|---|
| Belgium | at the beginning of the incident | Risk assessments<br>Communication (prelimnary information) | Mail exchange |
| The Netherlands | at the beginning of the incident | Risk assessments<br>Communication (prelimnary information) | Telefonconferences and bilateral calls<br>Mail exchange |
| Austria | Contacted by BfR on 10.08.2017 | no | no |
| France | Contacted by BfR on 10.08.2017 | Request for Information via Mail | Mail exchange (at the end of the incident) |

→ Improvement is necessary

# Ongoing processes in Germany

- Federal Control Plan
  - Monitoring until 31st October 2017
  - Approx. **800** samples
  - Testing for Fipronil and its metabolites in processed products
  - Results expected in December 2017

- National Residue Control Plan (NRCP)
  - Long-term control of residues
  - Focus on Fipronil added to the Plan 2018 and 2019

- EU-Adhoc-Program
  - Results expected in November 2017

# Challenges (1)

- Exchange of information, data, and risk assessments (including divers versions in national languages)

***How can we strengthen international collaboration?***

- Founding of joint working groups for risk assessment in times of transnational incidents/crisis (also virtual)

***Is there a necessity for such activities? How can we implement this?***

- Possible role of EFSA as a coordinator in transnational crisis

***How can EFSA give support in cases of transnational crisis?***

- Conflict of food fraud and illegal use of products/substances in contrast to food safety/public health

***Is there a priority of legal investigations/prosecution?***

# Challenges (2)

- Risk communication regarding vulnerable groups (children, pregnant and breastfeeding woman)

***Is there a necessity for harmonized communication?***

- Collection of supply chain data is unstructured.

***When, finally, do we start to collect data in a meaningful way?***

- Harmonization of risk assessment strategies

***How can we avoid different results in risk assessments as a consequence of using ARfDs  or consumption studies from different national backgrounds?***

- Assessment of products/substances with multi-functional use (veterinary drug, biocide, pesticide)

***How can we implement a collaboration of affected departments or organizations at a very early stage?***

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# Thank you for your attention

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