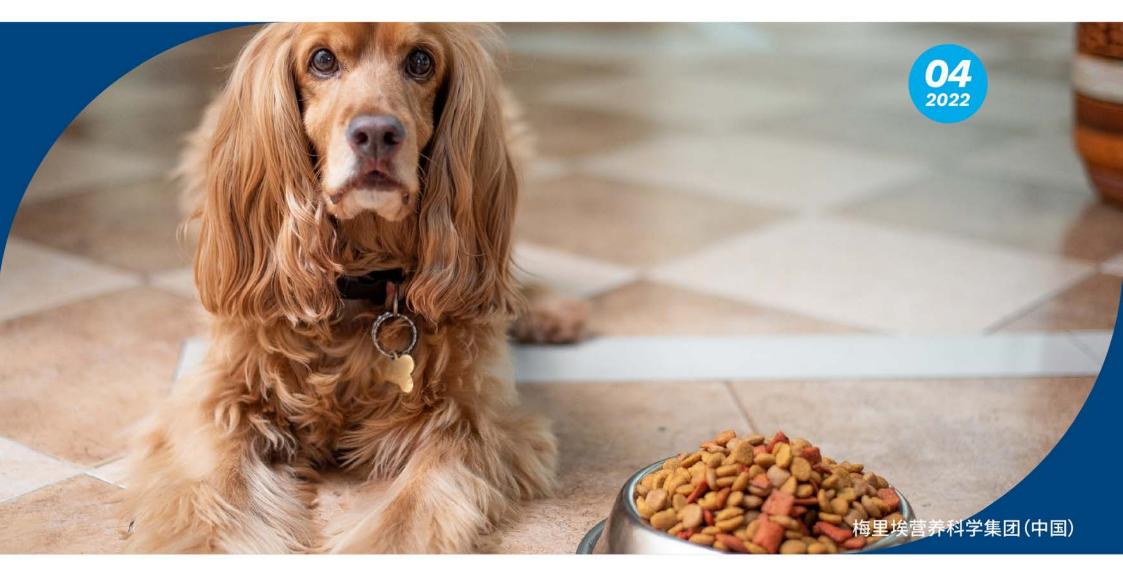
PETFOOD NEWS





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CVM Updates

FDA Issues Final Guidance on Animal Drug Compounding from Bulk Drug Substances

Today, the U.S. Food and Drug Administration issued a final guidance, entitled "Compounding Animal Drugs from Bulk Drug Substances," that will help protect animal health by recognizing the need for access to certain compounded animal drugs. The guidance describes the agency's approach to situations where veterinarians use unapproved compounded drugs to provide appropriate care for the medical needs of the diverse species they treat. The FDA recognizes that this final guidance covers a wide range of stakeholders and plans to focus on education and stakeholder engagement before shifting resources toward inspectional activities in Fiscal Year 2023. We will take appropriate actions, as we currently do, when compounding practices threaten human or animal health.

Animal drug compounding is the process of combining, mixing or altering ingredients to create a medication tailored to the needs of an individual animal or a small group of animals. Animal drug compounding using an FDA-approved drug as the starting point is already allowed under existing law and regulations. Animal drugs compounded from bulk drug substances are not FDA-approved and the agency has not evaluated

them to ensure that they are safe, effective, properly manufactured to ensure consistent quality, and the labeling is complete and accurate.

"We are taking this step because we recognize the need for veterinarians to have access to compounded animal drugs that aren't available as approved products and that would make a clinical difference in patient care," said Steven M. Solomon, D.V.M., M.P.H., director of the FDA's Center for Veterinary Medicine. "We believe this policy strikes the right balance between maintaining access to drugs veterinarians need to treat diverse animal populations, while ensuring human and animal health is protected from poorly-compounded products, or ones that attempt to copy existing FDA-approved drugs."

There are more than 1,600 drugs that are FDA-approved, conditionally approved or indexed for use in animals, as well as approximately another 20,000 FDA-approved human drugs that could be prescribed for animal use. At the same time, there are many different species of animals, each with various diseases and conditions for which no suitable FDA-approved or indexed drugs are available for which access to compounded animal drugs may be necessary.

