

## COMPLIANCE & REGULATORY REQUIREMENTS FOR

# FOOD SAFE LUBRICANTS

Lubricants needed by food, beverage and pharmaceutical producers have to meet stringent requirements, both technical and hygienic. Technically, they must meet national and international specifications, original equipment manufacturer specifications and end-user requirements to ensure no-loss food processing and equipment protection.

Hygienic requirements include having the lowest impact on living organisms, no impact on taste or odor and antibacterial and antifungal properties. To be used in food processing equipment lubricants must be listed on the National Sanitation Foundation (NSF) White Book, have FDA approval (for example, 21CFR 178.3570) and comply with ISO 21469: "Lubes with incidental product contact."

Speakers at a recent forum addressed the diverse issues involved in

selecting lubricants suitable for use in food processing equipment.

### **Safety & Brand Protection**

According to Jürgen Towara, senior food contact expert at Intertek Germany, food safety and brand protection go hand in hand. Simply put, he said, brand protection requires that a lubricant comply with the European Union's Framework legislation on food safety and packaging materials.

"Depending on the application, all materials

that come in contact with food must conform to the requirements of measures such as EU 10/2011," he said. There are no specific regulations for lubricants with incidental food contact; however, risk assessment is required for any nonintentionally added substances.

"Food grade lubricants must be used in all areas where contact with a food product cannot be fully excluded," Towara cautioned. This includes any lubricant, heat transfer fluid and corrosion protection on machinery used to process foodstuffs, cosmetics, pharmaceuticals and tobacco products.

The H-system defines categories of materials used on food processing equipment. H1 products are food-grade lubricants not intended for human consumption and are acceptable for incidental contact with food. They are composed of substances listed in 21CFR 178.3570.

"H2 lubricants can be used on equipment and machine parts with absolutely no food contact," said Towara. The component substances are not listed; however, the formulation must not contain heavy metals or CMR (carcinogenic, mutagenic or toxic to reproduction)





Automatic production line of fruit ice cream.

substances.

Fragol's Andre Adam made it clear in his presentation that H2 designates industrial lubricant and is not for use in food plants, according to the European Hygienic Engineering & Design Group. "If a non-H1 product is stored alongside an H1 product, the wrong product will be

used," he emphasized.

"H2 or common industrial products present an unnecessary risk. A hydraulic hose on a fork lift can burst, oil can be transferred due to a vacuum collapse or with compressed air, and seals can fail, leading to contamination."

H3 materials are used

to clean or prevent rust. 3H materials are release lubricants, including edible oils, generally regarded as safe and FDA compliant mineral oil. HT1 fluids are used in heat transfer equipment.

Wouter Burggraaf of Burggraaf & Partners B.V., explained that the EHEDG is a consortium

of equipment manufacturers, food industries, research institutes and public health authorities that promotes hygiene during the processing and packing of food products. "Comprising more than 100 members, EHEDG's goal is to improve hygienic engineering and design in all aspects of food manu-



facture,” he said.

A voluntary organization, EHEDG has issued 44 guidelines on hygiene standards and hygiene awareness. It works with 3-A Sanitary Standards Inc. in the United States to enhance product safety for consumers of food, beverages and pharmaceutical products through the development and use of sanitary practices.

“EHEDG recommendations address cleaning and disinfecting equipment, and hygienic and aseptic production,” said Burggraaf. “In Europe, the organization’s efforts led to the development of ISO 14159, concerning the

hygiene requirements for machinery design.”

#### **Assessing Lubricant Safety**

Towara related that ISO 21469 covers lubricants that can come into incidental contact with food, cosmetics, pharmaceuticals, tobacco and animal feed. “Certification to ISO 21469 requires the lubricant formulation to comply with international standards and legislation such as CFR 21 178.3570,” he said. “The manufacturing process also must be validated, and a risk assessment – also known as a hygienic assessment – must be made of the potential

sources of contamination.”

Finally, the lubricant must be registered; for example, in the NSF White Book. NSF International maintains listing of approved food-safe lubricants. The organization certifies lubricants and manufacturers according to ISO 21489. An alternative to NSF is InS Services.

Lubricants with incidental food contact can be used safely on machinery used to produce, manufacture, pack, process, prepare, treat, package, transport or hold food, subject to the provisions of ISO 21469. The lubricants must be prepared from one or more of the substances

identified in paragraph (a) (3) of the standard.

According to Towara, validating a lubricant’s manufacturing process involves reviewing the formulation to ensure its safety and accuracy. “This is done by testing to verify the integrity of the product’s composition, supported by external auditing.”

A hygienic assessment evaluates all potential sources of contamination from the manufacturing process to the end use, understanding that contamination has diverse sources such as bacteria and chemical changes. Corrective measures and

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preventive actions should be identified for each risk.

The assessment should follow well-established Hazard Analysis Critical Control Point (HACCP) principles to identify all lubrication points in the food processing equipment where direct contact between lubricant and food is possible. "In addition," Towara noted, "every possible point where the lubricant can be contaminated during transport, storage and processing must be identified." Another requirement is to ensure that relevant personnel have ready access to instructions and documentation on the replacement and checking of lubricant use and quality.

He then presented examples of potential hazards, including infrequent lubricant replacement, improper filling (mostly overfilling oil reservoirs or over-packing bearings with grease). Other potential hazards relate to the use of the wrong lubricant or a non-food grade lubricant.

"The use of improper lubricating equipment can also cause contamination," he cautioned. "Finally, failure to follow work instructions and lack of training are also causes of lubricant contamination."

