

Despite their innocuous-sounding name, a good thing to remember about food-grade lubricants is "they're not meant to be 'eatable,'" says Scott Harold of Ciba Specialty Chemicals, in Tarrytown, N.Y. No one should snack on food-grade lubricating grease, or down a slug of food-grade hydraulic oils.

Rather, food-grade lubes are intended for use in food and beverage processing and packaging equipment where there is risk that lubricants and additives may leave

worldwide. Nevertheless, Harold believes only about 20 percent of food processors actually use food-grade lubricants. "So there's great potential for growth — and also great risk of liability for not using them," he cautioned.

CONTAMINATION COSTS

A closer look at these risks came from Sarah Krol, business unit manager for the non-food compounds registration program of NSF International in Ann Arbor, Mich. She pointed out that safety issues are having an

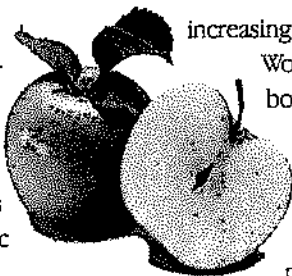
RUMBLES IN FOOD-GRADE LUBES

some residue in food or on food-contact surfaces. The U.S. government has strict rules about what ingredients may be used to make food-grade lubricants, and a new ISO standard, ISO 21469, is now in place to cover the hygienic manufacture of food-grade lubes.

For lubricants used where incidental contact may occur, the permitted ingredients are listed in the U. S. Code of Federal Regulations at 21 CFR Section 178.3570; this also sets the maximum treat rate that may be used for each component. Also allowed are ingredients that are generally regarded as safe (GRAS), found in parts 182 and 184. Products that satisfy these requirements can be registered as "H1" lubricants by the not-for-profit NSF International.

Given their limited slate of ingredients, formulators need great ingenuity to create effective food-grade lubricants, especially when it comes to additives, Harold pointed out in May to the annual meeting of the Society of Tribologists and Lubrication Engineers, in Philadelphia. For example, small amounts of various antioxidants, both aminic and phenolic, might be combined to build up the lubricant's antioxidancy while staying below the threshold limit for each ingredient. "So 0.5 percent of one and 0.71 percent of another gets used," he explained.

The U.S. regulations for food-grade lubricants are known and referenced



increasing impact on the food industry. Worries of contamination, food-borne illnesses, security and even bioterrorism are among the risks that must be weighed by food and beverage processors. Still fresh in consumers' minds is February's massive 39-state recall of contaminated peanut butter; that cost \$60 million in recall efforts alone, not including the cost to clean up the source of the trouble, a salmonella-tainted ConAgra food plant in Georgia.

"A primary concern for food processors is contamination by chemical hazards and biological hazards, and the Centers for Disease Control say the risk is rising," Krol told a special STLE session on food-grade lubricants, sponsored by Afton Chemical Co.

Food processors also must comply with the 2002 U.S. Bioterrorism Preparedness and Response Act, which requires strict recordkeeping and identification of both the immediate source and the downstream recipient of food products in the supply chain — the "one up/one down" rule. This creates food traceability and speeds recalls, in case of problems.

Despite such measures, the CDC estimates that there are some 76 million cases of illness in the United States each year, 325,000 hospitalizations and 5,000 deaths due to food-borne pathogens.

"Even one instance of a food-borne illness outbreak can devastate an industry," Krol observed. Last summer's nationwide e. coli outbreak traced to bagged spinach and salads is estimated to have cost the food industry about \$100 million in business, for example.

NO RISKS, PLEASE

Lubricants don't cause bacterial outbreaks, of course, but they are subject to

the same recall rules if contamination occurs. These rules today share one unifying philosophy, Krol said. "Our approach in the United States is risk based. Historically the regulations were focused on additives, drugs and pesticides, but now farm-to-fork safety is the goal, and Hazard Analysis and Critical Control Points — HACCP — is used to identify and mitigate risk. This includes the use of nonfood compounds such as

food-grade lubricants for use where incidental contact might occur."

Kenji Yano of Ann Arbor-based Yano Consulting also spoke at the Afton-sponsored STLE session. Yano originated and managed the nonfood compounds program at NSF, then went on to launch his own firm to help specialty chemical companies gain product acceptance and navigate the thicket of food and environmental safety requirements.

The U.S. has plenty of regulations covering food-grade lubricants and other nonfood compounds, he pointed out. There's the Agriculture Department's Food Safety & Inspection Service (FSIS) to inspect meat and poultry plants. The Food and Drug Administration handles all other food plants. And the Environmental Protection Agency keeps an eye on pesticides used on food crops and animals.

When food does turn out to be contaminated, a recall can be needed. "When it comes to enforcement, the FSIS and FDA food recalls are voluntary, and the two agencies oversee and monitor the recalls," Yano explained. "The threat of regulatory action and legal liability, however, forces participation of the food processor."