The FDA released this guidance in 2019 and received comments from veterinarians, pharmacy compounders and other stakeholders. In response, the agency has made significant changes to the final guidance to recognize flexibilities for veterinarians to access animal drugs



compounded from bulk drug substances for those animals that need them.

The final guidance:

- Addresses compounding of unapproved animal drugs from bulk drug substances, which is the practice of preparing a medication without using an FDA-approved or indexed drug as the starting point.
- Outlines flexibilities for pharmacists and veterinarians who compound animal drugs from bulk drug substances for individual patients, as well as for those essential drugs needed for immediate or emergency use that they need to keep in their inventory (also known as "office stock").
- Balances the need for accessing animal drugs compounded from bulk drug substances for the patients that need them, while also providing ways to better identify safety issues associated with compounded products.
- Describes the types of animal drugs compounded from bulk drug substances that the FDA believes pose the greatest risk to human and animal health. The agency will prioritize these products for enforcement action, as well as those made under poor compounding practices.

• Explains FDA's policy on animal drugs compounded from bulk drug substances that are copies (same active ingredient and route of administration) of marketed FDA-approved or indexed drugs. The agency generally intends to prioritize these products for enforcement action when the compounding pharmacy has not recorded a medical rationale for prescribing a copy instead of an FDA-approved or indexed drug.

Industry News

Pet food inflation update: Still rising, relief in sight?

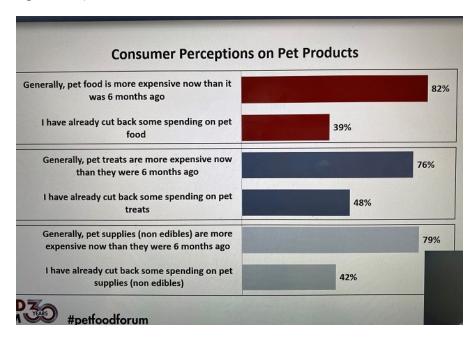
Recently the U.S. Bureau of Labor Statistics (BLS) released U.S. inflation data for March 2022, and the news (not good) spread fast and wide: The Consumer Price Index (CPI) rose 8.5% compared to 2021 levels, the largest increase since 1981. How did pet food fare?

Also not good. Pet food inflation increased 5.9% vs. March 2021 and 2.3% over February 2022, according to BLS data shared and analyzed by John Gibbons, aka the Pet Business Professor. "They are being measured against a deflationary year, but that increase is almost triple the pre-pandemic 2.1% increase from 2018 to 2019," he wrote.

For the overall pet care category, inflation surged 7.5% compared to 2021,



not far below the overall 8.5% CPI increase. In December 2021, Gibbons noted, the "petflation" index was up 4.1% year-over-year (YOY), lower than the 7% CPI at the time; so since then, the gap has narrowed significantly.



Pet owners, and pet food producers, feeling rising prices

While pet care and pet food inflation still lag behind that for other staple categories such as food at home (10%) and its subcategories like meat, poultry, fish and eggs (13.7%), and fruits and vegetables (8.5%), the ongoing rise in pet food and pet product prices is a concern. And it's

affecting pet owners and consumers overall.

Michael Johnson, CEO of Finn Cady and a pet market expert, cited recent survey data showing 48% of U.S. consumers believed the economy was good for them just six months ago (fall 2021), but now just 27% do. Specific to pet owners, 82% of respondents in the same survey (Johnson didn't cite the actual source) believe pet food is more expensive than it was six months ago, and 39% are already cutting back their spending on it. Similarly, 76% think pet treats are more expensive than six months ago, with 48% having cut back their spending on treats.

(Note: Johnson will be speaking on consumer marketing of pet food at Petfood Forum 2022 on May 3 in Kansas City.)