Towara added that end-users must be proactive in protecting critical control points from contamination by maintaining and implementing a lubrication plan. "The plan should include suitable storage of lubri-

cants and the selection and use of the correct lubricant for each machine lubrication point," he said. "Each lubricant, lubrication point and the tools needed to lubricate that point should carry identification tags to ensure the right lubricant is used in the right place."

Another important aspect of the plan is to establish a lubrication schedule and identify the minimum quantity of lubricant necessary to provide the required protection. Finally, procedures must be established for the proper replacement of a lubricant by another, the removal of used and contaminated lubricants and their packaging as well as a training program for all maintenance and technical employees.

#### **Getting Additives Approved**

Evonik's Andreas Bernhard related that additives for food grade lubricants can be selected from the NSF White Book listing. "The registration process for a lubricant is simplified when using only NSF-listed additives," he said. The White Book lists the additive trade name and the maximum treat rate.

Bernhard explained that registering a food-grade additive can take as long as 8 years. The steps and costs involved are shown in the figure and requires a HACCP analysis, as described above.

"The typical result of a HACCP analysis is a

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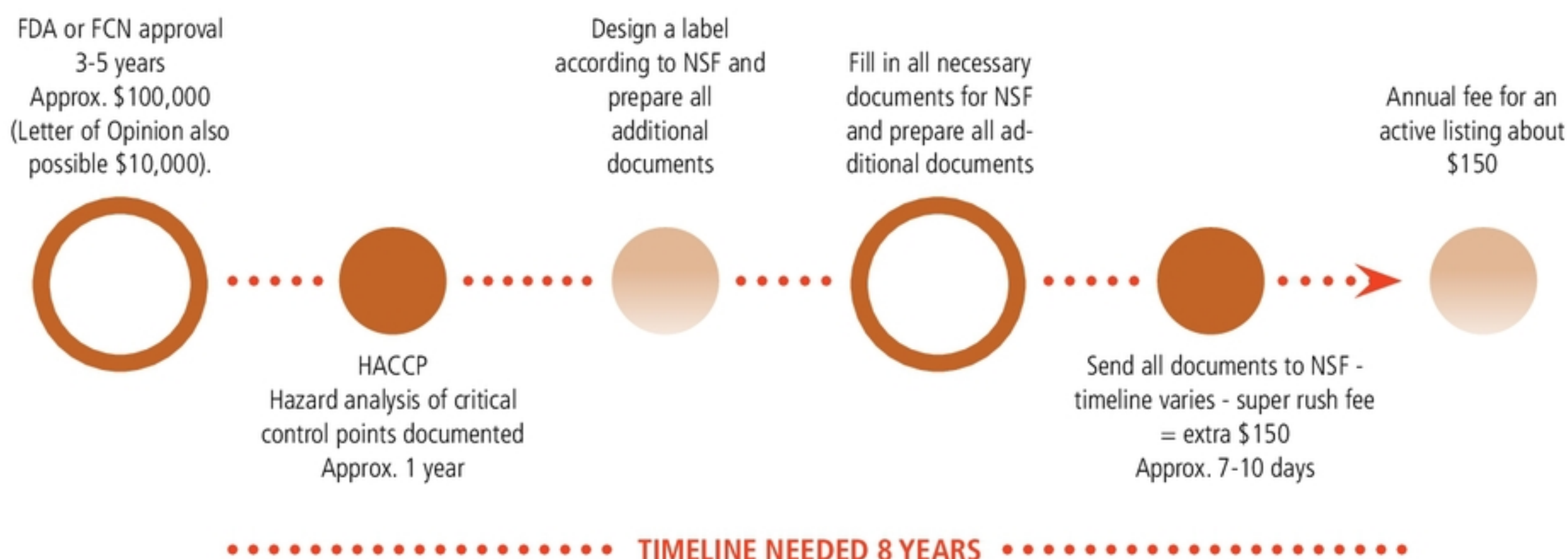
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## Registering a Food-Grade Additive



Source: Evonik

finding that a production site has critical control points and points where no further action is required," he said. "For critical

processes, use of H1 lubricants is mandatory. For noncritical processes, use of H2 lubricants is possible. For critical processes,

a mix-up of H1 and H2 fluids must be rendered impossible."

Bernhard then provided some general recommendations for formulating food grade lubricants. "First, select a suitable base fluid. Generally, PAOs and esters provide a number of benefits. However, PAO and white oils can have limited additive solubility, so it is necessary to carefully check the additive solubility in the selected base fluid."

In discussing lubricant selection, Fragol's Adam offered these guidelines:

1. Know the lubricant properties.
2. Polyalphaolefins for low temperatures.
3. Group II or III for heat transfer, gears and hydraulics.
4. Polyalkylene glycol for worm gears.
5. Polyol esters for high temperature chain oils
6. Combinations of the above to get the right

result.

The maximum treat rate of an additive is limited by the FDA approval. "Sometimes additives with a similar profile must to be used to produce a given level of performance while staying within the allowed limits," Bernhard said.

Additives can have synergistic and antagonistic effects. "Typically, corrosion inhibitors and antiwear additives have to be balanced to ensure proper performance," Bernhard cautioned. Finally, the formulation has to be tested both in the lab and in the field.

All information submitted with the application to NSF is kept confidential in accordance with NSF Policy. Registration is current when the label requirements are met and product names are listed at the NSF website. Up to six products containing the same ingredients can be submitted as a range. □



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