

Procedure for Issuing Health Safety Certificates of Packaging Materials

Regulation No. 43 of 29 July 1998 of the Minister of Social Affairs

Pursuant to section 5(2) of the Packaging Act (RT (State Gazette) I 1995, 47, 739; 1997, 53, 836) and in accordance with section 5 of Decree No. 699-k of 1 August 1995 of the Government of the Republic of Estonia on the drafts of legislative acts developed pursuant to the Packaging Act (RT I 1995, 71, 1168; 1996, 26, 549), I hereby establish:

to approve the procedure for issuing health safety certificates of packaging materials.

Mait Klaassen, Minister of Education (acting Minister of Social Affairs)

Jaani Rütmann, Secretary General

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1. This Procedure regulates the issuing of health safety certificates of packaging materials (hereinafter: the certificate). For the purpose of this Regulation “certificate” and “sales packaging” shall mean a certificate and sales packaging as defined in the Packaging Act.
2. Certificates shall be issued for the materials used for sales packaging of foodstuffs, including beverage and mineral water, cosmetics, sanitary goods, and of other goods which come into direct contact with human skin and/or mucous membranes. This Procedure shall not apply to the materials used for sales packaging of medicines and medical instruments.
3. The certificate shall be obligatory if the material (or any of its components) of which the packaging is manufactured does not have such certificate, or if the technology used for manufacturing of packaging can affect the health safety of packaging.
4. The products referred to in section 2 of this Procedure may be sold or made otherwise available to the public use only if the packaging materials of such products are provided with a certificate registered in the Register of the Health Protection Inspectorate.
5. Certificates (format presented in the Annex to this Procedure) shall be issued or invalidated by the Health Protection Inspectorate. The certificate shall be issued in one copy and on the paper provided with security elements; a duplicate of the certificate shall be filed in the Health Protection Inspectorate for five years.
6. Any manufacturer or importer of packaging and/or packaging material must apply for the certificate and, upon such request from the user, shall be obliged to forward a copy of the certificate to him/her. Any legal or natural person or subsidiary company of a foreign trading company in Estonia using the packaging may, if necessary, apply for the certificate or receive the relevant information from the Health Protection Inspectorate or from the Packaging Register.
7. In applying for a certificate for the first time or in order to prolong the validity term of the certificate, the applicant must submit the following documents:

1. application indicating the name and information on the applicant (address; location; telephone and fax number, e-mail address; business registration number; legal persons must indicate the ID code and in case they do not have it, the date of birth), and the activity involving packaging material. In the case the applicant and the manufacturer are not the same, the applicant must also submit the above-mentioned information on the manufacturer. In addition, the information must include identification data of the packaging material, the purpose and conditions of their use, and any other relevant information on the use of the packaging material;
 2. duplicates of the documents describing the composition, properties and manufacturing process of the packaging material produced in Estonia;
 3. test reports on the packaging material produced in Estonia concerning their health safety, issued by a laboratory or authorised assessment body; for making out such reports, accredited or recognised methods must be used;
 4. in the case of imported packaging material, conformity statement or conformity certificate complying with the requirements established by the Conformity Certification Act (RT I 1997, 81, 1362), or the certificate or decision concerning the health safety and field of use of the packaging material concerned, issued by a competent health or other competent institution of the country of the manufacturer. The officials of the Health Protection Inspectorate shall have the right to request from the applicant the results of the tests on the basis of which the above-mentioned documents have been issued or any additional information;
 5. example of the packaging material.
8. The Health Protection Inspectorate shall make a decision concerning the issuance, prolongation of the validity term or refusal of the certificate not later than on the twentieth day of receipt of the relevant documentation.
 9. If issuance of the certificate have been rejected, the decision and reasons for rejection shall be communicated to the applicant in the written form.
 10. The Health Protection Inspectorate shall have the right to send packaging materials to the laboratory for further testing.
 11. The first certificate shall be issued to the applicant for one year, and later for three years, if the production and marketing of the same packaging material is continued under the same conditions as stated previously.
 12. To prolong the validity term of the certificate, in order to continue the production and marketing of the same packaging material under the previously stated conditions, an application shall be submitted confirming the accuracy of the information presented previously.
 13. If the production technology or composition of the packaging material is changed during the term of validity of the certificate, a new application must be submitted within ten calendar days; if other changes are made that alter the information submitted previously, the institution who has issued the certificate must be informed thereof within ten calendar days.
 14. The certificate shall be invalidated or prolongation of its validity term refused if:
 1. in applying for the certificate false data have been submitted;
 2. new circumstances significantly affecting the assessment of the health safety of the packaging material (new scientific data, undesirable side effects, etc.) arise;

3. changes in the information that served as the basis for issuance of the certificate were not forwarded to the relevant institution within ten calendar days;
 4. supervision has given evidence that health safety requirements have not been complied with.
15. The Health Protection Inspectorate shall inform the National Packaging Register about the issuance, prolongation or invalidation of the certificate within five working days.

Annex to the Procedure for Issuing Health Certificates confirming the Safety of Packaging Materials

Health Protection Inspectorate

Paldiski mnt. 81

EE0006 Tallinn

Business Registration No. 01005376

Telephone, fax, e-mail

Health Safety Certificate of Packaging Material

No.

Date of issuance: Date of termination of the validity of the Certificate:
.....

Applicant:

Name/name of the enterprise, business registration No. /ID code

Postal address:
.....

Location
.....

Telephone and fax number/e-mail address

Manufacturer:
.....

Name/name of the enterprise, business registration no. /ID code

Postal address:
.....

Location
.....

Telephone and fax number/e-mail address

Packaging material:

Name, type

Field of use:

Certificate is valid for

Type of the packaging material/shipment No. /

batch/ series/single product, etc.

Packaging material complies with the requirements of
.....

Name and place of publication of the document establishing
health safety requirements

Sections 1 and 2 shall be filled in upon the request from the applicant:

1. Name of research laboratory:
.....

Postal address
.....

Location
.....

Telephone and/or fax number/e-mail address

.....
Competence (authorised, accredited, recognised)

Test record No. Date:

2. Test results:

Indicator	Test result	Permitted limit value

.....
Signature

.....
Name, General Director

Stamp of the Health Protection Inspectorate

Applicant:

.....
Signature

.....
Name

.....
Position