As you are probably acutely aware, pet food manufacturers are suffering from inflation, too. According to Producer Price Index data shared by Gibbons, prices for dog and cat food manufacturing soared 8.9% in March 2022, the largest YOY monthly increase since 2009. Breaking that down, dog food manufacturing was at that same level (8.9%), cat food rose 10.5% and for other pet species, the increase was 12.5%.

Ongoing storms, with some good news sprinkled in

Unfortunately, pet owners and consumers in general, along with the pet food industry, will likely keep feeling the pain of rising prices for the near future. Some economic experts believe relief, but not the immediate end,



may be in sight.

Paul Krugman, a professor of economics and longtime columnist for the New York Times, said recently that the March 2022 inflation report may have presented a somewhat misleading picture, because "living on COVID time," things are still changing very quickly. The CPI this time, he wrote, "probably missed a downward turn that began in late March and is accelerating as you read this. Inflation will probably fall significantly over the next few months."

Yet Krugman also cautioned that we shouldn't get too excited by this, because the improved numbers don't completely mitigate the fact that the U.S. economy (including wages) is still "overheated," and some good news may be offset by a return of negative factors.

For example, he linked to an article by Greg Miller on American Shipper/FreightWaves.com explaining that, though the bottleneck at U.S. West Coast ports has started to ease—the "queue of ships waiting for Southern California berths fell. Velocity of cargo moving through terminals increased. And more boxes were unloaded at Southern California docks."—this could be the calm before another storm, as a new COVID-driven shutdown of a major port area in China, Shenzhen, could dramatically slow global shipping again.

The bottom line, according to Krugman, is that we will still be dealing with inflation for some time, but he doesn't believe it will become

entrenched as it was in the 1980s, which was partially spurred by consumer expectations. "Consumers expect high inflation in the near future, but medium-term expectations haven't moved much, suggesting that people expect inflation to come down a lot," he wrote. "If you think today's report showed inflation spiraling out of control, you're wrong. In fact, we're probably about to get some misleadingly good news on that front."

In other words, pet food consumers, manufacturers and suppliers need to strap in for an ongoing rocky ride, but it may start to smooth out later this year.

Avocado toxic to dogs? Science explores pet food potential

Avocados trees are a common feature in backyards throughout Latin America. Many pet dogs don't hesitate to eat a dropped fruit, but the dogs don't drop dead.

Researchers added to the evidence that avocado has potential as a novel dog food ingredient, contrary to veterinary and popular recommendations against the fruit. Avocados contain a chemical called persin, a natural fungicide, which could be toxic to dogs that eat the fruit. However, in an experiment, persin seemed to be destroyed and inactivated during kibble production, leaving the resulting product safe



for dogs. The Journal of Animal Science published the results.



Maria Cattai de Godoy, associate professor at the University of Illinois Urbana-Champaign, led a team of scientists that conducted an experiment to test if avocado-based ingredients truly were dangerous to dogs. Dogs snatching fallen avocados from beneath trees in her Brazilian homeland inspired Cattai de Godoy's research, she said in a press release.

Avocados originated in what is now Latin America. For millennia, people from Mexico to Peru have grown avocados and incorporated the fruit into their culture and mythology. Along with commercial avocado

orchards, the trees remain a common feature in backyards throughout the region. Pet dogs don't hesitate to eat a dropped fruit, but the dogs don't drop dead.

The Illinois research team first analyzed the avocado and products produced from it. They looked for concentrations of persin in various parts of the fruit.

"Persin is structurally similar to a polyunsaturated fatty acid, meaning there are a lot of double bonds," Cattai de Godoy said in the press release. "They're not very stable; heat and light can make them break down. Processing is very likely breaking down persin, which is probably why we cannot see it in the meal.

"In fact, the concentration was so small in the avocado meal that it was out of our standard curve linear range, meaning it was below detection level. We observed, however, detectable amounts of persin in the raw fruit, including the peel, pulp, and pit."

