OEKO-TEX® ACCREDITATION AGREEMENT

Annex I

Requirements for the

OEKO-TEX® INSTITUTES

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1. Introduction

ANNEX I defines the requirements that OEKO-TEX® INSTITUTES need to fulfil in order to guarantee that the CONFORMITY ASSESSMENT ACTIVITIES are carried out according to specified requirements, specific rules and procedures.

The CONFORMITY ASSESSMENT ACTIVITIES provide confidence to consumers, regulators, industry and other market participants that certified products, processes and facilities conform to specified requirements. These requirements reflect and implement the mandatory requirements of Directive (EU) 2024/825 (EmpCo Directive) for sustainability labelling certification systems, in particular the requirements of objectivity, competence, credibility, independence, and transparency pursuant to its Article 10.

2. Definitions

Unless otherwise defined hereinafter the definitions of the ACCREDITATION AGREEMENT apply to this ANNEX I.

3. References

ANNEX I is applicable for the provision of all OEKO-TEX® SERVICES.

4. General Requirements

4.1 Non-Discriminatory Conditions

The INSTITUTE adheres to the principle of non-discriminatory conditions. This means that the INSTITUTE must make its services available to all applicants who are able to fulfil the conditions of an OEKO-TEX® STANDARD. Access to the OEKO-TEX® SERVICES must not be dependent on the size of the customer or on a membership in an association or group, nor must CONFORMITY ASSESSMENT ACTIVITIES be dependent on the number of OEKO-TEX® CERTIFICATES already granted.

CONFORMITY ASSESSMENT ACTIVITIES can be refused if there are important reasons. Such reasons are for example, but not conclusive, if a potential customer is or was involved in illegal activities or is in non-conformity with the requirements in an OEKO-TEX® STANDARD or if an EXISTING CUSTOMER has violated the terms of the CERTIFICATION AGREEMENT.

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4.2 Confidentiality

The INSTITUTE is responsible for the handling and record-keeping of all information obtained or created during the performance of the CONFORMITY ASSESSMENT ACTIVITIES including application documents, test documents, test results and reports. The INSTITUTE must ensure that such information must (i) be treated confidentially by the contract partners and (ii) only be used for the purpose intended by the contractual relationship and (iii) not be made accessible to unauthorised third parties. No measures must be taken which could lead to publication unless expressly provided for in the CERTIFICATION AGREEMENT. Information about the EXISTING CUSTOMER that originates from sources other than the EXISTING CUSTOMER (e.g. complainants, authorities) must also be treated as confidential.

The INSTITUTE must ensure that the CERTIFICATION AGREEMENT includes provisions pursuant to which information which (i) was already in the recipient's possession before it was disclosed by one of the parties, (ii) is already in the public domain at the time the CERTIFICATION AGREEMENT was concluded or (iii) subsequently becomes publicly known through no fault of the recipient, is exempt from the secrecy and restricted use obligation. Furthermore, the obligation of confidentiality in the CERTIFICATION AGREEMENT does not apply to information, which the recipient has to disclose due to a legal obligation, provided that in such cases the recipient must, if possible, inform the other party prior to such disclosure and try to agree with the other party on the smallest possible extent of such disclosure.

The INSTITUTE must inform the CUSTOMER in advance of any information obtained by the CUSTOMER it intends to disclose.

4.3 Liability and Financing

The INSTITUTE must have the financial stability and resources necessary for the performance of CONFORMITY ASSESSMENT ACTIVITIES.

In order to be able to cover potential liabilities arising from the CONFORMITY ASSESSMENT ACTIVITIES, the INSTITUTE shall have adequate arrangements in place (e.g. insurance coverage).

4.4 Transparency

The INSTITUTE must have the following information publicly available, provide links to such information or provide such information upon request:

- information about the OEKO-TEX® STANDARDS and OEKO-TEX® SERVICES, including CONFORMITY ASSESSMENT ACTIVITIES, rules and procedures for granting and maintaining OEKO-TEX® CERTIFICATES, extension or restriction of the scope of OEKO-TEX® CERTIFICATES, suspension, withdrawal or refusal of OEKO-TEX® CERTIFICATES;
- information about the fees charged to obtain OEKO-TEX® CERTIFICATES;

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- information on the rights and obligations of applicants and EXISTING CUSTOMERS, including requirements, restrictions or limitations on the use of the CONTRACT TRADEMARKS of OEKO-TEX®, the labelling guidelines and the way reference is made to the OEKO-TEX® CERTIFICATES;
- information on procedures for handling complaints in connection with the CONFORMITY ASSESSMENT ACTIVITIES.

