

Production and Use of Food-Grade Lubricants

This article is an extended summary of the report prepared by the Lubricants Subgroup of the European Hygienic Equipment Design Group (EHEDG) published in February 2002. It is the 23rd in the series of EHEDG summaries to be published in *TIFS*. The full report prepared by Piet Steenaard (Chairman), Henk Maas, Jan van den Bogaard, Richard Pinchin and Marcel de Boer, is available from CCFRA at pubs@campden.co.uk. Information about EHEDG can be found on the website at <http://www.ehedg.org>. The production of EHEDG guidelines is supported by the European Commission under the Quality of Life Programme, project HYFOMA (QLK1-CT-2000-01359).

Introduction

The machinery used to prepare and process food-stuffs, cosmetics, tobacco products, pharmaceutical products needs lubricants, grease and oil for lubrication, heat transfer, power transmission and corrosion protection of machinery, machine parts, equipment and instruments. Incidental contact between lubricants and food cannot always be fully excluded and may result in contamination of the food product. In all cases where product contact cannot be fully excluded food grade lubricants must be used. This guideline lays down the general requirements and recommendations for the hygienic manufacturing and supply of food-grade lubricants. The hazards that may occur during the use of food-grade lubricants and the actions required to eliminate or reduce these hazards are also covered.

Definitions

Food grade lubricants are not intended for human consumption or for contact with the skin or mucous membrane. They must correspond to the former USDA H1 classification as being ‘...acceptable for incidental food contact...’

Definitions of food-grade lubricants can be found in the following documents:

- H-1 of the USDA;
- ELGI/NLGI/EHEDG document FGL1/2001/issue 2;
- DIN V 0010517;
- NSF draft for an ANSI standard.

These definitions include the registration of food grade lubricants (H-1) by a competent third party organisation. No change in composition of the product or grade substitution is permitted without prior evaluation and re-registration.

Food-grade lubricants shall be composed in such a way that if applicable, technically unavoidable residues in the processed product are innocuous for health, taste and odour and that they may not have any other adverse influence on the product.

They shall withstand temporal, chemical, thermal and mechanical loads under the expected operating conditions.

Recommendations for manufacture and supply

The manufacturing and supply procedures of the producer of food-grade lubricants should incorporate the following recommendations, based on GMP, into a Quality Management system e.g. ISO 9001, which is subject to an independent audit.

Raw materials

- Have evidence that the raw materials or ingredients meet the FDA requirements and comply with the supplier's certificates
- Incorporate Supplier Quality Assurance: a programme of actions to ensure the safety and quality of the raw material supply
- Systematic entrance sampling to exclude the use of contaminated materials and to verify the quality of the raw materials
- Operate a system to keep these materials free of contamination e.g. systematic stock control to exclude contamination during storage and use of outdated raw materials, and registration of batch data
- Operate a system to avoid the use of incorrect materials

Production

- Have evidence that the correct formula is always used
- Where appropriate, undertake factory trials and carry out testing to verify product formulation according to the definition
- Shelf life shall be established taking into account lubricant formulation, packaging, factory environment and subsequent storage conditions
- Operate a system to identify points where the lubricant could be contaminated during production, storage and pack filling
- Use preventive measures to eliminate hazards or reduce their impact or occurrence to acceptable levels
- Critical limits should be defined which can be used to take action and reduce the risk of a deviation
- For each case where contamination of the lubricant during production occurs, an appropriate corrective should be taken. For example; adjusting the process to get it under control again and identifying non-conforming lubricants
- Operate a system to ensure the lubricant is packed into suitable clean containers and is correctly labelled
- Perform adequate quality control checks, tests and keep records. Ensure only approved lubricants are released for sale

Distribution

- Have evidence that the packs are sealed so that contamination cannot occur during transport
- Provide and follow advice on the storage of packs so that the lubricant is not subject to temperatures etc. that could cause degradation
- Provide and follow advice on handling and transport of packed materials separate from dangerous materials (acids, pesticides, etc.)
- Operate a system that prevents the distribution of outdated or contaminated lubricants
- When a problem occurs the primary task is to maintain control of events and protect consumer's health. Therefore it is essential to be able to trace batches of raw materials or products in the event of a problem
- An adequate recall plan should be in place to allow speedy withdrawal of any defective product.

