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Modernizing the antimicrobial residue monitoring programs for pig meat in Europe – The balance between flexibility and harmonization

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ABSTRACT

The EU Residue Directive is currently being renegotiated. One key question is how to balance flexibility and harmonization. To address this, we reviewed Danish, Dutch and Swiss monitoring programs for antimicrobial residues in pig meat using the recently developed RISKSUR design tool. The results identified variation regarding number of surveillance components, reactions to suspect and positive findings, prevention activities, diagnostic method, sample matrix, use of targeted/risk-based approaches, and sampling frequency. This variability could largely be explained by differences in overall surveillance objective: Denmark and the Netherlands have a large pork export and higher need for documenting compliance with legislation, whereas Switzerland only trading with EU has a lower need for spending resources on monitoring. It is recommended that the future EU Directive should set standards for monitoring to ensure a basic level of monitoring enabling comparison of results. Minimum handling of carcasses with residues above maximum residue level should be harmonized. Risk-based sampling should be encouraged, and results from risk-based and random sampling should be reported separately. Harmonization is unnecessary for number of surveillance components (but a private component is recommended), prevention, diagnostic method, and way of sampling – assuming that the diagnostic method and sampling matrix combination have sufficient validity.

1. Introduction

The consequence of human exposure related to consumption of meat with residues originating from veterinary medicinals with an antibacterial effect may be considered limited, because of the low level of residues resulting in very few, acute human cases, and symptoms are usually mild, if seen at all (Tscheuschner, 1972; Berends, van den Bogaard, Van Knapen, & Snijders, 2001; Baptista, Alban, Olsen, & Petersen, 2010). The most serious may be considered allergic reaction to penicillin, where symptoms include rashes, hives, itchy eyes, and swollen lips, tongue or face. Treatment with corticosteroids has shown to be successful in those cases (Tscheuschner, 1972). Long-term exposure or repeated exposures might result in disturbance of the intestinal microbiota, whereas single exposures are not considered to be able to induce such turbulence (Berends et al., 2001). In all cases, consumers perceive presence of residues of e.g. antimicrobials in food products as indeed unwanted. Three out of 10 Europeans mentioned chemical residues from pesticides (31%), antibiotics (30%) and pollutants like mercury and dioxins (29%) as risk to be "very worried" about - according to a European survey about consumer perception about food safety (TNS, 2010).

To secure consumer confidence and trade, actions must be taken to prevent presence of residues of antimicrobials in meat. Monitoring of meat can be interpreted as an evaluation of the compliance of the actions taken earlier in the supply chain; a high prevalence will indicate that compliance is low, whereas a low prevalence will indicate that compliance is high. Findings of residues in meat at border inspection may result in rejection of the import on certain markets (Alban, Rugbjerg, Petersen, & Nielsen, 2016).

The current legislation regulating the area of residues in meat within the European Union (EU) originates from 1996 and is called EU Directive 96/23/EC. This Directive requires EU Member States to

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implement a national residue monitoring plan for residues. It describes the minimum requirements for official sampling frequency for specific groups of residues among livestock in a country (The Council for the European Communities, 1996). Accordingly, 0.05% of the pigs produced are to be checked for all kinds of residues through official sampling. Among these, 0.03% are checked for veterinary drugs and contaminants (Group B substances), and again, 0.01–0.02% are checked for drugs with antibacterial effect (Group B1 covering antibiotics and sulphonamides – in the following called antimicrobials). The remaining 0.02% of the samples are analysed for substances, which have an anabolic effect and prohibited substances (Group A substances). A minimum of 5% of these samples are analysed for Group A6, which covers prohibited veterinary substances including among others chloramphenicol, chlorpromazine, metronidazole and nitrofurans. A MRL cannot be established for these substances (The EU Commission, 2010).

Presence of residues of prohibited substances is monitored either in live animals on the farm or in various animal tissues (including meat) at the slaughterhouse. Residues of antimicrobials are monitored only in relation to slaughter, where the matrix is target animal tissue/fluid or meat. Furthermore, the Directive lays down the framework for the reporting of information from monitoring. In line, EU Regulation 37/2010 establishes maximum limits for residues (MRL) of veterinary medicinal products in food-producing animals and animal products (The EU Commission, 2010).

