‘Black swans’ are a widely used metaphor for surprising, extreme events, generally with devastating consequences, that lie far outside the realm of anticipated possibility. Because they are inherently challenging to predict using traditional probability theory, black swans pose formidable challenges to risk analysis and risk management, regardless of whether the event is truly unknown to the scientific community (‘unknown unknowns’) or whether it is merely not known or adequately considered by the relevant parties.

Risk-based food safety systems are designed primarily to handle current, known food safety risks, even though they also possess some inherent capacity to address the inevitable emergence of new threats. Some emerging risks, though not known precisely beforehand, may be fairly well predictable, based on historic data and our current scientific knowledge – such as the emergence of novel strains of known pathogens with new virulence or antimicrobial-resistance genes. Others, however, are true ‘black swans’.

The goals of this study were to: 1) better understand the public health risks posed by the emergence of microbial risks, including black swans; 2) evaluate the ability of the current U.S. regulatory system to address such emerging risks, and 3) identify systemic factors that promote resilience and the ability to address unanticipated emerging threats. We analyzed microbial food safety hazards that have emerged over the past fifty years, and the regulatory and scientific responses to these emergence events. Common characteristics are identified and systemic factors that promote resilience and rapid response are highlighted. The potential utility and limitations of risk-based approaches for identifying and preparing for potential emerging threats, including black swans, are highlighted through selected scoping studies. Specific recommendations are made that help prioritize key research needs, improve emerging disease preparedness, and allow for the more rapid detection and control of emerging microbial risks.

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