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Ministry of Agricultural, Nature and Food Quality
To the office of 10.2.e , 10.2.e
Bezuidenhoutseweg 73
2594 AC Den Haag

Subject: 2-amino-flubendazole

Dear 10.2.e , 10.2.e ,

Vion Food has a long lasting relationship in exporting pork to 10.2.a . During 2019 the 10.2.a authorities reported to the Dutch authorities a detection of the presence of 2-amino-flubendazole in samples taken from a shipment of Dutch pork. In response to this observation of the 10.2.a authorities the Dutch pork processor Vion Food has taken several actions. We would like to clarify the actions and adjustments of the Vion private monitoring programme, in response to the detection of 2-amino-flubendazole. In this letter Vion describes the following:

- the private monitoring programme of Vion, including the background of this programme
- the comparison between commonly used substances in The Netherlands and the registration status in 10.2.a
- the root-cause of the detection of 2-amino-flubendazole and test results from the Vion private monitoring programme
- The preventive actions in relation to the detection of 2-amino-flubendazole

1 The private monitoring programme of Vion

Vion has an intensive private monitoring programme which is exceeding the EU legislation, see "appendix 1 Risk based antibiotic residue monitoring programme, part of the supply chain inspection of pork". This private monitoring programme compliments the official public monitoring plan (the National Residue Monitoring Plan) and is firstly based on hazard analysis but also includes third market export requirements and specific customer requirements. Vion has an extended hazard analysis in which all identified hazards are described and the risks are assessed. To perform an update of the hazard analysis, relevant data in scientific literature is collected and summarized, together with information from other trusted sources such as 10.2.a, 10.2.a, EFSA and WHO. The private monitoring programme is part of the Pork Supply Chain Inspection programme and is supervised by the Dutch competent authority. The Pork Supply Chain Inspection is a private supply chain integrated integral food safety system for pork production within Vion. The Pork Supply Chain Inspection (and its private monitoring programme) supervised by means of annual audits from the competent authorities

1.1 Hazard analysis in short

Food safety control within Vion is based on HACCP principles. Hazards are regularly, and at least annually, reassessed. The identification and control of hazards follow the following steps:

1. A description of the hazard is provided; this description characterizes the hazard.
2. The associated consequences for human health are described and the frequency of occurrence in human is estimated.
3. The behavior of the hazard in the supply chain is described; how does the hazard spread and disperse in the supply chain and what is the behavior of the hazard in the different parts of the supply chain.
4. Finally the control of the hazard in the supply chain is described.

1.2 Monitoring of chemical contaminants within the private monitoring programme

On top of the samples taken in relation to the National Residue Monitoring Plan, Vion takes additional samples as part of the private monitoring programme based on the hazard analysis. This private monitoring programme runs for more than 10 years. Collection of samples for chemical contaminants related to veterinary drugs are based on a risk-based approach. Samples are taken on the basis of observations made during slaughtering of pigs. By using these observations farms can be put in a "risk group", which is part to the Vion private monitoring programme. Samples are tested in the state laboratory RIKILT.

Subject of this laboratory analytical programme are currently the following groups of veterinary substances based on the Vion hazard analysis:

- Tetracycline
- Macrolides – Beta Lactam
- Quinolones
- Aminoglycosides
- Sulfonamides

In average Vion tests in The Netherlands around 10.1.c samples of pork carcasses per year. The following table shows the results of the private monitoring programme from 2016 till 2019, the total number of samples taken and the % of positive findings is shown.

Table: Overview of the results of the private monitoring programme during 2016, 2017, 2018 and 2019

	2016	2017	2018	2019
Pork NL	(10.1.c)	(10.1.c)	(10.1.c)	(10.1.c)
% of tests >MRL	10.1.c	10.1.c	10.1.c	10.1.c

2 The comparison between the commonly used substances and 10.2.a registration status

Vion has made an analysis of the substances that are part of Good Veterinary Practices for animal treatment within Dutch pork production. Specific guidelines for use of veterinary medicines are effective in the whole pig supply chain. All use of e.g. antibiotics, are only allowed with a prescription of the independent practicing veterinarian. The selection of an active compound to treat diseased animals with antibiotic is based on guidelines for Good Veterinary Practice. Pigs may only be treated with antibiotics after a confirmed diagnoses of the veterinarian of a disease.

