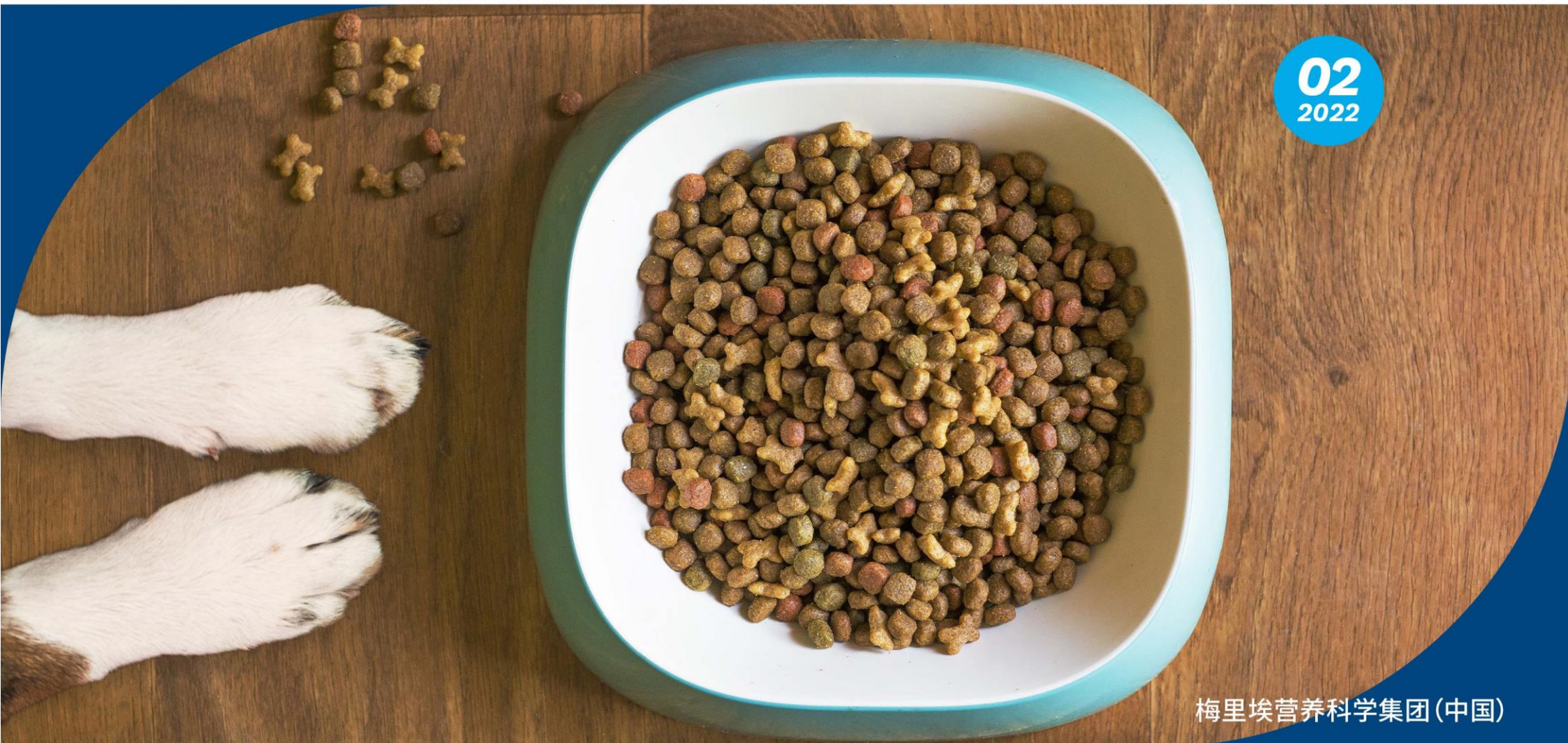


PETFOOD *February 2022* **NEWS**



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Better Food. Better Health. Better World.

