Food and Drug Administration (FDA)
The FDA is part of the U.S. Government and among other activities establishes the requirements for the food, cosmetics and drug industries, including in the former’s case, incidental contact lubricants or lubricants designed for use in food machinery. FDA compliance and claims are made through self-certification by the company marketing the lubricant. The FDA regulates substances added to food or in contact with food as food additives.

Food Additives
Any substance in which the intended use results or may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristic of any food.

Direct Additive
Added to food for a functional effect or used to process food (21 CFR Parts 172-173).

Indirect Additive
Used in food contact applications and may migrate into food (21 CFR Parts 175-178).

FDA CFR 178.3570
This is the self certification process to meet the FDA requirements for a lubricant for ‘incidental food contact’. This is not for lubricants directly in contact with food (such as mould release oils for bread making) but for those lubricants that could potentially leak into and onto the food material. Products that comply should be formulated from materials identified in the FDA 21 CFR (Code of Federal Regulations) or from the ‘GRAS list’ ie components that are Generally Recognised As Safe.

United States Department of Agriculture (USDA)
The USDA was the original body that issued official authorisation to formulations and ‘products for incidental contact’ by review against the FDA requirements. If compliance was shown, the (USDA) H1 category was awarded to the lubricant. In 1998 however the USDA authorisation program was abandoned and the H1 approval process was transferred to the NSF as long as the company had been registered. Hence, as long as the transfer process was completed during the early 2000s, valid H1 registrations came under the auspices of the NSF.

National Sanitation Foundation (NSF)
The NSF is a US based, not-for-profit, non governmental organization that provides standards development, product registrations, product certifications and risk-management services for public health and safety. It identifies the needs of the public and industry to generate and manage a list of Proprietary Substances and Non Food Compounds (which lubricants are included).
**NSF H1 Registered Lubricants**

NSF H1 lubricants are in practice potential ‘indirect food additives’ as they may have incidental contact with food due to leaks, spillages or faults in the equipment.

The NSF has established a list of H1 registered lubricants based on review of the lubricant suppliers’ data against the requirements of the FDA and prior USDA reviews. It registers these products once they have confirmed the material is in compliance with the FDA/GRAS listings and places them on their web-site for public access under the On-Line ‘White Book’.

**Hazard Analysis and Critical Control Points (HACCP)**

Developed by NASA in the 1960s to help protect astronauts, HACCP is a systematic, scientific based process system to identify, evaluate and manage food safety hazards in processing, packaging and transportation and helps identify ways to control or prevent them to ensure food production is safe. It identifies many aspects of food safety including contaminations with non food stuffs, bacterial control and risk identification. HACCP has become an important tool globally for regulators, customers and recipients.

Based on the audit and analysis, any required preventive action must be defined so that the identified risks can be prevented or at least minimized. In summary, it

- identifies the points at which risks for food may occur
- analyses the potential risks to food contamination in the process
- defines which points would be critical
- defines and carries out effective testing and monitoring procedures of these critical points
- checks the risk analysis after every change to the production process.

NSF H1 registered lubricants must generally be used if, during the process and before the consumer receives the product, occasional contamination of food by lubricants cannot be ruled out or prevented with complete certainty.

Manufacturers who do not conduct an HACCP analysis or have not implemented it correctly can be in breach of some food-safety regulations and directives and this could lead to a failed food-safety audit.

**Kosher**

Kosher foods are those that conform to Jewish dietary law. Certain animal species are allowed such as cattle, sheep, poultry and fish whereas pigs and shellfish are not. Foods that contain no dairy or meat content are known as Pareve, examples being most drinks, all fruit and simple raw vegetables. The assessment of the manufacture and suitability of a lubricant that confirms to Kosher is made on the formulation and manufacturing procedure through a technical and religious certification process. The formulation is assessed on its basic ingredients and the manufacturing facility is audited on a regular basis to assess the risk of contamination by non Kosher materials.

**Halal**

Halal is an Arabic term meaning ‘permissible’. In English it frequently refers to food that is permissible according to Islamic law. A variety of substances are considered forbidden which includes pork and pig based products, blood and all intoxicants, including alcohol. The assessment of whether a lubricant is suitable for Halal is very similar to that for Kosher. The ingredients of the oil or grease are reviewed technically and the manufacturing facility audited for its internal quality processes and potential cross-contamination. Certificates of conformity are normally issued.

**ISO 22000**

The ISO 22000 standard - Food Safety Management Systems - integrates the HACCP principles, system management and interactive communication between organisations in the food supply chain. ISO 22000 specifies the requirements needed for food safety management for each organisation in the food chain to ensure the final food is safe for human consumption.

**Good Manufacturing Practice**

Administered by the FDA under the authority of the Federal Food, Drug and Cosmetic Act, Good Manufacturing Practice (GMP) affects the manufacturers of drugs, blood and medical devices, requiring a quality approach to manufacturing to minimise contamination or mix-ups.

This document is not intended to constitute an all inclusive list of industry terms. For additional information, please refer to the sources cited throughout this article.

www.fda.gov
www.nsf.org
www.usda.gov