Risk Assessment and Animal Health Law: a scientific approach to support policy-making on the control of animal diseases

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INTRODUCTION

Regulation (EU) 2016/429 on transmissible animal diseases, known as the Animal Health Law (AHL), is new and has been in force in the European Union since 21 April 2021. The AHL, along with implementing and delegated regulations, constitutes a comprehensive legal framework on the prevention, control, and eradication of transmissible animal diseases in the European Union.

Within the context of the AHL, the European Commission (EC) requested EFSA to provide scientific advice on the effectiveness of different strategies to control the 14 category A animal diseases (those that do not normally occur in the EU and which require immediate eradication). More specifically, EFSA was requested to assess the effectiveness of i) the sampling procedures for the detection of disease in the event of suspicion, confirmation, repopulation and animal migration, ii) the length of the monitoring period, and iii) the radius of protection and surveillance zones and the active duration of such zones.

The aim of this assessment was to document the scientific rationale behind some of the control measures in place prior to the AHL, in order to assess how effective they are in containing the disease, and if appropriate, to propose amendments.

METHODOLOGY

The terms of reference of this mandate had to be divided into distinct scenarios with specific objectives, which were translated into scientific questions to be answered using measurable and comparable epidemiological parameters. Additional terms, such as the monitoring period used regularly in the AHL for different management purposes, had to be matched to the periods used in the epidemiology of infectious diseases.

Experts in epidemiology, statistics and laboratory methods selected as working group members identified the scientific entities behind the management terms and matched the scientific methods to the assessment.

Extensive and systematic literature reviews were conducted to estimate the key epidemiological parameters for each disease. The relevant data for the analysis were retrieved from existing databases or ad hoc requests. Stochastic epidemiological models were used to ascertain the spread of the diseases under certain conditions, supporting the calculations of the minimum number of samples needed to detect each disease. An uncertainty analysis was also conducted to investigate limitations and the impact they would have on the results.

RESULTS

The effectiveness of sampling procedures was assessed as regards the ability to detect or rule out the disease in establishments or zones, using the minimum sample size and the highest confidence level. For this purpose, the design prevalence was estimated, and information on the performance of diagnostic methods (sensitivity, specificity) was retrieved from the literature. The monitoring period, expressed in epidemiological terms as the period between the time of infection and the time at which the disease is suspected, was strongly related to the incubation period and affected by the clinical manifestation of the disease in the field. The length of the existing monitoring period was considered effective if it enabled the infection's introduction time and source to be identified, as well as epidemiological links to/from the affected establishment. The probability of disease transmission from an affected establishment beyond certain distances was estimated based on transmission kernels. The length of the radius used in the protection and surveillance zones was considered effective if the probability of transmission beyond it was lower than a previously agreed threshold probability.

DISCUSSION

This work provides a scientific approach to underpin the management tools used to control animal diseases and links them with measurable and comparable epidemiological and statistical entities. The conclusions and recommendations of the assessment and the uncertainty analysis will help managers when reviewing the control measures with a view to making them more effective.

The uncertainty of the results is mainly caused by limited scientific information and data and the fact that the required inputs came from various studies with different protocols, objectives, methodologies and limitations and not from primary research designed for the purposes of this work. Despite the limitations, this work shows how a risk-based and rational methodological framework can be used to support and justify decision-making on control measures for animal diseases. In addition, it is an opportunity to foster initiatives to further research gaps in knowledge and conduct targeted research on practical aspects of the control of animal diseases that will support managers to improve their decisions in the long term.