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FIPRONIL IN EGGS, EGG PREPARATIONS, PRODUCTS CONTAINING EGGS AND CHICKEN MEAT – GUIDELINES FOR RISK MANAGEMENT

This Guide is intended for food business operators, local food control authorities and inspection veterinarians. The Guide contains guidelines issued by the European Commission (*sections written in Italics*) as well as Evira's views on risk management activities to ensure the safety of food products in terms of fipronil.

According to the general principles of food safety, food business operators are responsible for ensuring that the food they have imported, produced, processed, manufactured or distributed is in compliance with requirements ((EC) No 178/2002). Pursuant to legislation, every food business operator has the obligation to ensure that the ingredients/raw materials used in the production of food meet the requirements of EU legislation. Accordingly, **food business operators shall ensure, where necessary, based on their own risk assessment that the eggs/egg products/products containing eggs used in the production of food do not exceed the maximum residue limit set for fipronil in the EU**. Naturally the same requirement also applies to any other chemical hazards related to food or ingredients of food.

Sampling

Official sampling for purposes of a pesticide analysis shall be carried out in accordance with Regulation 2002/63/EC of the European Commission (http://eur-lex.europa.eu/legal-content/FI/TXT/?qid=1502868688411&uri=CELEX:02002L0063-20020723).

According to the Finnish Food Act, the person taking **samples for in-house control** must be sufficiently competent in taking, handling and storing samples. The representativeness of the sample (size) for the purpose as well as the protection and marking of the sample should also be verified in order for the in-house control result to be considered adequately reliable. The sample shall represent the lot to be analysed in the best possible manner. The number and size of increment samples depend on the size of the lot, the distribution of the substance analysed in the lot (homogeneity/heterogeneity) as well as the particle size of the substance and the package size. The sample shall be traceable and it shall be protected against external factors, such as light and high temperatures prior to analysis. Compliance in in-house control with the requirements set forth for official sampling (e.g. size and number of increment samples) **will ensure that the result from in-house control is reliable and representative of the whole sample lot.** Some other, alternative sampling method can be used in in-house control, where applicable. It shall be verified in that case, however, that the sample is representative and the result obtained is reliable.

Analysis of samples

By virtue of the Finnish Food Act, Evira approves laboratories that perform analyses as laboratories approved to analyse official samples or as approved in-house control laboratories. Pursuant to Control Regulation (EC) No 882/2004 and the Decree of the Finnish Government on laboratories performing analyses by virtue of the Food Act, Feed Act and Health Protection Act (152/2015), samples taken for purposes of official control as referred to in the Food Act shall be analysed in an accredited laboratory that meets the requirements of international standard SFS-EN ISO/IEC 17025. In-house control analyses do not necessarily have to be performed in an accredited laboratory. However, it should be acknowledged that the commitment of the laboratory to quality systems increases the reliability of the analytical results.

As concerns the determination of pesticides residues, the following guidelines of the Commission are applied to quality assurance and application of measurement uncertainty: SANTE/11945/2015 Guidance

document on analytical quality control and method validation procedures for pesticides residues analysis in food and feed (https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_wrkdoc_11945.pdf).

Maximum residue limit for fipronil

The maximum residue limit (MRL) set for fipronil in eggs and chicken meat is 0.005 mg/kg ((EC) No 396/2005). This MRL value has been set for the sum of fipronil and its sulfone metabolite (expressed as fipronil).

When assessing the result, the measurement uncertainty of the determination method, and where applicable, the so-called processing factors are to be taken into account (cf. Interpretation of results).

Interpretation of results

The measurement uncertainty of the determination method is to be taken into account in the interpretation of the analytical result.

> Example 1. The laboratory analytical result for egg is 0.012 mg/kg. The indicated measurement uncertainty of the method is ±50 %. Thus the analytical result is 0.006-0.018 mg/kg. The result thus exceeds the MRL, taking the measurement uncertainty (0.006>0.005) into account.
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> Example 2. The laboratory analytical result for egg is 0.008 mg/kg. The indicated measurement uncertainty of the method is ±50 %. Thus the analytical result is 0.004-0.012 mg/kg. The result thus does not exceed the MRL, taking the measurement uncertainty (0.004<0.005) into account.

More information about the interpretation of the measurement uncertainty is provided in Section 6 of Evira Guide 17069/1 (https://www.evira.fi/globalassets/tietoa-evirasta/lomakkeet-ja-ohjeet/elintarvikkeet/kemiallinen-vaatimustenmukaisuus/eviran_ohje_17069_1_fi.pdf (in Finnish), https://www.evira.fi/globalassets/tietoa-evirasta/lomakkeet-ja-ohjeet/elintarvikkeet/kemiallinen-vaatimustenmukaisuus/eviran_ohje_17069_1_se.pdf (in Swedish)).

The changes in the concentration of fipronil due to drying, dilution or processing, or the relative proportion of the ingredient in the processed food (processing factor) **shall also be taken into account** in the interpretation of the analytical result, **where applicable**. There is no harmonised list of processing factors available in Europe. The processing factors are always determined specifically in each case, and must be assessed and justified specifically for each ingredient/product.

> Example 1: The analytical result of powdered eggs gives a fipronil concentration of 0.030 mg/kg, taking the measurement uncertainty into account. According to the Fineli database (https://fineli.fi/fineli/en/index), the basic nutritional content of eggs is about 22 g/100 g and that of powdered eggs is about 88 g/100 g. A processing factor of 4 can be derived from this for powdered eggs. The maximum residue limit applied to the assessment of the result is then 4*0.005 mg/kg = 0.020 mg/kg, i.e., the measurement result obtained exceeds the MRL.
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> Example 2: A cookie produced using 4% of the powdered eggs referred to above. The calculated concentration of fipronil in the cookie is 0.030 mg/kg*0.04 = 0.0012 mg/kg. The result is compared with the concentration of 0.005 mg/kg in accordance with the

Commission's guidelines (cf. Required risk management activities), which shows that no actions are required with respect to the cookies.

Required risk management activities

- Pursuant to the Commission's guidelines (RASFF 2017.1065, fup 297), *in case the analytical result in the eggs is above 0.72 mg/kg or in chicken meat above 0.77 mg/kg, the eggs/chicken meat that have reached consumers* ***have to be recalled from the consumers.*** *Any products processed of these raw materials have to be traced and* ***withdrawn from the market****.*
- Pursuant to the Commission's guidelines (RASFF 2017.1065, fup 11 and 69), *in case of finding of a level of fipronil in a processed food above the limit of 0.005 mg/kg, taking into account the changes in concentration due to drying, dilution, processing (processing factor) or the relative proportion of the ingredient in the processed food,* ***the contaminated lot of processed food has to be withdrawn from the market.***
- Food business operators may not use in the production of food raw materials or ingredients which are not in compliance with regulations. In case raw materials/ingredients that are not in compliance with regulations have been used by an operator in the production of food, **the product must not be allowed to move forward in the food chain**, despite the dilution effect.
- In case the product tests positive in the analysis, but taking both the measurement uncertainty and the processing factor into account, where applicable, the result is <0.005 mg/kg, the product complies with regulations and **thus no actions are required based on the analytical result**.

For more information, please contact:

MRL values, required control activities:
Sanna Viljakainen, Senior Officer, tel. +358 50 464 9354 (sanna.viljakainen@evira.fi)

Chemical analytics, interpretation of analytical results:
Kati Hakala, Senior Researcher, tel. +358 40 489 3404 (kati.hakala@evira.fi)