There also are GMP regulations ("good manufacturing practices") under the FDA, which cover drugs, medical devices, and some food and blood products. "These require a quality approach to manufacturing, and are what led to HACCP, which the FDA established for the canned food, seafood and juice industries. HACCP shifted responsibility to food manufacturers," stressed Yano. Using HACCP principles, food manufacturer must identify the biological, chemical and physical hazards that are likely to occur, and take steps to control those risks.

"Food-grade lubricants provide the food manufacturer with a tool to control the risk in this area," Yano said. He pointed to the FSIS rule which says that food-grade lubes not only must comply with 21 CFR 178.3570, but also says their use "should be limited to the amount needed for the technical purpose," not over-applied or used in a haphazard manner that may lead to contamination.

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Nevertheless, within the United States some 60 percent of food and beverage manufacturers do not use food-grade lubricants, Yano estimated. Why? First, much of the food industry falls outside the jurisdiction of the FSIS, which only inspects meat and poultry plants. All others are supposed to be under the FDA's watch, but its enforcement of the requirements to use food-grade lubricants is weak.

A HIGHER STANDARD?

Broader adoption of food-grade lubes was one goal of a new ISO standard to promote hygienic manufacturing of incidental-contact lubricants. ISO 21469, "Safety of Machinery Lubricants with Incidental Product Contact, Hygiene Requirements," issued last year, aims to cover the life span of the food-grade lubricant, from manufacture to use and application, NFS's Krol explained. It also reaches beyond food processing to include the cosmetics, pharmaceutical and animal feed industries.

"ISO 21469 says that the lube manufacturer must have a strategy for selecting hygiene measures over the lubricant product's life span," said Krol. It requires lubricant manufacturers to have a plan in place for manufacturing, handling and transporting the products, and to consider the potential hazards associated with the product and to communicate these risks to the end user. It also provides for third-party certification that the standard is met, including site inspection and formula review.

For a fee, NSF says it will offer certification to the new ISO 21469 standard for lubricant manufacturers who want it, but the voluntary standard so far is not seeing much industry support. One long-standing concern is that it's redundant and costly; hygienic manufacture of food-grade lubricants can easily be incorporated into a manufacturer's ISO 9001 quality certification, argue its opponents.

ISO 21469 also fails to support HACCP programs at the food plant, critics point out. What happens in the lubricant man-

ufacturing process won't make any difference if the end-user misapplies or fails to use the food-grade lube where it's needed, or neglects to take steps to avoid contaminating foodstuffs with it.

That is a flaw, Yano agreed. "Under HACCP, responsibility for the lubricant's use and handling still will be with the user," he pointed out, and so it's not something the lubricant manufacturer can control.

The new standard also faces indifference from the food industry. When he surveyed end users and government agencies about ISO 21469, Yano got mostly shrugs. One food processor responded, "Based on industry history, 'it's not reasonably likely to assume' [a key HACCP phrase] that contaminations would result from the original manufacture of lubricants. It is more likely that lubricants could become contaminated while in use, at food processing facilities."

Another food-industry respondent told Yano, "I am uncertain as to how the [lube] manufacturer could control risks

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once the product leaves their control. They can control risks associated with the introduction of an agent into the lubricant during manufacturing. However, this seems like a very low risk — and it would be a shame if manufacturers had to spend much money to somehow bolster their food defense programs.”

The FSIS told Yano it is not affected by ISO 21469, and will only go by its own compliance guidelines, while the FDA pointed to its GMP and HACCP standards. So U.S. regulatory interest in the new standard also seems to be absent.

I WANT MY H1

The lubricants industry is even less enthusiastic about ISO 21469. Although the new standard is meant to be voluntary, NSF in April said it would sunset its popular “white book” registry of H1 food-grade lubricants in 2010, and so



NSF's standard mark should be used to identify registered H1 lubricants.

lube manufacturers should begin moving to the more stringent annual site inspection and testing called for under ISO 21469.

The outcry from lube manufacturers was swift and vehement — and NSF swiftly reversed course. The H1 listings will continue, it assured customers, and the program is in no danger of ending. Beginning in September, NSF will offer certification to ISO 21469 as an optional service, but the H1 registration program is safe, Krol said in a follow-up at last month's NLGI meeting in Scottsdale, Ariz.

A glance at the NSF H1 registration program shows just how important it has become, and why the threat of loss was so alarming. Of some 9,000 nonfood compounds included in the registration program, 60 percent are H1 lubricants —

and rising daily. (“We expect to have 8,000 food-grade lubricant products listed by 2008,” Krol told *Lubes'n'Greases*.) It has global support, too: Over 400 companies from 35 nations have registered products, and traffic on the website has boomed, as more food inspectors and lubricant buyers alike have found it a useful tool.