2.1 Antibiotics

The selection of active compounds is based on a cascade decision model in which the antibiotic of first and second choice is related on hazard analysis concerning public health and the prevention of dispersion of antibiotic resistance in the pork supply chain. The following list shows substances that are not registered for pork in 10.2.a , but are allowed to be used according Good Veterinary Practice:

- Sulfamethoxazol → Sulfonamides
- Sulfadoxin → Sulfonamides
- Colistin → Not commonly used
- Flumequin → Quinolones
- Paromomycin → Aminoglycosides
- Oxolinic acid → Quinolones
- Sulfadimidin → Sulfonamides
- Thiamphenicol → No oral administration

All the substances which are part of the guidelines of Good Veterinary Practice are subject of the private monitoring program. This means that all antibiotics which are not registered in 10.2.a are part of the Vion monitoring programme

2.2 Other veterinary medicines

Besides antibiotics, other veterinary substances can be used in the pig husbandry. The following list shows anthelmintic substances that are used in the Dutch pork production and the status of registration in 10.2.a :

- Doramectin → Registration in 10.2.a
- Ivermectin → Registration in 10.2.a
- Levamisol → Registration in 10.2.a
- Flubendazol → No registration in 10.2.a
- Fenbendazol → Registration in 10.2.a
- Toltrazuril → No registration in 10.2.a

Based on this analysis Vion has supplemented the private monitoring programme with Flubendazole and Toltrazuril thus extending the scope of the programme.

3 The root-cause

After the detection of 2-amino-flubendazole residues in 10.2.a, Vion has started a root-cause analyses. This analyses resulted in the observation that a farm treated his pigs during the fattening stage of the pig production with 2-amino-flubendazole to cure the pigs for a large roundworm infection. This finally resulted in residues of 2-amino-flubendazole in pork. After the observation Vion analysed additional samples on 2-amino-flubendazole as addition to the existing private monitoring programme and all samples (n=20) were negative regarding 2-amino-flubendazole.

3.1 Corrective Measure

As a result of the detection of 2-amino-flubendazole residues, the complete shipment in which the substance was detected has been transported back to the Netherlands preventing it entering 10.2.a food chain.

4 The preventive actions

After the detection and the root cause analysis, Vion has implemented several preventive actions.

4.1 Preventive actions after the observation of 2-amino-flubendazole residues

The group of Benzimidazole (to which Flubendazole and Fenbendazole belong) are within the EU legally registered anthelmintics for use in pigs. Residues of these anthelmintics must be below MRL according to the EU legislation.

In order to fulfil the requirements of 10.2.a authorities additional control measures are taken to prevent the use of 2-amino-flubendazole:

1. The presence of flubendazole will be no longer part of Vion Good Agricultural Practices at the farm where fattening pigs are raised
2. The control on residues of flubendazole is part of the private monitoring programme after the observation by 10.2.a authorities
 - a. The results of these samples analysed as part of the updated private monitoring programme show that all the samples (n=20) taken at Vion in 2019 were negative regarding 2-amino-flubendazole (See appendix 2, Lab results 2-amino-flubendazol.)

To verify the actions taken by Vion the results of the updated private monitoring programme on residues of 2-amino-flubendazole are exchanged with the competent authority. The updated private monitoring programme will be supervised by the competent authority, and it stays part of the audit scope executed by the competent authority.

5 Conclusion

The observation of 2-amino-flubendazole has resulted in several additional control measures instigated by Vion. Monitoring results of Vion after the implementation of the mitigating actions, showed a 100% absence of 2-amino-flubendazole residues in pork.

I am available for any questions or remarks concerning this subject.

Sincerely Yours,

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Appendix 1: Risk based antibiotic residue monitoring programme

Appendix 2: Lab results 2-amino-flubendazol