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CVM Updates

FDA Approves First Generic Tilmicosin Phosphate Aqueous Concentrate for Swines

The U.S. Food and Drug Administration's Center for Veterinary Medicine has approved Tilmovet AC, the first generic tilmicosin phosphate aqueous concentrate for oral use in drinking water for swine. Tilmovet AC is approved for the control of: **(1) swine respiratory disease associated with Pasteurella multocida and Haemophilus parasuis in groups of swine in buildings where a respiratory disease outbreak is diagnosed and (2) swine respiratory disease associated with Mycoplasma hyopneumoniae in the presence of Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) in groups of swine in buildings where a respiratory disease outbreak is diagnosed.**

Tilmovet AC contains the same active ingredient (tilmicosin phosphate) in the same concentration and dosage form as the approved brand name drug product, Pulmotil AC, which was first approved on February 13, 2014. In addition, the FDA determined that Tilmovet AC contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient.

The data submitted in support of the Original Abbreviated New Animal Drug Application demonstrate that Tilmovet AC, when used according to its label,

is safe and effective.

As part of our efforts to ensure judicious use of antimicrobials and since tilmicosin phosphate is in a class of antimicrobials that are deemed medically important, Tilmovet AC is only available with a prescription from a licensed veterinarian. A veterinarian's expertise is required to diagnose swine respiratory disease and to determine whether Tilmovet AC is an appropriate treatment.

The tolerances for residues and withdrawal period established for the approved brand name drug product (Pulmotil AC) also apply to Tilmovet AC. Data demonstrate that residues in food products derived from swine treated with Tilmovet AC will not represent a public health concern when the product is used according to the label.

Tilmovet AC is supplied in 960 mL plastic bottles. It is administered in drinking water for five consecutive days.

Tilmovet AC carries a warning to people administering the product, which notes that exposure to tilmicosin in humans has been associated with chest pain, increased heart rate, dizziness, headache, and nausea. Death has also been reported following ingestion or injection of tilmicosin. People administering tilmicosin products should avoid ingestion and direct skin and eye contact as well as wear protective clothing when administering the product to animals. In case of human exposure, call 1-877-426-7765 and consult a physician immediately.

AVMA

“Doggie breath” could be a sign of serious disease

Does your sweet pet have sour breath? That odor coming from your pet’s mouth could be more than a nuisance: it could signify a serious health risk with the potential to damage not only your pet’s teeth and gums but their internal organs as well.

To address the importance of oral health care for pets, the American Veterinary Medical Association (AVMA) is sponsoring National Pet Dental Health Month in February. AVMA President Dr. Jose Arce says regular dental exams are an integral component of a pet’s overall health care, and can help prevent more serious health problems.

“Oral disease is one of the most frequently diagnosed health problem for our dogs and cats, and it can have serious consequences for our pets’ health,” said Dr. Arce. “This is not just a matter of bad breath or stained teeth. In addition to causing receding gums, tooth loss and often significant pain, bacteria in the mouth can enter the bloodstream, potentially affecting the heart, liver and kidneys, which can be life-threatening.”

According to the American Veterinary Dental College, most dogs and cats have some evidence of periodontal disease by the age of three, often indicated by bad breath, a change in eating or chewing habits, pawing at

the face and mouth, and depression.

Although daily toothbrushing is advised for dogs and cats, a study published in the Journal of Veterinary Dentistry showed that only two percent of dog owners follow through with this practice. In addition, a survey of pet owners showed that only 14 percent of dogs and 9 percent of cats receive dental care at the veterinarian's office. Pet owners should work with their veterinarians to begin a pet dental care routine at home, in addition to regular dental exams and professional dental cleanings.

