International Journal of Food Microbiology 216 (2016) 79–90

Contents lists available at ScienceDirect

International Journal of Food Microbiology

journal homepage: www.elsevier.com/locate/ijfoodmicro

Quantitative assessment of human and pet exposure to *Salmonella* associated with dry pet foods

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ARTICLE INFO

Article history:
Received 23 March 2015
Received in revised form 17 July 2015
Accepted 5 September 2015
Available online 8 September 2015

Keywords:
Dry pet food
Low moisture
Zoonotic pathogens
Risk assessment
Household handling

ABSTRACT

Recent *Salmonella* outbreaks associated with dry pet foods and treats highlight the importance of these foods as previously overlooked exposure vehicles for both pets and humans. In the last decade efforts have been made to raise the safety of this class of products, for instance by upgrading production equipment, cleaning protocols, and finished product testing. However, no comprehensive or quantitative risk profile is available for pet foods, thus limiting the ability to establish safety standards and assess the effectiveness of current and proposed *Salmonella* control measures. This study sought to develop an ingredients-to-consumer quantitative microbial exposure assessment model to: 1) estimate pet and human exposure to *Salmonella* via dry pet food, and 2) assess the impact of industry and household-level mitigation strategies on exposure. Data on prevalence and concentration of *Salmonella* in pet food ingredients, production process parameters, bacterial ecology, and contact transfer in the household were obtained through literature review, industry data, and targeted research. A probabilistic Monte Carlo modeling framework was developed to simulate the production process and basic household exposure routes. Under the range of assumptions adopted in this model, human exposure due to handling pet food is null to minimal if contamination occurs exclusively before extrusion. Exposure increases considerably if recontamination occurs post-extrusion during coating with fat, although mean ingested doses remain modest even at high fat contamination levels, due to the low percent of fat in the finished product. Exposure is highly variable, with the distribution of doses ingested by adult pet owners spanning 3 Log CFU per exposure event. Child exposure due to ingestion of 1 g of pet food leads to significantly higher doses than adult doses associated with handling the food. Recontamination after extrusion and coating, e.g., via dust or equipment surfaces, may also lead to exposure due to the absence of pathogen reduction steps after extrusion or at consumer households. Exposure is potentially highest when *Salmonella* is transferred to human food that is left at growth-promoting conditions. This model can be applied to evaluate the impact of alternative *Salmonella* control measures during production, risk communication to consumers, and regulatory standards.

1. Introduction

Salmonella is recognized as a major zoonotic pathogen, and numerous outbreaks have been documented in association with eggs and poultry (WHO/FAO, 2002), meat (CDC, 2013; Gormley et al., 2011), produce (Hanning et al., 2009; Sivapalasingam et al., 2004), and food workers (CDC, 2005, 2009; Fang et al., 1991; Hoelzer et al., 2011; Younus et al., 2010). While historically foodborne *Salmonella* infections have been primarily linked to contact with high-moisture foods, such as raw meat, eggs, and some produce, several outbreaks have also been associated with low water activity foods, including chocolate, spices, nuts, and dry herbs (Beuchat et al., 2013; CDC, 2004; Jackson et al., 2013; Threlfall et al., 1998; Van Doren et al., 2013). Several recent outbreaks associated with dry dog foods and treats have highlighted the potential risks of human exposure to *Salmonella* due to contact with these classes of animal food (Behravesh et al., 2010; Buchanan et al., 2011; CDC, 2006, 2008a,b; FDA, 2013a; Finley et al., 2006; Health Canada, 2000). Outbreaks of salmonellosis due to contaminated dry food have also affected dogs (Schotte et al., 2007; Selmi et al., 2011). *Salmonella* and other zoonotic bacterial pathogens have been detected in processed pet food

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http://dx.doi.org/10.1016/j.ijfoodmicro.2015.09.005
0168-1605/

(Adley et al. 2011; Brazis et al. 2008; Fernandez Juri et al. 2009; Finley et al. 2008; Leung et al. 2006; Li et al. 2012; Martins et al. 2003; Nakajima et al. 1992). However, little information on prevalence and no information on concentration of salmonellae in dry pet food or its ingredients is currently available. A prevalence ranging from 6.1% (years 2007–2009, 153 samples) to 12.4% (years 2002–2006, 719 samples) was observed in the U.S. as part of large-scale surveillance programs by the U.S. FDA, Center for Veterinary Medicine (Li et al., 2012). Surveys conducted in Poland on a mix of locally produced and imported dry pet food batches reported prevalences between 0.15% and 1.7% in the years 2007–2010, for a total of 1.4% over 6243 samples (Kukier et al., 2012), and 1% over 2771 samples in earlier years (Wojdat et al., 2004).

