

# Human health risk of residues in Danish pork – in theory and practice

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## Abstract

Residues of pharmacological active substances or their metabolites might be found in food products from food-producing animals posing a potential risk to human health. Maximum Residue Limits (MRLs) for pharmacological active substances in foodstuffs of animal origin are established to assure high food safety standards, and residue surveillance programmes are required to verify compliance with legislation, export requirements and consumer confidence.

A residue surveillance programme in Danish pigs and pork has been in place since 1972. A qualitative risk assessment was conducted to evaluate the human health risk of residues in Danish pork. The hazard identification step identified the residues that could potentially be found in Danish pork. The release assessment evaluated the probability of release of antibacterial residues in Danish pork, based on antibacterial consumption data in 2008. The exposure assessment estimated the probability of human exposure, based on findings of residues in Danish pork in the surveillance that involved approximately 20.000 samples annually (2005-2009). Finally, the consequence assessment evaluated the potential public health consequences and likelihood of its occurrence, based on a literature search.

The risk associated with antibacterial residues was estimated to be low to negligible in sows (low risk associated with penicillin residues) and negligible in slaughter pigs. To further reduce the already very low prevalence of residues in Danish sows, increased focus on good management practices regarding antibacterial use and education of farmers and farm workers should be promoted to increase awareness regarding the impact of potential detection of residues. Although the probability is low, residues are found occasionally. Experience with recent findings of residues show that there is a need for risk-based control implying quick risk assessments in each case covering among others the purpose of the meat and the risk for humans related to consumption of such meat.

## Introduction

Use of veterinary medicinal products in food-producing animals might result in presence of residues of pharmacological active substances or their metabolites in food products from these animals. Hereby, humans might be exposed to residues via animal products which might have harmful human health consequences. To assure a high level of consumer protection at the EU level, specific legislation regarding surveillance of residues and contaminants in food of animal origin establishes the group of substances to be tested, including the sampling criteria (Council Directive 96/23/EC). Under this legislation, member states are required to have in place national residue surveillance plans, assuring the implementation of specific actions to detect and minimise the recurrence of residues in food of animal origin. Each year, more than 20,000 samples are analysed for presence of residues in Danish pork and the prevalence of residues in Danish pork are found at a very low prevalence (Baptista et al., 2010). The main part of the samples is taken as a part of the slaughterhouses own-check programmes.

This study aimed at evaluating the human health risk posed by residues in Danish pork.

## Material and Methods

A qualitative risk assessment was conducted to evaluate the likelihood and the human health consequences of residues in Danish pork, according to international guidelines (Vose et al., 2001):

- 1) Hazard identification – based on Danish residue surveillance data from 2005-2009;
- 2) Release assessment – based on antibacterial consumption data obtained in Vetstat database;

- 3) Exposure assessment – based on residue surveillance data from 2005-2009;
- 4) Consequence assessment –based on a literature search.

The literature search was conducted in May 2010 to identify reported cases of adverse reactions in humans to antibacterial residues in meat products via PubMed database. Abstracts obtained were screened to ensure they were original reports of adverse reactions to antibacterial residues in meat products.

The steps 1-4 were combined into a risk estimate, where the outcome of each step was expressed in the following qualitative terms: high (event occurs very often), medium (event occurs regularly), low (event is rare), very low (event is very rare but it cannot be excluded) and negligible (event is so rare that is not worth considering) (adapted from OIE, 2004). Final risk estimates were obtained by combining the qualitative outcomes.

Table 1. Qualitative risk assessment of human health risk of antibacterial residues possible found in Danish pigs, 2005-2009

Antibacterial	Assessment of risk <sup>1</sup>							
	Release <sup>2</sup>		Exposure <sup>3</sup>		Consequences		Risk estimate	
	Sows	Finisher pigs	Sows	Finisher pigs	Sows	Finisher pigs	Sows	Finisher pigs
Aminoglycosides	L	VL	N	N	N	N	N	N
Amphenicols	N	N	N	N	N	N	N	N
Cephalosporins	VL	N	N	N	N	N	N	N
Fluoroquinolones	N	N	N	N	N	N	N	N
Lincosamide/spectinomycin combinations	L	M	N	N	N	N	N	N
Macrolides (primarily tylosin)	L	H	N	N	N	N	N	N
Penicillins, $\beta$ -lactamase sensitive	H	H	L	N	VL	VL	L	N
Penicillins, other	M	L	N	N	VL	VL	N	N
Pleuromutilins (primarily tiamulin)	M	H	N	N	N	N	N	N
Sulfonamides/Trimethoprim	H	VL	N	N	N	N	N	N
Tetracyclines	M	H	VL	N	N	N	N	N
Other	N	N	N	N	N	N	N	N

<sup>1</sup> Qualitative risk terms: H = high (event occurs very often), M = medium (event occurs regularly), L = low (event is rare but the occurrence is possible), VL = very low (event is very rare but it cannot be excluded) and N = negligible (event is so rare that is not worth considering).

<sup>2</sup> Probability of release was evaluated based on the estimated number of antibacterial doses per pig per year: H = high ( $\geq 3.0$ ), M = medium ( $\geq 1.0$  and  $< 3.0$ ), L = low ( $\geq 0.5$  and  $< 1.0$ ), VL = very low ( $\geq 0.1$  and  $< 0.5$ ) and N = negligible ( $< 0.1$ ).

