Assuring Food Safety in Food Processing: The Future Regulatory Environment for Food-Grade Lubricants

Regulatory changes in the food industry affect the food-grade lubricant market of the future. The U.S. Department of Agriculture (USDA) Food Safety and Inspection System (FSIS) - in conjunction with the Food and Drug Administration (FDA) - long maintained a system of oversight by granting "prior authorization" for lubricants intended for use in food-processing facilities. In September 1998, USDA eliminated this authorization program and instituted the requirements of a Hazard Analysis and Critical Control Point (HACCP) system instead. This paper will discuss various initiatives within the industry to develop an alternative system of authorization and will assert that "third-party certifiers" will dominate in the future food-grade lubricant marketplace.

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INTRODUCTION
The processing of agricultural or animal substances into consumable food products is performed in a multifunctional manufacturing plant. Such processing includes one or more operations such as: cleansing, sterilizing, homogenizing, blending, mixing, stirring, freezing, chilling, baking, frying, cooking, cutting, slicing, packaging, canning or bottling. Large scale food processing is often done with machinery and support components such as: pumps, mixers, tanks, hoses and pipes, chain drives, and conveyor belts. Such machinery and associated support equipment contains mechanical or moving components. Hydraulic fluids, greases, gear and chain lubricants, and other oils are required to ensure reliable and efficient operation of these components.

While good engineering design can reduce the likelihood of adulteration of the food by these lubricants, a myriad of operating constraints and tradeoffs (economic, engineering, logistics, hygienic practice, quality assurance, applicable regulations, and others) tend to increase the contamination risk. Therefore it is essential that those lubricants that may incidentally contact the food product be physiologically safe.

Until February of 1998 (Wholesome Meat Act, (1967), Wholesome Poultry Products Act, 91968), Agriculture Handbook, (1979), Federal Register (1998)), the United States Department of Agriculture (USDA), Food Safety Inspection Service (FSIS) maintained a command and control system aimed at assuring minimal risk to the consumer from incidental or unintended contact. This system also implemented various FDA regulations. Under this system lubricants that were authorized by the USDA were rated as H1 for "incidental contact," H2 for "no contact," or H3 for "soluble oils." These authorized lubricants appeared on the USDA List of Authorized Proprietary Substances under Part II titled "Nonfood Compounds Used In the Plant Environment." (See United States Department of Agriculture, Food Safety and Inspection Service, (1995) and Appendix I).

New USDA regulations have shifted the burden of assessing risk. Implementation of those regulatory requirements are defined by "Hazard Analysis and Critical Control Point" procedures (HACCP). HACCP is a comprehensive guideline to control risks to the food; biological, toxicological and foreign materials. These regulations make the food processor (manufac-
turer) responsible for the proper selection of lubricants. However, the lubricant manufacturer and/or the equipment supplier (or OEM), still remain responsible for the composition and effectiveness of the lubricant.

HACCP requires the food processor to perform an assessment of each point in the operation at which contamination might occur. Implicit in this assessment is the need for the food processor to know and understand the physiological risk that a lubricant may pose. Such an analysis may require the processor to review and approve the chemical composition of the lubricant. Prior to February 1998, the USDA performed that review role.

Response within the Lubricants Industry

Because the HACCP regulations may require disclosure of confidential and/or proprietary formulation details, some in the lubricants industry sought alternative methods of compliance. Various trade and technical organizations with the lubricants industry have responded to the changing regulations and to the needs of the lubricant manufacturer.

Response of Other Industries and Organizations — Potentials for the Lubricants Industry

Other industries, such as the manufacturers of cleaners and sanitizers, were also affected by these regulatory changes. Industry trade groups, such as the International Sanitary Supply Association (ISSA), are responding to these changes in regulations. Published papers and talks give ideas, guidelines and options to aid the lubricants industry. The Independent Lubricant Manufacturers Association (ILMA) maintains a Government Relations Committee that seeks to keep its membership informed on the rules and regulations affecting them. From these organizations the author learns that there are essentially three options available to the industry to replace the USDA regulations: do nothing, provide certifications to individual customers, or provide a third-party certification.

The National (and European) Lubricating Grease Institutes (NLGI and ELGI), in conjunction with the European Hygiene and Equipment Design Group (ELGI/NLGI/EHEDG), formed a joint Food-Grade Lubricants Working Group to develop guidelines and recommended practices to replace the former USDA system. This group has recently published its “Procedural Requirements for the Certification of Food-Grade Lubricants” (See www.elgi.nl/groups or www.nlgi.com). These guidelines establish minimum requirements for companies wishing to provide a Food Lubricant Review and Listing Process similar to the former USDA procedures. A summary of these guidelines is presented in Appendix I. Development of a broader industry standard continues to be a focus of this joint working group.

At the Deutsche Institut für Normung (DIN) in Germany, efforts are currently underway to develop a Food-Grade lubricants standard (NLGI/ELGI/EHEDG Joint Committee minutes, (1999)). Future plans include development and implementation of an International Standard (ISO).