Hazards and how to eliminate or reduce them

Although it may not be necessary to use food grade lubricants in all locations in the food production site, some manufacturers prefer to use them everywhere to avoid accidental mixing or confusion between food and non-food grade lubricants. It is strongly recommended that food-grade lubricants be used, especially at Critical Control Points. The following tables outline potential hazards associated with using food grade lubricants during the production and packaging of food and beverages and corresponding preventative measures.

Receipt of food-grade lubricants

Hazards	Preventive measures
Incorrect labelling on the packing	Immediately upon receipt from the supplier or his agent verify that products are: <ul style="list-style-type: none"> • Correctly labelled with no evidence of tampering, adulteration nor appear to be counterfeit products; • In accordance with the goods ordered; • Not outdated and free of contamination.
Expired shelf life of the product	<ul style="list-style-type: none"> • If in doubt the company concerned should be contacted directly to verify the products are genuine and in good condition, ready for use.
Packs not properly sealed or damaged by transport and/or tampering	
Wrong, outdated or contaminated product	

Mechanical or procedural failures

Oil and grease contamination of food can arise from a variety of mechanical or procedural failures.

It is highly recommended to set clear procedures, which includes at least:

- A lubrication schedule
- The amount of lubricants used within a defined space of time. Only the minimum quantity necessary to achieve the desired technical effect should be used
- The employee(s) responsible and allowed to lubricate

Keep in mind that prevention will always be better and more cost-effective than cure.



Fig. 1. Use the right amount.



Fig. 2. Use dedicated equipment.

Hazards

Leakage from bearings

Drips and splashes from open lubrication points, such as chains and open bearings or gear systems

Leakage from oil circulation systems, especially those where the oil is circulated under pressure and a small leak can result in a fine spray of oil onto the food, and hydraulically (by oil) operated valves and other components

Leakage of oil from closed oil-filled heat exchange systems, notably those which are difficult to inspect for leaks and which may suffer corrosion

Contact between oil coated machine surfaces, such as slide ways, and food itself

Spillage of oil during machine maintenance

Contamination of compressed air by oil mists from oil-filled compressor pumps

Misuse of oil-based materials for cleaning machine parts, often with the intention of leaving an anti-corrosive oil film on the machine surface

Misuse of oils for mould-release coatings on food containers, notably in the bakery industry

Preventive measures

Avoid placing bearings or other equipment requiring lubricants in positions where contamination of food can occur. If this is impossible the following precautions should be taken:

- All excess lubricants should be wiped off and the soiled rags removed immediately
- Leaking equipment must be repaired promptly especially temporary repairs which should be made permanent as soon as possible because the materials used, such as adhesive tape represent a serious food contamination threat.
- Tools used should be sanitized and dried before use
- When repair work is completed the equipment and surrounding area should be thoroughly cleaned before production restarts
- An adequate preventive maintenance program shall be in place covering all items of equipment, which are critical to product safety.

Filter saturation failures often occur on in-line oil filters used on compressed air systems. Place all filters that tend to accumulate heavy amounts of oil on the preventive maintenance schedule.

To avoid the misuse of oil-based materials for cleaning machine parts and of oils for mould-release coatings on food containers, preventive measures must be laid down in specifications and procedures to guarantee the appropriate use of the right materials.

Deterioration of lubricants during operation

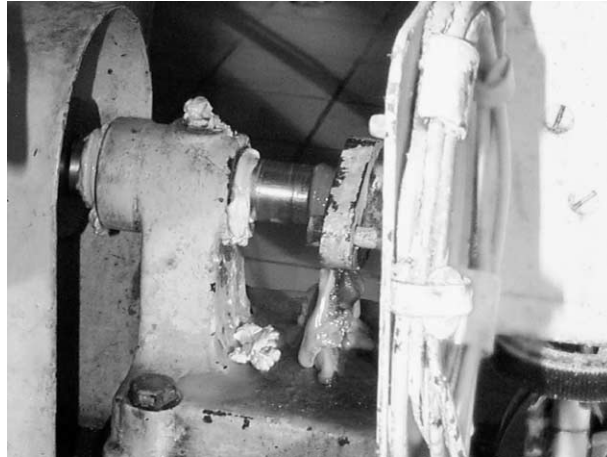


Fig. 3. Bad cleaning practices are a major cause of food contamination.

