Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products (ISO 29621:2010)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 29621:2011 sisaldab Euroopa standardi EN ISO 29621:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 29621:2011 consists of the English text of the European standard EN ISO 29621:2011.
Standard on kinnitatud Eesti Standardikeskuse 31.01.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.01.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
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English Version

Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products (ISO 29621:2010)

Cosmétiques - Microbiologie - Lignes directrices pour l'appréciation du risque et l'identification de produits à faible risque microbiologique (ISO 29621:2010)

Kosmetische Mittel - Mikrobiologie - Leitlinien für die Risikobewertung und Identifikation von mikrobiologisch risikoarmen Produkten (ISO 29621:2010)

This European Standard was approved by CEN on 22 December 2010.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 29621:2010 has been prepared by Technical Committee ISO/TC 217 “Cosmetics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 29621:2011 by Technical Committee CEN/TC 392 “Cosmetics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2011, and conflicting national standards shall be withdrawn at the latest by July 2011.

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

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Endorsement notice

The text of ISO 29621:2010 has been approved by CEN as a EN ISO 29621:2011 without any modification.

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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.

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ISO 29621 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

Introduction

Every cosmetic manufacturer has a dual responsibility relative to the microbiological quality of its products. The first is to ensure that the product, as purchased, is free from the numbers and types of microorganisms that could affect product quality and consumer health. The second is to ensure that microorganisms introduced during normal product use will not adversely affect the quality or safety of the product.

The first step would be to perform a microbiological risk assessment of the product to determine if the cosmetic microbiological International Standards apply.

Microbiological risk assessment is based on a number of factors generally accepted as important in evaluating the adverse effects on product quality and consumer health. It is intended as a guide in determining what level of testing, if any, is necessary to assure the quality of the product. Conducting a microbiological risk assessment involves professional judgment and/or a microbiological analysis, if necessary, to determine the level of risk.

The nature and frequency of testing vary according to the product. The significance of microorganisms in non-sterile cosmetic products should be evaluated in terms of the use of the product, the nature of the product and the potential harm to the user.

The degree of risk depends on the ability of a product to support the growth of microorganisms and on the probability that those microorganisms can cause harm to the user. Many cosmetic products provide optimum conditions for microbial growth, including water, nutrients, pH and other growth factors. In addition, the ambient temperatures and relative humidity at which many cosmetic products are manufactured, stored and used by consumers, will promote growth of mesophiles that could cause harm to users or cause degradation of the product. For these types of product, the quality of the finished goods is controlled by applying cosmetic good manufacturing practices (GMPs) (see ISO 22716) during the manufacturing process, using preservatives and conducting control tests using appropriate methods.

The likelihood of microbiological contamination for some cosmetic products is extremely low (or non-existent) due to product characteristics that create a hostile environment for survival/growth of microorganisms. These characteristics are elaborated in this International Standard. While the hazard (adverse effects on product quality and consumer health) may remain the same for these products, the likelihood of an occurrence is extremely low. Those products identified as “hostile” and produced in compliance with GMPs pose a very low overall risk to the user.

Therefore, products that comply with the characteristics outlined in this International Standard do not require routine microbiological testing.

The objective of these guidelines is to help cosmetic manufacturers and regulatory bodies to determine when, based on a “risk assessment,” the routine application of the microbiological International Standards for cosmetics and other relevant methods is not necessary.

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1 Scope

The objective of this International Standard is to help cosmetic manufacturers and regulatory bodies define those finished products that, based on a risk assessment, present a low risk of microbial contamination during production and/or use, and therefore, do not require the application of microbiological International Standards for cosmetics.

2 Terms and definitions

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

2.1
risk
effect of uncertainty on objectives

[ISO Guide 73:2009, definition 1.1]

NOTE Microbiological risk is associated with the ability of a product to:

— support the growth of microorganisms and the probability that those microorganisms can cause harm to the user;

— support the presence of specified microorganisms as identified in cosmetic microbiological International Standards, e.g. ISO 18415, ISO 18416, ISO 22717, ISO 22718 and ISO 21150.

2.2
risk assessment
overall process of risk identification, **risk analysis** (2.3) and **risk evaluation** (2.4)

[ISO Guide 73:2009, definition 3.4.1]

2.3
risk analysis
process to comprehend the nature of **risk** (2.1) and to determine the level of risk

[ISO Guide 73:2009, definition 3.6.1]

2.4
risk evaluation
process of comparing the results of **risk analysis** (2.3) with **risk criteria** (2.5) to determine whether the **risk** (2.1) and/or its magnitude is acceptable or tolerable

[ISO Guide 73:2009, definition 3.7.1]