International Sanitary Supply Association (ISSA), tells its members that the new regulations left the manufacturer (marketer) with three possible options: continue to claim USDA approval under the former system (“Proof of Previous Authorization”); “Self Certify” the composition; or provide a Certificate of Compliance from an external assessment agency. [The following is paraphrased and adapted from the presentation given by William Balek (Balek, 2000)].

For products not previously authorized by the USDA, ISSA tells its members that the FSIS/USDA recommends a Letter of Guaranty. While FSIS does not set forth a required format, it does recommend that the letter contain certain elements.

1. Name and address of the product’s supplier.
2. Brand name, code or other designation identifying the product(s).
5. Any limitations on the use or special directions relevant to meat and poultry facilities.
6. Signature.

Allowable Marketing Claims (per ISSA)

ISSA lists some acceptable marketing claims under a few different scenarios.

Previously Authorized Products

Products that were previously authorized under the USDA program are still considered to be authorized products. Therefore, it is allowable to continue to make statements such as “Authorized by USDA for use in federally inspected meat and poultry plants.”

Unauthorized Products

The following is an example of an allowable claim for a product that never received USDA authorization but which meets the guidelines previously used by USDA in authorizing products: “Product was formulated in accordance with the criteria established in the Guidelines for Obtaining Authorization of Compounds to be Used in Meat and Poultry Plants, Agriculture Handbook No. 562” (Note: A copy of this document is posted at www.issa.com.)

New Label for a Previously Authorized Product

A new distributor under a private label for which authorization is not available now will sell a previously authorized formulation. What type of claim can be made?

Because authorization was never granted to the distributor, the distributor cannot claim that the USDA authorizes the new private label. If the distributor minds revealing the identity of the supplier, then he can refer to the underlying authorized formulation. Otherwise, the distributor is free to make other truthful claims such as the one given in the paragraph above.

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Miscellaneous

Other marketing claims are allowable provided they convey truthful information about the product. For example:

- "Product meets USDA standards …"
- "Product complies with 21 CFR 178.3570"

[Note: The lubricants industry also has a fourth option not discussed in the ISSA paper, namely to provide the food processor/customer/prospect with detailed formulation details sufficient for their analysis and approval. Since this option is probably unacceptable to most business managers in the lubricant industry, the author will consider only the first three options.]

Other Organizations

Commercial organizations have also responded to the changes. Notably, NSF International (NSF Registration Program for Proprietary Substances and Nonfood Compounds used in USDA Meat and Poultry Facilities, (2000)) (see WWW.NSF.ORG) and Underwriters Laboratories Inc. (UL Recognized Component Program, (1999)). (WWW.UL.COM) are both not for profit organizations that have developed programs to offer “third-party” or “external-agency” certification programs.

It may interest the reader to note that the USDA/FSIS anticipated the possibility of a third party certifier when it originally issued its intention to change the regulations. “…FSIS specifically requests comments on whether an industry-recognized, non-government organization or laboratory could provide prior approval or a similar service to chemical manufacturers and distributors…” (See Federal Register 63, (1998)).

Procedural Requirements for the Certification of Food-Grade Lubricants (Third-Party External Certifiers)

This section discusses the NLGI/ELGI/EHEDG Food-Grade Lubricants Working Group recommended guidelines for a Certificate of Compliance issued by an external assessment agency for lubricants that may be used in the food industry (Lubricants for Incidental Food Contact).

Requirements

The ELGI/NLGI/EHEDG Food-Grade Lubricants Working Group guidelines and recommended practices were recently published as "Procedural Requirements for the Certification of Food-Grade Lubricants" (WWW.ELGI/NL/WGroups or WWW.NLGI.COM). These guidelines are intended to establish the minimal requirements for companies wishing to provide a Food Lubricant Review and Listing Process based on the former USDA procedures.

1. Lubricants are subject to the requirements of 21 CFR Part 178.3570 titled “Lubricants with Incidental Food Contact” (or with documentary evidence of approval from the FDA or USDA).

2. A Certificate of Compliance from an external assessment agency is required. This certificate includes, as a minimum: Product identification; a clause affirming the composition meets the requirements of point 1; the assessment agency identification; place and date of issue; and an authorizing signature.

This certification is based on a full composition analysis. The formula composition, including CAS numbers and chemical names, are based on IUPAC rules. This information is submitted to the third party assessment agency along with the information required by point 2 above. The criteria for assessing Food-Grade lubricants by these procedures are the same as under the former USDA evaluation system. Namely, for H1 lubricants, both the quality and quantity of the constituents are evaluated. Only constituents included in the U.S. FDA list of substances are permitted (21 CFR Title 178).

Certification Organizations

The certifier organization must meet the following requirements.

A. Certified according to ISO Guide 65.
B. The procedures must form part of the auditable Quality Assurance System.
C. QA systems must be subject to regular independent audit and the results may be subject to confidential inspection by ELGI/NLGI/EHEDG.
D. Strict confidentiality in the handling of submitted data.
E. Suitable administrative procedures and systems.
F. Experts qualified to carry out checks of the lubricant composition.
G. Corporate commercial independence from the lubricant industry.

