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The complexity of Food-Grade Lubricants regulations

t is always the negative experience or attention that sticks forever in people's minds. This is a daily threat, especially in the food-producing industry. Years of carefully constructed expansion and brand recognition can be wiped out in the blink of an eye in the case of negative news, often leading to high costs and a bad reputation. In the news, we have seen multiple instances where contaminated products are taken off the shelves or recalled, and some have caused casualties with legal consequences.

This awareness creates the basis of implementing various legislation articulately to avoid such risks, especially when manufacturing and processing food, feed, and pharmaceutical products. Moreover, the desire for increased output is an essential ingredient for organizations to be cost-effective and competitive; the risk of human error is raised, which may compromise food safety.



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Food Safety Management Systems

The food industry is familiar with many food safety management systems; the ISO 22000 maps out what an organization needs to demonstrate its ability to control food safety hazards to ensure that food is safe, consistently produced and controlled according to quality standards. GMP (Good Manufacturing Practice) ensures that products are consistently produced and controlled according to quality standards. At the same time, HACCP (Hazard Analysis Critical Control Points) addresses food safety through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling, to manufacturing, distribution and consumption of the finished product.

Legislation on lubricants in foodproducing plants

The legislation around the use of lubricants in food-producing plants is covered by the globally accepted regulation of the »

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US-based FDA (Food and Drug Administration). Title 21 of the Code of Federal Regulations (CFR 21 part 178.3570) covers the incidental contact of lubricants with food. Incidental in this respect means no more than 10 ppm of a lubricant is allowed to be present in food; in other words, practically none. The HACCP plan involves operators regularly checking for leakages and declining oil sump levels. In case of deviations, measures must be taken with the batches produced between the last two checks. Frequencies of these checks are therefore in tune with the hazard or risk of contamination to avoid significant product disposals.

Food-safe certifications

The lubricants and greases used in food production plants should be "food-safe", meaning registered as H1 (suitable for incidental food contact). This classification is given by two globally accepted organizations, NSF (US-based) and 2Probity (EU-based), which check for compliance of lubricant formulations with the FDA regulation mentioned above. Both organizations check whether a lubricant formula consists only of the substances and maximum dosages, as prescribed in the CFR 21 part 178.3570.

For applications where direct contact between the food and lubricant cannot be avoided, the FDA regulations 21 CFR 178.3620 and FDA 21 CFR 172.878 apply. NSF and 2Probity check for compliance with these regulations and provide 3H (direct food contact) registrations for such lubricants. Mold release or dust control agents are examples of that kind.

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These two classifications (H1 and 3H) are the most important for food producers. Other classifications of significance are:

- HX1 This applies to the registered substances used in food-grade
- H2 No contact allowed. In other words, not of interest to the food industry
- H3 No contact allowed. Soluble oils for rust protection
- HT1 Heat transfer fluids for incidental food contact
- A1 Cleaners for the food industry, incidental food contact

ISO 21469 certification

Food grade lubricants manufacturers are also required to be ISO 21469 certified. ISO 21469 certifications verify compliance with product formulation, manufacturing and packaging requirements. The ISO 21469 certification and H1 registration involve product ingredients and labelling reviews. However, ISO 21469 further focuses on the quality control of product manufacture. It includes mandatory product testing, label reviews, on-site validation of the formulation of the food-grade lubricant, and on-site au-



Beer bottles filling on the conveyor belt in the brewery factory. SOURCE | SHUTTERSTOCK / CAGKAN SAYIN



CTC (crush, tear & curl) Plant in a black tea manufacturing factory SOURCE | SHUTTERSTOCK / ANIL VARMA

dit of packaging and other risk assessment correctness. In simple terms, it is called a HACCP plan for the lubricant producer to assure hygienic and quality control measures during manufacturing, storage and transport. In this case, the lubricant producer uses safe components to prepare the lubricants and takes several steps to safeguard the production of the lubricant from, among other things, contamination. A critical factor is dedicated blending vessels and filling lines to rule out contamination from other industrial oils produced in the same site. Besides, tampered packaging and inner coatings of metal drums, to avoid contact of lubricants with the possible formation of rust during transport and storage, are options to optimize and better control this process. Plants obtain ISO 21469 certification after an extensive field audit by an external auditing company. The certification is extended yearly, enhancing the previous year's corrective actions and continuously optimizing production processes. In addition to food and beverage processors, ISO 21469 certified lubricants are also specified for the pharmaceutical, cosmetics and animal feed industries.

Other Certifications

Last but not least is that religious demands require similar control and verification processes. Religious laws specifically apply to food, but if something like a food-grade oil is certified, it can be used in food or food production without violating the end product's religious compliance. Therefore, food producers should also consider the critical cultural considerations and the benefits to their business for utilizing a food-grade oil supplier that is certified kosher, pareve, and halal.

All of the above legislation, regulations and limitations will set the standard for food and food-grade lubricant producers. Food-grade lubricant suppliers must meet or exceed these standards and educate their users. Food producers should be aware of today's standards and not be misled by food grade marketing

ventures that only tell one side of the story. In some markets, lack of knowledge and price-driven decisions lead to low cost (industrial grade) mineral oils, containing toxic substances being the first choice to be used in food production plants or production of food-grade lubricants. It should be clear that these oils should no longer be used in food-producing facilities or in the manufacture of food-grade lubricants to avoid the risks mentioned above.

Highly refined mineral oil grades, also called white oils, are suitable replacements for them. Technical grade mineral oils are used in lubricant formulations with H1 classification. Pharmaceutical grade mineral oils are even more refined and ideal for lubricant formulations with 3H classification. The refining process enhances the treatment of crude oils by distillation, solvent extraction, dewaxing and hydro finishing. The process is controlled by the IP 346 test method as an indicator of the carcinogenicity of lubricant base oils.

Conclusion

Clear communication to the market explaining why and where H₁ and ₃H lubricants are needed is a good starting point to make the world safer. The comprehensive production plants certification, frequent audits and validation in the context of ISO 21469, on the other side, will guarantee food safety using food grade lubricants. The goal should be to replace the non-Food-Grade lubricants with either H₁ or ₃H for the benefit of all persons or animals consuming the products produced safely.