Dry pet food, usually sold as kibble in sealed bags, is commonly produced industrially in large batches. The dry ingredients, a mixture of grains, soy, rendered protein meal (also called meat and bone meal), and minor ingredients such as vitamins and minerals, are first mixed together in a "mash" batch. *Salmonella* contamination has been observed in commodities of the same class as pet food ingredients (Lambertini et al., in press). The mash is then pre-conditioned, i.e., it is injected with steam in a large vat, further mixed, and brought to the moisture and temperature levels needed for subsequent extrusion. During extrusion, the pre-conditioned mash is further mixed with oil and steam, and extruded at high temperature and pressure. Besides shaping the product, extrusion is meant to substantially reduce any potential microbial contamination, and is commonly a Critical Control Point in the process' HACCP (Hazard Analysis and Critical Control Points) programs. After extrusion, the moist string of pet food is cut into kibble, dried in forced-air ovens, brought to room temperature, and temporarily stored. The finished product, made of one or more types of kibble, is then bagged in batches of 5 to 40 lb. (2.3–18.1 kg). Contamination during production may occur as a result of *Salmonella* presence in the initial ingredients, or as a result of cross-contamination of the intermediate product due to contaminated surfaces, equipment, air, or workers. Furthermore, while *Salmonella* populations have been observed to slowly decline on a variety of foods at room temperature (23–25 °C) and in low water activity conditions ($a_w < 0.85$) (Podolak et al., 2010), growth may occur during production if the product moisture is accidentally raised, e.g., due to water condensation, splashing, or dripping from surfaces. In the last decade the industry has substantially upgraded equipment, cleaning protocols, and product testing to meet higher safety standards (FEDIAF, 2010). However, a comprehensive and quantitative evaluation of the risk of accidental product contamination by *Salmonella* and the resulting consumer exposure is needed to establish processing and handling protocols aligned with food safety and public health objectives.

Consumers can become exposed to *Salmonella* through their hands by touching contaminated product (e.g., when removing pet food from its bag to feed the dog or cat, transferring the food from the retail bag to a different container, or handling the food bowl) and then touching their mouth. Children and infants can also be exposed via direct ingestion of pet food kibble. In addition, after touching pet food adults may prepare human food. If hands are not properly washed, *Salmonella* can be transferred to human food, possibly multiply if the food is kept at favorable temperature and moisture conditions, and then be ingested. Pets can also become exposed via ingestion. While *Salmonella* infections are often asymptomatic in dogs and cats, intestinal colonization or infection can result in fecal shedding at potentially high concentrations. Furthermore, as for infants and young children, salmonellosis can be a significant health risk in puppies and kittens. The risk of human and pet exposure to *Salmonella* associated with dry pet food is currently unknown. Interventions both during processing and at households could reduce the risk of exposure, but the relative impact of different exposure mitigation strategies has not been investigated systematically.

Until recently, U.S. food safety regulations have considered pet food similarly to other animal feeds, not as human food. In the European Community, pet food safety is regulated together with other animal feeds (EC, 2005). However, commercial pet food has been perceived to be as safe as human food by consumers, and handled accordingly. In the last decades regulations have moved in the direction of managing pet food safety at standards equivalent to human food. For instance, under the U.S. "Food, Drug, and Cosmetic Act" pet food should be "safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled" (U.S. Code, 2006), and pet food contaminated with *Salmonella* is considered adulterated (U.S. CFR, 2012). Facilities producing animal feed, including pet food, have to register as human food facilities (FDA, 2006). Most recently, the 2011 Food Safety Modernization Act mandates that the U.S. Food and Drug Administration (FDA) publish regulations to enhance the safety of pet food. As part of this effort, the FDA has recently issued a Compliance Policy Guide for *Salmonella* in Foods for Animals (FDA, 2013b), and is in the final stages of the Proposed Rule for Preventive Controls for Animal Food (FDA, 2014).

Increasingly, quantitative microbiological risk assessment models have been effective in providing a quantitative basis for new regulations and industry guidelines. However, no such evaluation has been developed for pet foods. Thus, the objective of this study was to develop an ingredients-to-consumer quantitative microbial risk assessment model to: 1) estimate pet and human exposure to *Salmonella* associated with dry pet food, and 2) assess the impact of industry and household-level mitigation strategies on such exposure.

2. Materials and methods

2.1. Risk assessment framework

Population levels of *Salmonella* during pet food production, from ingredients to finished product, were modeled within a probabilistic quantitative risk assessment framework. One metric ton (10^3 kg) of all ingredients mix was chosen as the reference batch size. *Salmonella* levels in the reference unit, starting from ingredients and along the production process until finished product in sealed bags, were estimated based on production processes and conditions. Main model outcomes were the concentration of *Salmonella* in a unit of finished product, as well as the dose (cell number, CFU) to which pets and their owners are potentially exposed (CFU ingested by the pet with a serving of food; CFU accidentally ingested by the adult owner by touching pet food and then touching their mouth; CFU ingested by a child eating 1 g of pet food). Variability in parameters affecting microbial growth, survival, and reduction were described using statistical distributions based on available data. To include this variability in the model outcomes, the simulation was set as a Monte Carlo framework of 10^5 iterations, as this number of iterations was sufficient for the main model outcomes' mean and 95% percentile to stabilize (fluctuations within $+/-3\%$, at a 95% confidence level). During each iteration, a Latin Hypercube sampling technique was used to select one value of each variable or parameter from its respective distribution. The seed was kept fixed at a value of 33. The model was coded and run in @Risk version 6.1.2 (Palisades Corporation, Ithaca, NY), an add-in to Microsoft Excel™. The variables and parameters used in the risk model are shown in Table 1.

2.2. Salmonella prevalence and concentration in ingredients

In all model scenarios except the uncertainty analysis on *Salmonella* prevalence, the central objective was to follow the fate of a production batch through the process when one of the ingredients is contaminated (i.e., contamination prevalence of 100%), and estimate the resulting exposure to pets and owners. To understand the effect of contamination prevalence in ingredients—for example representing the proportion of contaminated truckloads entering the plant in a year—on the distribution of exposure, an uncertainty analysis of the prevalence variable was conducted. Prevalence of *Salmonella* in two key ingredients (protein meal, and poultry fat) was profiled across a wide range reported