Afterwards, once the ingredient had tested toxin-free, the scientists used the avocado meal in a dog food formulation and fed it to Beagles. Nine dogs participated in all, divided into three groups. Groups ate a kibble made with one of three fiber sources: avocado meal, beet pulp or cellulose. During the two-week feeding trials, none of the dogs showed signs of toxicity from the avocados.



"From what we can tell, it seems to be a safe ingredient. We don't see a signal for persin in avocado meal, and there is not really a robust literature pointing to persin as a true toxin for dogs or cats" she said. "I certainly think there's still work to be done in order to say there are no concerns, especially if we were giving the fresh fruit. But according to our study, I think avocado meal is a safe bet and can be used effectively as a sole source of dietary fiber or in fiber blends."

Earlier research on avocado in dog and cat foods

Earlier research also published in the Journal of Animal Science, found that avocado meal could be a safe novel dietary fiber source for cats.

"There are three potential avocado ingredients that could be used in pet food: the avocado pulp/puree, avocado oil and avocado meal. Each has unique properties and potential market positioning that must be weighed against the customer value proposition. There is positive name recognition for marketing purposes and potential benefits to dog and cat diets. The only hurdle is whether there are limits to inclusion and/or long-term consumption by our pets — this has yet to be confirmed," Greg Aldrich, pet food program coordinator at Kansas State University, wrote in his Petfood Industry column.

Avocado appeared in more dog and cat foods' ingredient lists, according to data from more than 7,000 pet food ingredient panels compiled in 2017, the last date for which data is available. Some form of avocado,

such as oil powder or dried, made-up part of the recipes of 42 dry dog foods, or approximately two percent of the total. Twenty-three canned dog foods used some form of avocado. For canned cat foods, 18 products used avocado.

Mexican pet food companies investing heavily in new plants

Pet food producers Flagasa and Grupo Sesajal have invested to expand their facilities in the past six months.

Between 2021 and 2022, at least four pet food companies operating in Mexico have invested 3,120 million pesos (around US\$156 million) in the expansion or construction of new manufacturing facilities. Two multinational companies, Mars and ADM, and two Mexican-owned companies, Flagasa and Grupo Sesajal, have led the investment activity in the market.

This article focuses on the expansion of the Mexican-owned manufacturers.

New pet food facility for Flagasa

According to several press sources, Flagasa, an animal feed producer that entered the pet food market in the past few years, invested 220



million pesos (US\$11 million) in a new pet food plant inaugurated in late 2021. Other sources state the company will operate at a capacity of 8,000 metric tons per month of dry dog food.

The new manufacturing facility is in the Platah Industrial Park, in the state of Hidalgo in central Mexico. Flagasa produces and distributes dry dog and cat food regionally with the brands Bark, Flagacan, Pet Can, Centinela and Katyto.



Grupo Sesajal, the first Mexican oils company in pet food

Sesajal is a 30-year-old Mexican-owned oils company located in the western state of Jalisco. In recent years, the company entered the pet food market with brands such as Grateful, Shaggy and Felicats. According to press sources, in March 2022, the company inaugurated a new production line that will increase its production capacity 3.4 times, up to 9,000 metric tons per month.

This is the first oils company in Mexico to enter the pet food industry. Moreover, oil was one of the raw inputs that saw price increases and scarcity due to the pandemic inflationary crises.

Pronúa aims to become a pet food market leader

Although it occurred nearly three years ago, it is worth mentioning the investment of Pronúa (Los Belenes). The company inaugurated its new pet food production plant in 2019 with a capacity of 100,000 metric tons per year. The facility is located in Acatlán, Jalisco.

Los Belenes is a Mexican-owned pet food manufacturer that participates in the market with several owned brands, a few exclusive brands they produce for retail chains and some contract manufacturing for third parties.



Purina unveils Australian cat food factory expansion

The new facilities will use local ingredients to produce cat food. More than 85% of raw materials used at the Nestlé Blayney factory will be sourced locally, including meats and grains.



Adapted from a press release:

Nestlé Purina PetCare unveiled a US\$90 million upgrade to its Blayney, Australia facility, which will increase pet food production capacity. As well, the Purina team has expanded to meet increased pet food demand, with 20 new jobs now created on site. The facility creates cat foods such as Felix, Fancy Feast, Pro Plan and Purina One.