4.5 Data Protection

The INSTITUTE must include data protection provisions in their CERTIFICATION AGREEMENTS with the EXISTING CUSTOMER in accordance with the EU GDPR (Regulation (EU) 2016/679), the Swiss Federal Act on Data Protection (DSG) where applicable, and further applicable data protection laws in their specific jurisdiction, including in particular the requirements of the relevant national implementing legislation.

4.6 Legal Compliance

The INSTITUTE shall comply with applicable legal regulations in any country it operates in the context of providing OEKO-TEX® SERVICES.

The INSTITUTE must obtain, hold and maintain at all times the governmental licenses and permits required to provide the OEKO-TEX® SERVICES under the ACCREDITATION AGREEMENT in all countries it operates and report it proactively to OEKO-TEX®.

5. Structural Requirements

5.1 Legal Form

The INSTITUTE must have an adequate legal form to guarantee the governance and organisational requirements defined in section 5.2.

5.2 Governance and Organisational Structure

The governance and organisational structure of the INSTITUTE must be established and managed in such a way as to ensure compliance to the core principle of transparency, confidentiality, credibility, impartiality and independence.

The INSTITUTE must document its governance and organisational structure. It must specify the duties, responsibilities and powers of management and employees in detail.

The governance and organisational structure shall provide information in particular about:

- decision making body of the INSTITUTE;
- employees responsible for research and development activities in relation to OEKO-TEX® STANDARDS;

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- employees responsible for the implementation, compliance with, and monitoring of ANNEX I and ANNEX II;
- quality management system of the INSTITUTE (see section 6.1);
- employees responsible for maintaining ISO accreditation (see section 6.2);
- employees responsible for the complaint process (see section 6.3);
- employees responsible for the DETERMINATION ACTIVITIES (see section 8.1.3);
- employees responsible for the REVIEW ACTIVITIES (see section 8.1.4);
- employees responsible for the CERTIFICATION ACTIVITIES (see section 8.1.5);
- system and employees responsible for contract management;
- provision of adequate resources for the CONFORMITY ASSESSMENT ACTIVITIES;
- system in place for the monitoring the finances of the INSTITUTE.

The governance and organisational structure must be made available to OEKO-TEX® upon request.

5.3 Impartiality and Independence

5.3.1 General policy

Impartiality refers to the quality of being fair, unbiased, and neutral in judgment, ensuring no favouritism toward any party involved.

Independence refers to being free from external influence, control, or pressure, especially from parties, institutions, or interests that could compromise judgment.

The INSTITUTE must have a general policy in place which states that it is impartial and independent and provide documentation on adequate arrangements to ensure that its operations are not compromised by any conflicts of interest in relation to the customer receiving an OEKO-TEX® CERTIFICATE and to OEKO-TEX®. This general policy must be made publicly available.

If the INSTITUTE has corporate connections to other legal entities, it must ensure that the activities of those legal entities are not in conflict with and do not compromise its own CONFORMITY ASSESSMENT ACTIVITIES.

5.3.2 Commitment

The top management of the INSTITUTE must commit itself to this general policy of independence.

5.3.3 Mechanism for safeguarding impartiality and independence

The Institute must continuously identify and assess risks to its impartiality and independence and that of its laboratory. This includes potential conflicts of interest that may arise from ownership structures, customer relationships or other business relationships.

The mechanism for safeguarding impartiality and independence must meet the following criteria:

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- the INSTITUTE must evaluate the independence of the CONFORMITY ASSESSMENT ACTIVITIES as well as the governance of the INSTITUTE (see section 5.2) at least once a year;
- the INSTITUTE must ensure that its employees adhere to the requirements for impartiality and independence and receive regular training in this regard;
- if risks to independence are identified, the INSTITUTE must immediately take preventive, mitigative and/or corrective measures to control and/or eliminate them. The INSTITUTE shall inform OEKO-TEX® of the measures taken;
- the INSTITUTE must document the identified risks, the preventive and mitigation measures taken as well as their effectiveness, and reviews them regularly, at least once a year; and
- the INSTITUTE monitors compliance with the independence requirements and counteracts tendencies that could promote commercialisation at the expense of the objectivity of CONFORMITY ASSESSMENT ACTIVITIES.