The certifier performs the following tasks.

1. Check the composition of the lubricant against the procedural requirements.
2. Issue Certificates of Conformance.
3. Maintain a database of approved products to the procedures and make that information available to interested parties.
4. Acknowledge receipt of an application within one month (along with information relevant to the applicant).
5. Notify the results of the review to the submitting company.

Termination of Authorization

A certification may be terminated for any of the following reasons.

- An attempt to mislead the certifying organization (incorrect identification of constituents in the products or to its acceptable use). Including: product labeling, sales literature, data sheets and advertising.
CONCLUSIONS

The regulatory environment for Food-Grade lubricants has changed significantly since 1998. In the future, the author can expect to see any one or more of at least three possible certification systems: reliance on the former USDA approval, self-certification or third-party certification. Current efforts of the third-party certifiers focus around adopting the former USDA guidelines, however, industry groups are at work to more rigorously define "Food-Grade lubricants." These steps are the precursor to the development of an ISO Standard. Some groups, such as the European Hygiene Equipment Design Group, seek to evolve standards that go well beyond the current "gate keeper" standards evolved through the former USDA guidelines. The ongoing efforts to strengthen the foundation strongly suggest that "third-party" certifiers will play the dominant role in the future food-grade lubricant marketplace.

REFERENCES

(4) "Elimination of Prior Approval for Proprietary Substances and Nonfood Compounds (Docket 91-007N)," (1998), Federal Register, 63, 2, pp 7319-7322.
(7) NLGI/ELGI/EHEDG Joint Committee published minutes, (1999).
(10) UL Recognized Component Program, (1999), private correspondence with the author.
(11) "Elimination of Prior Approval for Proprietary Substances and Nonfood Compounds (Docket 91-007N)," (1998), Federal Register, 63, 2, pp 7319-7322.

APPENDIX I

On the Change of Procedure for the Authorization of Certain Lubricants Intended for Use in Some Food Processing Establishments

This appendix summarizes the practice and procedure for authorizing the use of certain lubricants in food processing establishments until a policy change announced on 13 February, confirmed on 14 April 1998 and implemented in September 1998. This practice was developed and controlled by The United States Department Of Agriculture (USDA), Food Safety And Inspection Service (FSIS) and is supplied for historical reference.

A Policy Change “Elimination of Prior Approval for Proprietary Substance and Nonfood Compounds” per Docket No. 97-007N appeared in the Federal Register on February 13, 1998 (Volume 63, Number 30, pp 7319-7322). This policy change eliminated the prior approval of proprietary substances and nonfood compounds including lubricants. In its place, USDA (under its Hazard Analysis and Critical Control Point System) shifts the burden of authorization from the US Government to the Food Processor. This policy change is problematic to many lubricant producers because it potentially requires disclosure of confidential and proprietary formulation details to a wide range of organizations.

Overview

The USDA previously granted authorization of a proprietary lubricant (compound) for use in a food processing plant based upon the confidential submission of a product formulation (along with product label and a representative sample). The USDA then evaluated the product formulation against various lists of approved chemicals (e.g. 21 CFR 178.3570). USDA made no judgment about the efficacy of the compound as a lubricant. The ultimate responsibility for performance and fitness for use in a particular application was left to the equipment OEM, lubricant marketer and the food processor. Thus, the USDA authorization offered a first-step assurance to the food processor that the compound presented was acceptable for incidental food contact.

Implications of the Change of Policy

For the lubricant marketer, manufacturer or distributor, the implications of this policy change violate normal business protocols and industry norms. Docket 97-007N filing tells us that such companies will be subjected to: “…HACCP plans, and the use directions, pest control certifications, and other materials furnished to establishments by chemical manufacturers and suppliers; and requests for formulation information from chemical manufacturers themselves. In light of this, FSIS anticipates that establishments considering the purchasing and using nonfood compounds and proprietary substances will demand formulation and other information from chemical manufacturers as part of their decision making in the private marketplace. Manufacturer’s failing to provide information could expect to lose their market share.” In other words, give your formulation and proprietary information to your customer (or prospect), or your competitor will. The implications include the following: impact on other industries (bottling, canning, pharmaceuticals, etc.); increased probability of fraud and misrepresentation; industry chaos; inadequate return on investment that will stifle product development and research.

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Rationale for the Policy Change

The USDA believes that the former system of preauthorization and control were inconsistent with the intent of the Hazard Analysis and Critical Control Points (HACCP) systems that have recently gone into effect.

Under HACCP, all meat and poultry establishments must identify critical control points within their processes where hazards such as lubricant contamination can occur, establish controls to prevent or reduce these hazards, and maintain records documenting that these controls are working. All facilities must implement standard operating procedures for sanitation.

HACCP regulations transfer total responsibility for safety of meat and poultry products to the processing establishment. Consistent with this change of philosophy, USDA also transferred total responsibility for selecting and using appropriate lubricants to the regulated establishment. This transfer also allowed USDA and FSIS to redirect its resources to ensuring the implementation of HACCP regulations.