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Handling of cases where a pig producer calls in regarding delivery of slaughter animals prior to the end of the withdrawal period

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Introduction

Withdrawal periods are set to ensure that the concentration of residues of legal medicinals is below the maximum residue limits (MRL) when animals are delivered to slaughter. Very few human cases are reported dealing with adverse effects related to consumption of meat with residues of antimicrobial origin. This is presumably related to the low prevalence as well as the low concentration of these substances at the time of consumption of the meat. In the official Danish surveillance and the abattoirs' own check of veterinary medicinals, the carcass is withheld pending the test result. If residues are found >MRL, the carcass is condemned. Occasionally, a pig producer calls the abattoir to inform that - by mistake - an animal has been delivered prior to the end of the withdrawal period. If the producer calls in time, the abattoir finds the animal in the lairage and ensures that it is not slaughtered but euthanized and destructed. However, if the animal is slaughtered, it may be difficult for the abattoirs to find the carcasses. In line, the by-products may be mixed with by-products from animals slaughtered on the same day.

A case arose in Denmark in 2018, where a pig producer informed the abattoir that two pigs had been delivered to slaughter too early. The drug used was Ethacillin, a penicillin product with protracted effect. The pigs were slaughtered 28.8 hours after treatment, and the withdrawal period is 96 hours. When the abattoir was informed, the pigs were already slaughtered. An analysis showed that the residue concentration was above MRL at the time of slaughter. The carcasses were identified and destroyed. The organs, blood and fat were mixed with similar tissue from the other pigs slaughtered on the same day. For blood and fat, a dilution had taken place whereby the concentration would have been below MRL. However, as the abattoir was unable to find the organs from the affected animals, all organs from the slaughterday were condemned due to a health concern because of the presence of the organs from the two treated pigs.

The decision to condemn should be seen in the context of the Danish interpretation of the residue programme as surveillance requiring action. In

other EU Member States, the programmes are run mainly as monitoring implying that the carcasses are not withheld, but where follow-up visits are made to herds from which a positive animal (>MRL) is detected.

The abattoir and the pig producers have product responsibility insurances in place. The maximum amount which can be paid in relation to the insurance is €660,000, and the producer would have to pay around €5,000 as own risk. These maximum amounts were reached in the case which this paper deals with.

The question is how to balance between avoiding unnecessary food waste and complying with EU legislation to ensure consumer confidence. We suggest using Allowed Daily Intake (ADI) as an alternative to MRL, specifically for the situation where the producer contacts the abattoir to inform about slaughter animals delivered before the end of the withdrawal period.

Material and Methods

The two pigs were weighing 100 kg and had each been given 5 ml Ethacillin in a concentration of 300 mg per ml. Hence, they had each received 1500 mg Ethacillin. The pigs were slaughtered 28.8 hours after they had received the injections.

The amount of Ethacillin left was calculated based upon information about the half-life of the drug, which is around 9 hours. The amounts left were compared to EU MRL of penicillin which is 50 µg/kg in muscle, fat, liver and kidney.

Next, we estimated the amount of Ethacillin present in 1) 150 g meat and 2) 50 g sausage, if made from meat from the two pigs.

ADI is the maximum daily dose, which a person may consume without experiencing negative reactions. For penicillin, ADI is 0.03 mg (30 µg) (http://www.inchem.org/documents/jecfa/jecval/jec_2002.htm and <http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=1938>).

Results

Using a half-life of 9 hours implies that the amounts of residues left in the body at the time of slaughter was halved 3.2 times ($28.8/9=3.2$). Hence, $0.5^{3.2} = 11\%$ of the original concentration was left - corresponding to 165 mg.

This amount was assumed to be dispersed evenly in the body, whereby the concentration would have been: 1.65 mg/kg (165 mg / 100 kg) or 1650 µg/kg, which is 33 times higher than the MRL.

If a person has consumed 150 g of meat or 50 g of sausages, the person would have been exposed to eight times the ADI (for meat) or three times (for sausages).

If the meat, organs, fat and blood had been used as category 3 animal by-products, then the processing involving chopping and mixing would have resulted in a concentration below MRL and ADI.

The amounts of residues in the sausage portion would have been below ADI, if the slaughter had taken place 40 hours after treatment, whereas 56 hours after treatment would have to pass for the amounts to be below ADI for the serving of 150 g meat.

Discussion and Conclusion

The present case shows that there are two threshold values that are of importance for the assessment of the food safety impact: MRL og ADI. Both represent an indicator of what humans can be exposed to every day over a long time without experiencing negative human effects. Moreover, in the establishment of MRL and ADI, safety factors are used. The current EU Directive 96/23 only operates with MRL. We suggest that both MRL and ADI are used in the handling of potential presence of residues of legal medicinals. First, information about the treatment should be obtained (time, product, volume, concentration, and way of administration). Next, the residue concentration at the time of slaughter is calculated. If the concentration is above MRL, then the intended use of the meat, organs, blood or fat should be considered by calculating the amount of drug present in a relevant serving size. The effect of dilution - through chopping and mixing - should be included. In the case described above, the organs could for example have been used as category 3 animal by-products, because organs from the two pigs would have been chopped and mixed with similar organs from the same slaughterday. This view is in line with the risk assessment approach already taken in Denmark to the handling of blood and fat, since there are no concerns for toxicity and cancerogenic concerns for veterinary medicinals already approved for legal use. In EU Member States where the residue programme for legal veterinary medicinals is interpreted as monitoring, meat and organs from an entire slaughterday would all be used for human consumption, without any restrictions.

Disproportionate actions are creating a disincentive for producers to report. From a food safety culture perspective, reporting of mistakes should be encouraged, so we can learn and improve our practices. Moreover, it is the Good Farming Practices (GFP) - including marking and registration of treated animals - which ensure that the withdrawal periods are complied with, not the surveillance system.

A generic risk assessment model which includes intended use of meat or organs could be used as support for the local authorities and the abattoirs. Use of such a tool would lead to a systematic,

science-based and objective decision, where harmonisation with EU legislation and various trade requirements should be ensured. Hereby, unnecessary food waste may be avoided.