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**Safety of machinery — Lubricants with  
incidental product contact — Hygiene  
requirements**

*Sécurité des machines — Lubrifiants en contact occasionnel avec des  
produits — Exigences relatives à l'hygiène*



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Published in Switzerland

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21469 was prepared by Technical Committee ISO/TC 199, *Safety of machinery*.

## Introduction

During the production of foodstuffs, cosmetics, pharmaceutical, tobacco and animal feeding products — including packaging in direct contact with the product — it is essential to avoid contamination with lubricants from machine elements such as gears, bearings, hydraulics, pneumatics, compressors, slideways and chains. In all cases where product and lubricant contact cannot be fully prevented, lubricants have to be used which are acceptable for use should cross-contamination occur.

Up until 1998, the United States Department of Agriculture (USDA) issued the USDA H1 authorization for lubricants, which met these requirements. Use of such lubricants gave users confidence that they were complying with best practice in relation to their duty of care to the consumer. Following the end of the USDA scheme, the need was recognized for an International Standard to be developed in this area.

The structure of safety standards in the field of machinery is as follows.

- a) Type-A standards (basis standards) give basic concepts, principle for design, and general aspects that can be applied to machinery.
- b) Type-B standards (generic safety standards) deal with one or more safety aspect(s) or one or more type(s) of safeguards that can be used across a wide range of machinery:
  - type-B1 standards on particular safety aspects (e.g. safety distances, surface temperature, noise);
  - type-B2 standards on safeguards (e.g. two-hands controls, interlocking devices, pressure-sensitive devices, guards).
- c) Type-C standards (machinery safety standards) deal with detailed safety requirements for a particular machine or group of machines.

This International Standard is a type-B standard as stated in ISO 12100-1.

When provisions of a type-C standard are different from those which are stated in type-A or type-B standards, the provisions of the type-C standard take precedence over the provisions of the other standards for machines that have been designed and built according to the provisions of the type-C standard.

# Safety of machinery — Lubricants with incidental product contact — Hygiene requirements

## 1 Scope

This International Standard specifies hygiene requirements for the formulation, manufacture, use and handling of lubricants which, during manufacture and processing, can come into incidental contact (e.g. through heat transfer, load transmission, lubrication or the corrosion protection of machinery) with products and packaging used in the food, food-processing, cosmetics, pharmaceutical, tobacco or animal-feeding-stuffs industries. Included in this document are registration criteria that can be used to assess conformance with this International standard for lubricants with incidental product contact (see Annex B). It is not applicable to substances used as product additives or to those in direct product contact (see Annex A), but confines itself to hygiene without addressing occupational health and safety matters. Nevertheless, it is considered essential that where occupational health and safety is associated with the processes concerned it be considered along with hygiene so that measures satisfying the needs of both can be taken.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 6743-99:2002, *Lubricants, industrial oils and related products (class L) — Classification — Part 99: General*

ISO 6743 (all other parts), *Lubricants, industrial oils and related products (class L) — Classification*

ISO 12100-1:2003, *Safety of machinery — Basic concepts, general principles for design — Part 1: Basic terminology, methodology*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

### 3.1

#### **lubricant**

substance capable of reducing friction, adhesion, heat and wear when introduced as a film between solid surfaces

### 3.2

#### **product**

any substance intended to be applied or taken into humans or domestic animals, e.g. by ingestion, injection, topical application, insertion

### 3.3

#### **manufacture**

obtainment, production, preparation and processing of lubricants and of products

**3.4  
processing**

unit operations such as weighing, measuring, filling and refilling, stamping, printing, packing, container filling, container sealing/closure, cooling, storage and transportation of products

**3.5  
intended use**

use of a lubricant in accordance with the instructions of the lubricant and machinery manufacturers in consideration of the expected operating conditions including service life, chemical, thermal and mechanical loads

**3.6  
incidental product contact**

contact with product that is not intended but which is not preventable

**4 List of hazards**

The hygiene hazards that could possibly be associated with incidental product contact include the following:

- a) biological factors, such as pathogens, spoilage micro-organisms or toxins;
- b) chemical factors, such as toxic, carcinogenic or mutagenic substances;
- c) physical factors, such as wear metals.

NOTE It is recognized that in some countries there may be limits on the amount of lubricant that can come into incidental product contact.

**5 Hygiene requirements**

**5.1 Basic strategy for selection of hygiene measures by the manufacturer**

The basic strategy for the selection by a manufacturer of hygiene measures for the design of incidental product contact lubricants shall be in accordance with ISO 12100-1:2003, 5.1, including

- a) identification of the product/process with which the lubricant is to be associated,
- b) the hazards associated with the product(s) produced (see Clause 4),
- c) the risk assessment associated with each hazard identified (see 5.2),
- d) design methods which can eliminate hazards or reduce risks associated with those hazards (see 5.3),
- e) means of verification of the effectiveness of the risk reduction method (see Clause 6), and
- f) a description of residual risks and any additional precautions that are deemed necessary (see Clause 7).

NOTE Guidance on the process for selecting hygiene measures is also given, schematically, in ISO 14159.