According to Directive 2001/82/EC marketing authorization for veterinary medicinal can be granted either via a national, a decentralized, a mutual recognition or a central procedure (The EU Commission, 2001). All MRL values are determined at the central level by the European Medicines Agency's Committee for Medicinal Products for Veterinary Use (CVMP). The withdrawal period is determined through the MRL value for the substances (e.g. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000039.jsp) and a residue depletion study as described in the Guideline "Approach towards harmonization of withdrawal periods" (EMEA/CVMP/036/95). There may be differences in length of the withdrawal period between Member States due to individual interpretation of the residue depletion studies, if the product has been approved via national procedures. CVMP has the faculty to harmonize withdrawal periods via article 34 in Directive 2001/82, if considered necessary. Systematic compliance with withdrawal periods cannot be controlled easily, as it would require control visits to the individual herds during which recordings of use of antimicrobials are compared with dates of delivery of animals to slaughter. Therefore, to ensure feasibility focus is on the presence of residues in the meat at the time of slaughter.

The aim of the existing residue legislation is to harmonize the control of residues in the Member States, thus ensuring a high level of health protection, while avoiding disruption in intra-Community trade (The EU Commission, 2003). The national residue monitoring plans were not designed originally to assess general consumer exposure to residues, but to reinforce supervision and monitoring of illegal use of pharmacologically active substances as stated in EU Directive 85/358 (The Council for the European Communities, 1985). The EU Directive 96/23 will be repealed by December 14, 2019 (EU Commission Residue Working Group, 2017a); this implies that negotiations about a new legislation will take place from now until 2019. The aim is to have a transparent and simplified legislation. A reflection paper about this issue was developed by the EU Commission in (2003). According to this document, the overall goal is to determine new means to balance consumer protection, animal health, welfare and trade requirements (The EU Commission, 2003). Ideally, the coming legislation should be flexible, so it can reflect the level of need for monitoring in the individual Member States, while still having sufficient harmonization to avoid disruption of trade. Moreover, risks may shift over time. Therefore, a flexible framework based upon risk-based sampling should be aimed for to support the most effective method of detection and control of illegal/wrong use of antimicrobials and other veterinary substances (The EU Commission, 2003).

In 2014, 15 Member States reported a total of 46,023 official samples tested for one or more antimicrobial substances in pig meat among which 74 were non-compliant samples. The most commonly found antimicrobial class consisted of tetracyclines including chlortetracycline, doxycycline, and oxytetracycline which represented 32 out of the 74 samples (with 77 non-compliant results). Other substances found included amoxycillin (N = 2), benzylpenicillin and other penicillins (N = 4), ciprofloxacin (N = 1), dihydrosteptomycin (N = 9), enrofloxacin (N = 3), florfenicol (N = 1), gentamycin (N = 1), lincomycin (N = 3), substances containing sulfa (N = 18), trimethoprim (N = 4) and tularthromycin (N = 1). Moreover, 26,541 samples were tested for presence of prohibited substances (Group A6) for which there is a zero tolerance; here one sample was positive for chloramphenicol and two were positive for metronidazole/hydroxymetronidazole (EFSA, 2016). Hence, a substantial number of samples are tested for residues of antimicrobials in livestock products and only very few are found positive each year in the EU.

Monitoring data can be used to document a low prevalence of residues of antimicrobial origin. A distinction is here made between monitoring and surveillance. Monitoring is defined as a data collection, which is not linked with actions related to a positive finding or a prevalence above a certain threshold. This is contrary to surveillance, where actions are clearly defined (Hoinville et al., 2013). In the case of residues, the routine sampling may be considered monitoring, because the meat is already distributed on the market unless carcasses are withheld during testing. Still, positive findings require postponed action, which is an element of surveillance. When the dimensioning of a surveillance program is planned, it is important to identify the expected cost of error, which in the case of antimicrobial residues may be defined as the probability of missing one or more cases times the economic consequences of this (adapted after Cameron, 2012). As stated above, importing countries may react negative to finding residues of antimicrobials in imported meat. In the worst case, this may imply that exports from a country may be denied for months, leading to substantial costs. Based upon this, it may be hypothesized that the surveillance objectives may vary between countries in the sense that A country, which is exporting meat, may have a higher need for in-country up-to-date monitoring data compared to a country with no export or a country importing meat. Other factors might also influence – such as risk perception regarding presence of residues.

Trading partners and consumers demand meat with a documented low prevalence of residues. However, sampling is associated with costs, and the veterinary authorities are responsible for a variety of monitoring and surveillance programs, making it necessary to prioritize carefully the need for and ways of sampling. Risk-based sampling may represent a way of improving the cost-effectiveness; if animals or herds with an increased probability of the condition of interest are sampled, a higher number of positive cases may be found compared with representative (random) sampling. This may result in a higher efficiency of the system without loss of efficacy (Stärk et al., 2006). Two recent studies from Denmark have shown that the cost-effectiveness of a residue surveillance program in slaughter pigs could be improved by increasing the sampling frequency in high-risk herds compared to random sampling. High-risk herds were defined as finisher pig herds with a within-herd prevalence of chronic pleuritis twice as high or higher than the average (Alban et al., 2014, 2016). The