Dr. Arce says a pet’s teeth should be checked twice a year by their veterinarian or a board-certified veterinary dentist for early signs of a problem and to keep their mouths healthy. However, pet owners should also have their pet’s teeth checked if they observe any of the following problems:

- Bad breath
- Broken or loose teeth
- Extra teeth or retained baby teeth
- Teeth that are discolored or covered in tartar
- Abnormal chewing, drooling, or dropping food from the mouth
- Reduced appetite or refusal to eat

- Pain in or around the mouth
- Bleeding from the mouth
- Swelling in the areas surrounding the mouth

What to expect

Pet dental visits begin with an oral exam of your pet's mouth by a veterinarian. Radiographs (x-rays) may be needed to evaluate the health of the jaw and the tooth roots below the gumline. Because most dental disease occurs below the gumline, where you can't see it, a thorough dental cleaning and evaluation are performed under anesthesia. Dental cleaning includes scaling (to remove dental plaque and tartar) and polishing, similar to the process used on your own teeth during your regular dental cleanings.

After the exam, your veterinarian will make recommendations based on your pet's overall health and the health of your pet's teeth, and provide you with options to consider. Talk with your veterinarian about any dental products, treats, or dental-specific diets you're considering for your pet, or ask your veterinarian for their recommendations.

Why does dentistry require anesthesia?

No matter how smart they are, your pet does not understand the benefit of dental procedures, and they react by moving, trying to escape or even

biting. Anesthesia makes it possible for veterinarians to perform dental procedures with less stress and pain for your pet and allows cleaning below the gumline where most dental disease occurs. If radiographs (x-rays) are needed, your pet needs to be very still to get good images, and this is unlikely without heavy sedation or anesthesia. Most pets can go home the same day of the procedure, although they might seem a little groggy for the rest of the day.

Industry News

China lifts ban on wet pet food imports of avian origin

Avian-related epidemics will not affect wet pet food exported into China if they are commercially sterilized.

On February 7, 2022, the General Administration of Customs, P.R. China, announced that exported canned pet compound food (wet food), exported pet snacks and other commercially sterilized canned pet food of avian origin will not be affected by avian-related epidemics and will be allowed to be exported to China. This change applies to such exported pet food products going forward.

So far, 19 countries have been approved to export finished pet food products or raw materials to China: Netherlands, France, Belgium, Germany, Denmark, the Czech Republic, Italy, U.S., Canada, Brazil,

Argentina, New Zealand, Australia, Austria, Spain, Thailand, Philippines, Uzbekistan and Kyrgyzstan

Change for pet snacks imported into China, too

In addition to the new policy for avian-origin wet pet food, exported pet snacks do not need to apply for the registered license issued by the Ministry of Agriculture and Rural Affairs.

The official statement from General Administration of Customs, P.R. China, on the new avian-origin policy reads:

Animal derived raw materials of specific products are subject to dynamic restrictions in the list of prohibited animals and their products sourcing from countries and regions where animal epidemics are prevalent (except for commercially sterilized canned pet food of avian origin).

Further, regarding commercial sterilization, the administration specified:

After moderate sterilization, canned food does not contain pathogenic microorganisms or non pathogenic microorganisms that can reproduce in it at normal temperature. Such condition is called commercial sterility.

Feed China Registered License Center offers free evaluation, by specific production processes and formula, of pet food products intended for export into China.

US pet food exports to China up after Phase One agreement

After signing of the U.S.-China Phase One Economic and Trade Agreement in January 2020, pet food exports from the U.S. to China increased 197% in 2020, then doubled over 2020 numbers through November 2021, according to U.S. Census Bureau data analyzed by Gina Tumbarello, American Feed Industry Association director of international policy and trade. Despite the increases, Chinese pet food imports have yet to reach the purchasing commitments set by the nations' diplomats. For example, U.S. pet food export growth to China from 2019 to 2020 was equivalent to .012% of what China committed to import.

Retest of soy, corn and peanut byproducts for pet food



Researchers tested soy flakes, peanut flour, soybean meal and corn gluten meal for the digestibility of the amino acids contained in the byproducts.

Competing pet food trends create a paradox for protein byproducts from oil seeds and cereal grains. Dog and cat owners want brands to reduce resource use and environmental impacts. Yet at the same time, pet owners want “human-grade” ingredients for their animals, which often entails rejecting all byproducts.