<sup>3</sup> Probability of exposure was evaluated based on the maximum proportion of antibacterial residues (%) above maximum residue limits: H = high ( $\geq 1.00$ ), M = medium ( $\geq 0.50$  and  $< 1.00$ ), L = low ( $\geq 0.10$  and  $< 0.50$ ), VL = very low ( $\geq 0.01$  and  $< 0.10$ ) and N = negligible ( $< 0.01$ ).

## Results

The probability of occurrence of residues other than antibacterials was considered insignificant and therefore excluded from the analysis. Although found at a low prevalence, antibacterial residues in Danish pork of sow origin might – if judged very conservative – be considered a potential hazard for human health for people that are allergic to penicillin. Table 1 presents an overview of the risk assessment and the risk estimated for the most commonly used antibacterials in Danish pig production.

## Discussion

It is generally accepted that “zero risk” is impossible to achieve in the context of food safety (FAO, 1998). However, in this study the definition of negligible could not be differentiated from zero and hence, according to the classification matrix used, the product of negligible probability implied that the risk was negligible, indicating that the event was “so rare that it was not worth considering”.

Antibacterial residue surveillance in Danish pigs includes 0.1% of the total slaughter pig population and more than 1% of the sows slaughtered in the previous year, exceeding the 0.03% level required by EU authorities. Antibacterial residue prevalence in Danish pigs has been consistently very low. Human cases of allergic reactions to penicillin residues in food are few and not that well-documented. The best documented case deals with a German butcher who was known to be allergic to penicillin. The butcher ingested pork originating from a pig that he had slaughtered himself. However, the pig had been treated with penicillin 3 days prior to being slaughtered. The butcher developed skin symptoms which declined after treatment with corticosteroids (Tscheuschner, 1972).

Overall, the results show that the human health risk associated with antibacterial residues in Danish pork is low to negligible in sows and negligible in slaughter pigs. The difference between sows and finishers might be explained by different practices regarding antibacterial use and management. The most common causes of positive findings were related to poor keeping of treatment records and/or inadequate identification of treated animals (data not shown). This is more likely to occur in sows, where individual management is used (against batch management in slaughter pigs) and time of slaughter is not defined. Still, the number of sows represents only a minor proportion of the total pork consumed in Denmark, which further reduces the already low overall risk posed to Danish consumers.

Study findings presented here are in agreement with previous studies assessing the human health risk of antibacterial residues in food products (Berends et al., 2001; Dayan, 1993; Dewdney et al., 1991). Accordingly, in the Netherlands, the human health risk associated with presence of tetracycline residues was estimated to be 80,000 times lower than the risk of human salmonellosis through pork products (Berends et al., 2001). Moreover, the small concentrations of antibacterial residues through which humans are exposed through food represent a negligible proportion of the total amount of antibacterials consumed by humans (Cerniglia and Kotarski, 2005). Hence, long-term effects are also not likely to be expected from consumption of Danish pork as human exposure to antibacterial residues is very low to negligible and below the average daily intake (ADI) for lifetime exposure. This is in agreement with previous studies (Paige et al., 1997). Furthermore, at the EU level, very conservative assumptions are used for determining ADIs, MRLs and withdrawal times, assuring a very high level of protection to consumers. Accordingly, it has been shown that when MRLs for tetracyclines in meat are exceeded by a factor of 400, the risk of an adverse reaction in humans is estimated to be 1 in 3 millions exposed consumers (Berends et al., 2001).

To further reduce the very low prevalence, increased focus on good management practices regarding antibacterial use and compliance with withdrawal periods should be advocated for. Awareness should be increased regarding the impact of potential detection of antibacterial residues above the MRLs on industry reputation and exports. Moreover, experience with recent findings of residues show that there is a need for risk-based control implying quick risk assessments in each case covering among others the purpose of the meat and the risk for humans related to consumption of such meat. A reporting system should be in place that will motivate farmers to make immediate notification if animals by mistake are sent to slaughter to enable correct action. The human health risk associated with residues in Danish pork is negligible in general. However, reasons other than food safety might apply and require that residue surveillance activities are in place. Residue data might be used as an indicator of animal health and welfare, use of veterinary drugs and meat quality. In line, consumers in the EU have residues of antibacterials and other similar substances high on the agenda (Anon., 2010). Above all, residue surveillance is required to document fulfilment of regulations and export requirements.

Denmark has several risk mitigating initiatives in place regarding use of antibacterials in pig production, which further contributes to mitigate the human health risk of antibacterial residues in pork. These are described in detail in Andreasen et al. (2011) and will only be listed here in brief: Vetstat database recording antibacterial use data, official guidelines for antibacterial treatment of food-producing animals, no use of fluoroquinolones in livestock, and in 2010 a 2-year ban on use of cephalosporins in Danish pigs was put in place by the industry. Furthermore, the industry has extended the withdrawal period for tetracyclines to 30 days and banned use of sulfadimidine in sows and slaughter pigs. Regardless of the substance used, withdrawal periods of less than 5 days are not accepted.

## Conclusion

Risk assessment results showed that the human health risk associated with antibacterial residues in Danish pork is low to negligible in sows and negligible in slaughter pigs.

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