The expansion may position Nestlé Purina as a key regional supplier, with both wet and dry pet food exported from Blayney to New Zealand, Thailand and Japan.

The new facilities will also see a significant quantity of local ingredients used in production. More than 85% of raw materials used at the Nestlé Blayney factory will be sourced locally, including meats and grains.

The Nestlé factory in Blayney began operations in 1989 and manufactures brands such as Felix, Fancy Feast, Pro Plan, Supercoat and Purina One. Nestlé Blayney employs more than 300 people and supports more than 60 local businesses and contractors in western New South Wales.

Nestlé Blayney Factory Manager Charlene De Wit said the new facility is a testament to Nestlé's commitment to local manufacturing and support for the central west Australian community.

"We are proud to produce quality Purina pet food for our much-loved furry friends across Australia and around the region, right here in Blayney," De Wit said. "Our expanded facilities will allow us to scale up production of single-serve wet cat food by over 120% – as well as the dry cat and dog food we already produce."

The opening brings Nestlé's total investment in the factory to more than US\$200 million over the past 10 years, as the business has increased



production and developed new capabilities. The wet cat food facility, which opened in late 2014, was developed to create premium products.

"We have an incredibly dedicated and highly skilled team here at Blayney," DeWit said. "By bringing leading technology to our factory and continuing to use high-quality ingredients in our product, we are even more confident that we will continue to enrich the lives of pets and the people who love them for years to come."

More about Nestle Purina PetCare

According to Petfood Industry's Top Pet Food Companies Current Data, Nestlé Purina reported strong organic growth in its pet care products in 2020, led by its premium brands Purina Pro Plan, Purina ONE and Felix. Long a leader in the U.S. market, Nestlé Purina also operates pet food factories in 19 countries. Nestlé Purina claims three headquarters globally: St. Louis, Missouri, USA, for its North American and Latin American operations; Lausanne, Switzerland, in Europe; and Sydney, Australia, covering Asia, Oceania and Africa. Its parent company, Nestlé's world headquarters, is in Vevey, Switzerland.

European pet food industry responds to Russia-Ukraine War

"Pet food companies will be actively looking for alternative suppliers of raw materials that are no longer available such as sunflower seeds," a European Pet Food Federation representative said. "They may also be looking to substitute these with alternative ingredients."

Repercussions for the global pet food industry may grow as the Russia-Ukraine War throws the continent into chaos. While relatively insignificant compared to the loss of life and livelihood in Ukraine, pet food makers around the world may face increasing disruptions to already snarled supply chains.

"The pet food industry has been affected by global events in the past," a representative of the European Pet Food Federation (FEDIAF) told Petfood Industry in an email. "While with the help of governments, authorities and other stakeholders our industry has managed to continue supplying pets around the world, this war has the potential of creating a major disturbance in international logistics.

"As a result of the war in Ukraine, ships cannot leave Black Sea ports and therefore all exports and trade have stopped. In addition, the international sanctions on many Russian companies will have an impact. In the midst of the developments, many pet food manufacturers have suspended trade with Russia while some have chosen to continue supplying – as they have employees to consider and pets to feed in the local population.

"The Pet Food Industry is resilient. The pet food industry will be working hard behind the scenes to ensure that the supply of pet food



meets the demand," the representative said and answered more questions about how the Russia-Ukraine War might affect cat, dog and other pet food industries in Europe.



1. How might pet food ingredient shortages or supply disruptions result from the war?

Although pet food manufacturers use different raw materials and supply chains, there will be huge repercussions for the food industry. We will be affected by the limited availability of some key raw materials such as sunflower oil and derived ingredients. There are also concerns relating to

white fish, packaging raw materials and wider impacts on global cereals markets. Plus, disruption to logistics and the availability of Russian fertilizer and fuel will be a shock to the market.