Byproducts from soy, corn and peanuts have traditionally been used in pet foods as sustainable, inexpensive and protein-rich ingredients, wrote a team of researchers in the journal *Translational Animal Science*. Scientists have documented the nutritional value of these plant-based byproducts in pet food formulations.

“However, the on-going demonization of soy- and corn-based ingredients continue to hinder their use in pet food and treat formulations,” the scientists wrote. “Ideally, the further demonstration of their protein quality and nutrient composition may encourage their favorable return as acceptable ingredients in pet foods and treats.

Building on an existing body of evidence, the researchers tested soy flakes, peanut flour, soybean meal and corn gluten meal for the digestibility of the amino acids contained in the byproducts. All of the pet food ingredients contained a profile of indispensable amino acids. The scientists used the precision-fed cecectomized rooster assay. This surgical procedure, similar to a human appendectomy, turns roosters into an effective, efficient model for dogs’ and cats’ digestive systems

Only peanut flour was low in lysine. Soybean meal and corn gluten meal had the highest amino acid digestibility. Compared to Association of American Feed Control Officials (AAFCO) recommended values for adult dogs, the first-limiting amino acid was lysine for peanut flour and corn gluten meal. For soy flakes and soybean meal, methionine was the

limiting amino acid. Considering AAFCO values for adult cats, the first-limiting amino acid was lysine for peanut flour and corn gluten meal, while threonine limited soy flakes. Soybean meal had no limiting amino acid for cats.

“The high-protein, high-fiber, and low-fat compositions of these ingredients make them easy to incorporate into pet food formulations,” wrote the scientists in their conclusions. “Their varied amino acid compositions provide an opportunity to combine them to create complementary proteins to meet the nutritional requirements of dogs and cats.”

However, pet food makers must account for differences in the processing of these plant-based byproducts that could influence protein quality, they wrote. For example, under-processing could lead to the formation of anti-nutritional factors. Likewise, overly high temperatures could reduce amino acid levels. Ultimately, scientists will need to conduct feeding trials in dogs and cats to determine how processing parameters influence amino acid digestibility in soy, corn and peanut byproducts.

Hazard analysis most common issue in pet food inspections

The number of pet food inspections has decreased significantly during

the pandemic, says FDA.

U.S. pet food inspections conducted for compliance with Food Safety Modernization Act (FSMA) regulations in the Food and Drug Administration’s (FDA) fiscal year (FY) 2021 yielded 89 citations for violations, and hazard analysis—failure to identify or implement this safety component—topped the list at 12 citations. Preventive controls (PC) violations came in second at eight, followed by lack of a food safety plan at five, then pest control and corrective action citations at four each.

The inspection data was provided via a video presentation by Dave Edwards, Ph.D., director of the division of animal feeds for FDA’s Center for Veterinary Medicine, during the American Feed Industry Association’s 2022 Pet Food Conference, held January 25 at the International Production and Processing Expo in Atlanta, Georgia, USA.

Inspections down during COVID, common violations

In contrast to the pet food numbers, animal feed inspections drew 135 total citations, also led by hazard analysis (17), PC (13) and lack of a food safety plan (eight), but plant maintenance (seven), corrective action and environmental monitoring (five each) also made that list.

Edwards did not share historical data of animal feed and pet food inspection citations for comparison, but his data did provide context for

the 2021 numbers, as the COVID-19 pandemic caused FDA to dramatically decrease its number of FSMA inspections during FY 2020 and 2021. From FY 2019 highs of about 950 animal feed and pet food inspections conducted for compliance to current good manufacturing practices (CGMP) regulations and nearly 250 for PC regulations, the number of inspections fell to about 750 CGMP and 150 PC inspections in FY 2020, then to about 300 CGMP and 140 PC in FY 2021.