## 5.2 Elements of manufacturer's risk assessment

The following are representative of the range and types of factors that shall be considered as elements in the risk assessment of a lubricant during its manufacture, handling, storage, use and replenishment:

- a) contamination of the lubricant by the packaging material;
- b) contamination of the lubricant with biological factors;
- c) contamination of the lubricant by the product;
- d) contamination of the lubricant with water;
- e) the service age of the lubricant;
- f) chemical/physical changes caused by temperature exposure, mechanical activity, oxidation and degradation;
- g) reasonable foreseeable misuse.

The outcome of the risk assessment should translate into corrective and preventative actions in accordance with defined lubricant quality and usage criteria.

NOTE It is recognized that product contact can lead to changes in product aspect, taste, odour or texture.

## 5.3 Hygienic design

### 5.3.1 Classification

Lubricants for incidental product contact are to be selected from ISO 6743-99:2002 according to the intended application. They shall conform with the description given in the relevant other part of ISO 6743 and comply with the related ISO specifications.

### 5.3.2 Cross-contamination

Lubricants shall be composed in such a way that if cross-contamination with the product occurs, residues in the processed product are innocuous with respect to the health of the consumer, as well as taste and odour and such that they do not have any other adverse influence on the product's intended use.

### 5.3.3 Composition

Lubricants shall meet the qualitative and compositional requirements if they consist only of substances regarded as being safe for product, or incidental product, contact by governments or other recognized international organizations. These substances should be included in listings published by government or recognized international organizations (see Annex A), or which are authorized by them, for use in lubricants with incidental product contact.

### 5.3.4 Good manufacturing practice

Manufacturers should exercise care in the manufacturing and packaging of lubricants in order to avoid contamination such as that from lubricants not intended for incidental product contact.

## 6 Manufacturer's compliance verification

The manufacturer shall verify the compliance of the lubricant with the requirements of this International Standard by means of the following, as appropriate:

- a) examination of the formulation and its ingredients;
- b) assessment of procedures and practices used in the manufacturing process against defined quality standards;
- c) use of competent third parties providing independent inspection of, for example, the formulation and/or manufacturing practices;
- d) undertaking specific testing when available;
- e) use of competent laboratories undertaking testing required for lubricant registration.

## 7 Information for use

Following hygienic design and manufacture, the hygienic use of the lubricant is dependent on the user taking additional precautions, at the least those indicated by the manufacturer of the lubricant.

The manufacturer shall provide the user of the lubricant with the following:

- a) clear and correct labelling, which shall include an indication of shelf life and the suitability for use as an incidental food contact lubricant;
- b) appropriate packaging adequately protecting the product from tampering, adulteration, transit, storage and package deterioration;
- c) suitable storage requirements.



## Annex A (informative)

### Acceptable substances for hygienic product contact

The following are examples of suitable national/international sources specifying acceptable substances.

- Joint FAO/WHO Expert Committee on Food Additives (JECFA):  
[www.fao.org/es/esn/jecfa/database/cover.htm](http://www.fao.org/es/esn/jecfa/database/cover.htm)
- Council Directive 95/2/EC of the 18th March 1995 on food additives other than colours and sweeteners. Official Journal of the European Communities, No. L61/1
- United States Code of Federal Regulations (CFR) 21, Part 178.3570, revised April 2002: *Lubricants with Incidental Food Contact* [including references to other paragraphs of CFR<sup>1</sup>]

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1) Able to be obtained from the US Government Printing Office Superintendent of Documents, Mail Stop: SSOP, Washington, DC 20202 9328

## Annex B (informative)

### Registration criteria for incidental product contact lubricants

#### B.1 Basis of registration

**B.1.1** A separate application for registration should be filed for each lubricant product. All customer information required by the registrar for registration should remain confidential. Similarly, information shared between manufacturer and distributor should remain confidential.

**B.1.2** For checking the composition of a lubricant, the lubricant manufacturer should provide full details on the product's composition and name. Composition data should include the qualitative and quantitative (percentage weight) make-up of all constituents. Chemical abstracts services (CAS) numbers, when available, and chemical names based on IUPAC (international union of pure applied chemicals) rules should be indicated.

**B.1.3** Applications should include, on the appropriate form and in addition to compositional data, the following information:

- a) brand name;
- b) indication of a new or a revised formulation;
- c) indication of any product approvals from bodies other than those to which the submission is being made;
- d) product label stating the size of the container and, if more than one size of container is used, copies of the labels for each size.

It is the obligation of the applicant to notify the registration organization before making changes to the formulation. In cases of a change to the formulation, a new registration should be applied for.

**B.1.4** The criteria for evaluating a product formulation is based on 5.3.3.

**B.1.5** Ingredients not appearing in the references given in Annex A may be used if they have been approved by governments or other recognized international organizations. In such cases, the pertinent written confirmation by the government or other recognized international organization should be made available to the registrar.

**B.1.6** The registration organization should maintain lists of issued registration certificates which are made publicly available; the organization should comply with, and maintain by regular external audit, ISO/IEC Guide 65 accreditation.

## Bibliography

- [1] ISO 14159, *Safety of machinery — Hygiene requirements for the design of machinery*
- [2] ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*

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**ICS 13.110; 67.020**

Price based on 7 pages