Hazards	Preventive measures
Contamination of food-grade lubricants can render them unsuitable for further use:	Identify and analyse all lubrication points in the production process where contamination of the lubricant is reasonably expected to occur and describe the preventive measures that can be used to control these hazards
Contamination with non food-grade lubricants	
Contamination with water, which will reduce the working life of machine parts	Failure to properly clean out equipment after maintenance repair is one of the major causes of food contamination. It is highly recommended to maintain and implement an adequate sanitation program. Use only food-grade cleaning solvents and potable water and take care when using high pressure cleaning
Contamination with water, drinks or food, which creates a breeding ground for the growth of bacteria and fungus	
Contamination by physical and chemical substances, which may cause oxidation and/or other chemical reactions—decreasing the proper function of the lubricants	It is advisable to set up a control plan to analyse the lubricants during their use with respect to the proper function of the lubricants and/or their level of contamination
Contamination by corrosion particles caused by rust of machine parts or packaging	Your supplier of food-grade lubricants will be able to provide operational and analytical advice if required

Critical Control Points

Some equipment may be identified as CCP because of the risk of lubricant contamination.



Fig. 4. Bearing as a high risk lubrication point.



Fig. 5. Open lubrication point: a risk for contamination.

Hazards	Preventive measures
Replacement of lubricant not frequent enough	Maintain and implement an adequate lubrication plan, which includes:
Improper filling, mostly over-filling of oil reservoirs, and over-packing of bearings with grease	<ul style="list-style-type: none"> ● Suitable storage of lubricants ● The selection and use of the correct lubricant for each machine lubrication point ● Use of identification signs on each specific lubricant, lubrication point and the tools needed to lubricate that lubrication point
Improper function of the lubricant	<ul style="list-style-type: none"> ● A lubrication schedule and the minimum quantity necessary to achieve the desired technical effect ● Procedures for the proper replacement of a lubricant by another
Filling up of marked lubrication points with improper lubricants e.g. using the wrong product on the lubrication schedule or adding of non food-grade lubricants and/or other food-grade lubricants to formerly applied food-grade lubricants	<ul style="list-style-type: none"> ● The removal of used and contaminated lubricants and their packaging ● A training program for all maintenance and technical employees
Use of improper equipment which can lead to contamination of the lubricant	
Procedures and/or work instructions are not being followed properly	
No or insufficient training of the maintenance personnel	

Identifying and marking lubrication points

All lubrication points in equipment where direct and/or indirect contact between lubricant and food is possible require careful attention to prevent contamination with non food-grade lubricants or even food-grade lubricants. These points must be identified properly and marked visibly with clear signs for each specific lubrication point.

Although it is good practice to use only food-grade lubricants in food plants, it is still advisable to mark the lubrication points to indicate which food-grade lubricant should be used.

Replacement of conventional lubricants

In the full document flow diagrams are presented describing sequential steps by which the maintenance department can effectively replace the conventional lubricants with food-grade (H-1) lubricants, especially for critical equipment where the lubricant used may come into contact with food.

It is highly recommended to carry out a proactive validation process with the help of the supplier of the

lubricants to ensure that each replacement of conventional lubricants by H-1 lubricants will be effective and efficient. The lubricant supplier can assist you with the latest techniques, recommendations and analyses needed for the proper replacement of conventional lubricants by H-1 lubricants.

Disclaimer

EHEDG is an independent foundation, which in the absence of official certification procedures has drawn up a guideline for establishing procedures relating to the manufacture of food grade lubricants and for use of these lubricants in the food industry, specifically in relation to incidental food contact. These procedures described by EHEDG reflect the good manufacturing practice as understood within the lubricants industry and the food and feed industry. EHEDG does not monitor the manufacturing process nor does it monitor post-marketing developments. EHEDG is not liable in any manner whatsoever for the safety of the lubricants and food products.



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