Edwards added that in FY 2021, most animal feed and pet food inspections were conducted by state regulatory partners, rather than FDA inspectors.

FDA: Pet food recalls call for good lot code practices

While providing only a few specific data, Edwards said the top pet food recall causes over the past few years have been pathogens, aflatoxin (especially in 2020 and 2021) and vitamin D levels; he noted that the latter problem had led to six recalls in 2019 and four in 2021.

In relation to recalls, Edwards emphasized the importance of product lot codes. Though there are no regulatory requirements for them, he said, pet food manufacturers should follow good business practices. Lot codes can:

- Make it easier to track and report if a problem occurs, aiding both the manufacturer and FDA;

- Help limit the scope of a recall, due to faster and more efficient tracking;
- Conversely, if a lot code is not well applied—e.g., used for a long time for month after month—it can result in a larger recall.

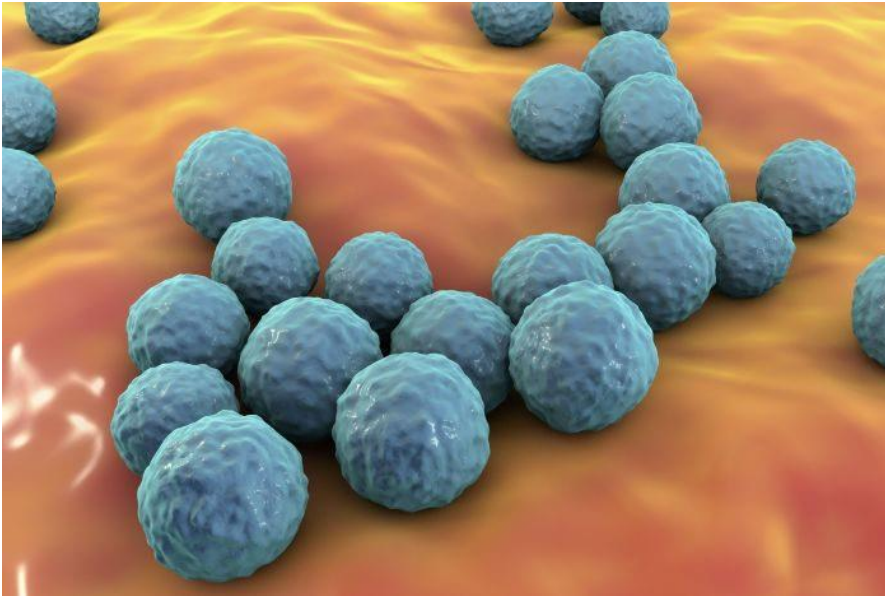
Antibiotic-resistant germs grown from pet food in Europe

Antibiotic-resistant Enterococcus bacteria, including vancomycin-resistant strains, most frequently infect hospital patients and people with immune system issues.

Microbiologists grew antibiotic-resistant Enterococcus bacteria found in samples of both dry and wet pet foods bought in Portugal. The microbes held genes granting resistance to clinically important drugs, such as linezolid and vancomycin. Although pet food hasn't been documented passing these germs to people, a reservoir of antibiotic resistance genes could be created in the gut of dogs, study co-author Ana Freitas, Ph.D., assistant professor at the University Institute of Health Sciences (Instituto Universitário de Ciências da Saúde) in Portugal, said. That store of genes in the environment could potentially reach humans. The International Journal of Food Microbiology published her teams' results.

The example of Salmonella, a true zoonotic bacteria, has already demonstrated this, she said.

“One problem is that the requirements of pet food do not include the screening of antibiotic-resistant bacteria such as Enterococci, just pathogenic bacteria like Salmonella or Campylobacter,” she said.



Antibiotic-resistant Enterococcus bacteria, including vancomycin-resistant strains, most frequently infect hospital patients and people with immune system issues. The bacteria cause thousands of deaths in the United States each year, according to the Centers for Disease Control and Prevention.