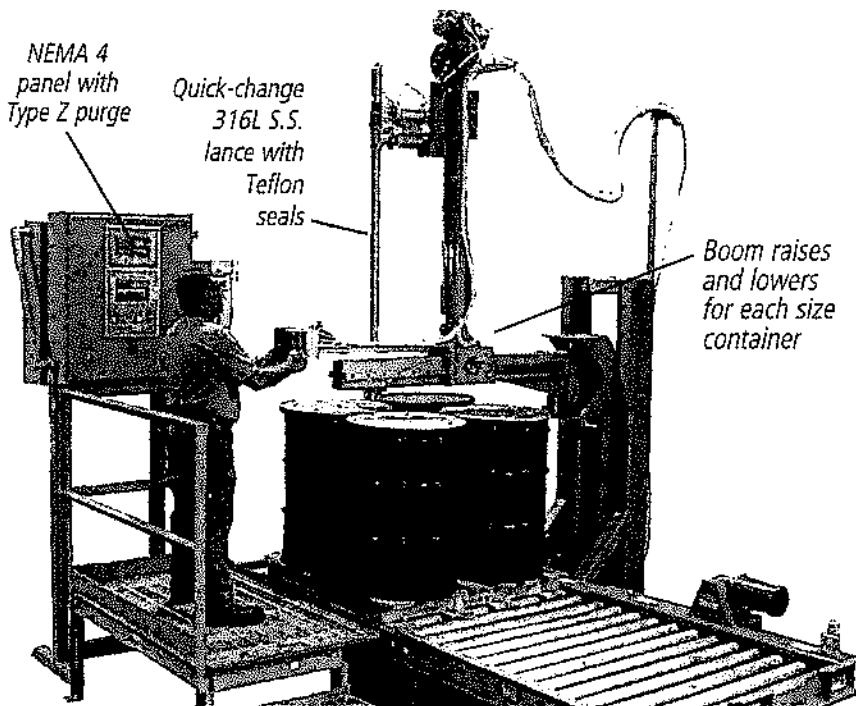
“This clearly shows the importance and acceptance of registered lubricants across the globe,” Krol said.

NSF's H1 registration program will see some administrative changes, however. Companies with products on the H1 list will be asked to supply an annual verification — a signed document that attests there has been no change in their formulation, product or label. The annual fee to maintain a company's H1 listing on the NSF website was raised recently to \$500 a year, from a previous fee of \$125. “And we'll also want people to use the standard NSF mark, the one food processors are most familiar with, on any new label going forward or when any revisions to their labels are made,” said Amy Rice of NSF. ■

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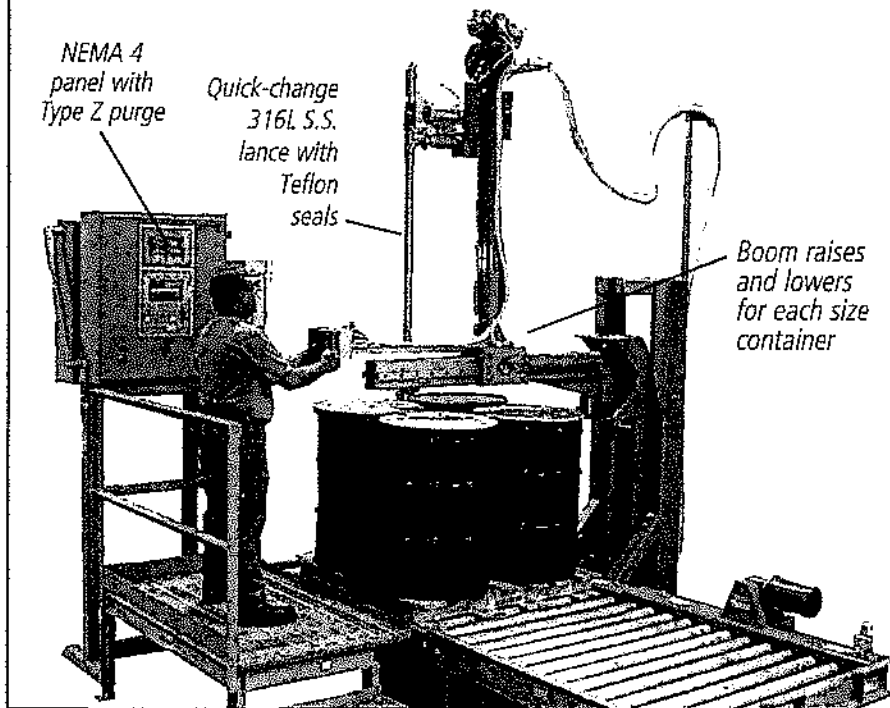
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