Ukraine and Russia are both large food producers. Ukraine is the EU's fourth-biggest external provider of food. The EU has traditionally received over half its corn imports, around a fifth of soft wheat imports and a quarter of its vegetable oil from Ukraine.

Russia is the world's top exporter of nitrogen fertilizers and the second leading supplier of both potassic and phosphorous fertilizers.

Russia is also the EU's top gas supplier; we rely on Russia for 40% of our gas. Although supplies have remained reliable since the invasion, prices have soared.

2. What can pet food companies do to adapt?

The pet food industry successfully navigated the challenges of the pandemic by adapting supply chains and sourcing alternative raw materials.

However, pet food companies will all be looking to the future. Pet food companies will be actively looking for alternative suppliers of raw materials that are no longer available such as sunflower seeds. They may also be looking to substitute these with alternative ingredients.



Any change in raw materials can impact supply chains and availability. It also has an impact on product labels. As members of FoodDrinkEurope, we are working to ensure flexibility around product labeling to minimize potential disruption to supplies, whilst maintaining food quality and safety.

3. How are pet food companies working to help Ukrainians and their pets?

FEDIAF members have been responding in numerous ways to support the Ukrainian people and their pets. Members have donated financial aid in addition to pet food.

Many companies are continuing to look for ways of helping those in Ukraine plus the refugees in neighboring countries. FEDIAF is coordinating with companies to identify the best channels for this aid.

FEDIAF is also pleased that the Commission quickly eased the regulation concerning the entry into the EU of pets so that member states are allowed to develop permit arrangements applying to Ukrainian refugees traveling with pets.

Fresh pet sales trends rising; Grain-free searches down

Along with the types of pet foods people buy, the places they buy the products have been changing too.

With so many new pet owners joining the market and driving sales of pet food and pet supplies forward, there seems to be opportunity everywhere, Raha Alavi, senior vice president of retail client services for NielsenIQ, told Petfood Industry in an email.



"However, we have noticed some potential downward trends in some types of products," she said. "For one, there's been a stark drop in searches for the term 'grain-free' in dog food, whereas search for refrigerated and frozen wet dog and cat food have gone up significantly."



Across all pet foods, specialized diets and ingredients are experiencing strong growth, she said, quoting Nielsen's statistics for the overall pet retail market.

- Sales of dehydrated pet food were up 25.9% in 2021 vs. 2020
- Sales of freeze-dried pet food were up 31% in 2021 vs. 2020
- Sales of frozen pet food were up 19.6% in 2021 vs. 2020
- Sales of natural pet food were up 10.4 % in 2021 vs. 2020
- Sales of grain-free pet food were up 4.3% in 2021 vs. 2020

Changing pet food retail landscape

Along with the pet food types that people buy, the places where they buy the products have been changing too.

"The impact of online shopping on sales of pet food pre-COVID into early 2022 is substantial," she said. "Looking at the entire pet food category, sales from online-only buyers and omnichannel shoppers (buying from both online and in-store) have steadily increased over the last three periods compared to shoppers who only buy in-store."

• From Oct. 13, 2019 - Feb. 29, 2020, pet food brick-and-mortar-only sales were up 58.6%. That dipped to 51.7% for Oct. 11, 2020 - Feb. 27, 2021, and then dipped again to 46.5% for Sept. 12, 2021 - Jan. 29, 2022.

- From Oct. 13, 2019 Feb. 29, 2020, Omnichannel pet food sales were up 37.5%, and then up 43.2% for the following period and up 47.3% through the most recent period.
- Online-only sales of pet food, while smaller in share overall, are increasing year over year, up 3.9%, up 5.1% and up 6.3% through the same three periods.

"Given the rapid expansion across the category and how shoppers want to access products, one of the most important factors moving forward is going to be a more accurate and holistic view of how pet food shoppers are both searching for and buying these various product subsets, not just from your brand, but your competitors' as well," she said. With this data, brands can understand who is buying what products where, and they can create the most optimized and effective messaging to meet shoppers where they're buying.

MARKET NEWS - REPLY

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