Study on antibiotic-resistant Enterococcus bacteria in pet food

Freitas’ study included 55 samples from 25 brands of which 21 were sold internationally. The products included 22 wet, 14 raw frozen, 8 dry, 7 treats and 4 semi-wet. The researchers bought the products from nine retail outlets in the Porto, Portugal region between September 2019 and January 2020.

The microbiologists tested the bacteria for resistance to 13 antibiotics. The scientists identified clinically-relevant species (*E. faecium* and *E. faecalis*), antibiotic resistance (*vanA*, *vanB*, *optrA*, *poxtA*) and virulence (e.g. *ptsD*, *esp*, *sgrA*) genes using polymerase chain reaction (PCR).

Seven species of *Enterococcus*, mostly *E. faecium* and *E. faecalis*, occurred in 30 samples, representing 54% of the total. The scientists found the bacteria in 14 raw, 16 heat-treated, seven dry, six wet and three treats. *E. faecium* occurred most frequently in dry pet foods, with *E. faecalis* predominating in wet samples.

More than 40% of the bacteria taken from the pet foods were resistant to erythromycin, tetracycline, quinupristin-dalfopristin, streptomycin, gentamicin, chloramphenicol, ampicillin or ciprofloxacin. Lower rates of samples showed resistance to linezolid (23%; *optrA*, *poxtA*), or vancomycin and teicoplanin (2% each; *vanA*).

Multidrug-resistant samples (31%) mostly came from raw foods, although they were also taken from wet foods and treats.

“[In thermal processing,] Enterococcus are particularly resistant to temperature and dry conditions and not all bacteria will die, some will just stop their growth but can ‘resuscitate’ let's say when we give them proper conditions in the lab again,” she said. “That's why the more problematic bacteria were found in the raw dog food and less in the processed one.”

Normandise Pet Food expands, eyes Asian markets

The French pet food company is investing in new packaging lines and exporting to China.



French pet food producer Normandise Pet Food is investing to develop

its capacity and business, with plans to launch four new packaging lines this year and boost export sales to new foreign markets.

The company operates a factory in Vire Normandie, in the northwestern part of France, and makes a wide range of pet food products for cats and dogs. These include “tailor-made products based on animal and vegetable ingredients, in the form of pate, mousses, fillets packed in trays; and also chunks, fillets in sauce or in jelly, packed in pouches (freshness bags),” according to the manufacturer.

Julien Moureaux, head of communications at Normandise Pet Food, said the company sells its output under its own brands, but also supplies pet food to retailers under private label deals, as well as produces for domestic and foreign pet food brands.

Focus on premium pet food brands

The business sells its output under a number of brands, including Equilibre & Instinct, Les Repas Plaisir, Eco Diana and Eco Oscar, among others, according to information from Normandise Pet Food.

“This year, we are placing focus on our Equilibre & Instinct and Les Repas Plaisir premium dog and cat food brands,” Moureaux said, adding that the company is promoting the brands as “daily quality accessible to all” consumers.

In addition to investments in new packaging lines, the pet food business

is also carrying out a project to expand its headquarters and increase its logistics capacities, he said. “Investments must be continuous at a company that is successful and wishes to remain so,” he added.

Pet food exports drive increased sales

In 2022, Normandise Pet Food is aiming to continue its efforts to expand the producer's foothold in a range of foreign markets, according to Moureaux. The company's current focus is on the Chinese market.

“After last year, we received an approval to expand to China. Our team is working on registering our receipts, and the first products should be delivered [to the Chinese market] this year,” Moreaux said. “Our sales team is always searching for new markets, and they continue to develop our possibilities and contacts to allow us to be present everywhere” across the world.

should contact their healthcare providers.

Pets with Salmonella infections may be lethargic and have diarrhea or bloody diarrhea, fever, and vomiting. Some pets will have only decreased appetite, fever and abdominal pain. Infected but otherwise healthy pets can be carriers and infect other animals or humans. If your pet has consumed the recalled product and has these symptoms, please contact your veterinarian.