The mechanism for safeguarding impartiality and independence must be documented and be publicly available. Results must be made available to OEKO-TEX® upon request.

If risks to independence are identified, the INSTITUTE shall immediately take preventive, mitigative and/or corrective measures to control and/or eliminate them. The INSTITUTE shall inform OEKO-TEX® of the measures taken without undue delay, and in any event within 14 calendar days of identifying the risk. The INSTITUTE shall furthermore immediately notify OEKO-TEX® of any change in its ownership structure or corporate governance that could give rise to a conflict of interest with its CONFORMITY ASSESSMENT ACTIVITIES.

6. System Requirements

6.1 Quality Management System

6.1.1 General management system documentation

All processes, systems, records, etc. relating to the fulfilment of the requirements of ANNEX I and ANNEX II must be included in the documentation of the management system.

All employees involved in the CONFORMITY ASSESSMENT ACTIVITIES must have access to the parts of the management system documentation that concern themselves and that are relevant to their responsibilities.

6.1.2 Document control

The INSTITUTE must have processes in place for document control. These processes must define the procedure and ensure that:

- documents are reviewed for adequacy and appropriateness and signed off by the responsible person;
- changes in documents are marked as such, and the revision status is stated;
- documents are accessible and available at the respective places of use;
- documents are legible and identifiable;

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- external documents are marked as such; and
- the use of old documents is prevented and if old documents must be kept, they are marked as such.

6.1.3 Control of records

The INSTITUTE must have processes in place for the control of records. These processes must define rules for the designation, storage, protection, retrieval, retention period and location of the records of the INSTITUTE.

These rules must ensure compliance with the obligations put forward in the ACCREDITATION AGREEMENT, ANNEX I and ANNEX II.

6.1.4 Decisions

Based on the document control (see section 6.1.2) and the control of records (see section 6.1.3) the management of the INSTITUTE must continuously make decisions on the improvement and of the effectiveness of the management system and its processes as well as on the need for resources required to comply with the ACCREDITATION AGREEMENT, ANNEX I and ANNEX II.

Further data to be considered must include:

- results from internal and external audits;
- customer and other stakeholder feedback;
- feedback from the mechanism for safeguarding impartiality and independence;
- monitoring of preliminary effect of preventive measures and effectiveness of mitigation measures;
- feedback from the complaint mechanism (see section 6.3).

6.1.5 Internal audit

The internal audit process must orient itself on the requirements specified in ISO 19011.

The INSTITUTE must ensure that:

- internal audits are carried out by employees who are trained in audit implementation;
- auditors must not audit their own work;
- employees responsible for the area being audited are informed of the results of the audit;
- resulting preventive actions (see section 6.1.6) and corrective actions (see section 6.1.7) are adopted timely and adequately; and
- opportunities for improvement are identified.

The results of the internal audit must be made available to OEKO-TEX® upon request.

6.1.6 Preventive action

In order to eliminate potential non-conformities to the ACCREDITATION AGREEMENT, ANNEX I and ANNEX II, the INSTITUTE must implement a preventive action plan. The preventive action plan must fulfil at a minimum the following requirements:

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- the procedures for identifying potential non-conformities and their causes;
- assessing the need for measures to prevent the occurrence of non-conformities;
- establishing and implementing the necessary measures;
- recording the results of the measures taken; and
- evaluating the effectiveness of the preventive measures taken.

6.1.7 Corrective action

If non-conformities have already occurred, the INSTITUTE must:

- determine the causes of non-conformities;
- immediately correct non-conformities;
- assess the need for measures to ensure that non-conformities do not recur;
- determine and implement the necessary measures in a timely manner;
- record the results of the measures taken; and
- check whether the implemented measures are efficient.

6.2 ISO Accreditation

6.2.1 General

The INSTITUTE must be ISO/IEC 17025 accredited. OEKO-TEX® STANDARDS can require further accreditation in the respective standard document.

6.2.2 Core methods

The INSTITUTE must include the testing methods that OEKO-TEX® requires them to include as per relevant OEKO-TEX® GUIDANCE in the accreditation scope of their ISO/IEC 17025 accreditation.

If the INSTITUTE does not include the OEKO-TEX® GUIDANCE in the accreditation scope of their ISO/IEC 17025 accreditation, OEKO-TEX® will revoke the INSTITUTES permission to offer laboratory testing and provide OEKO-TEX® SERVICES.

6.3 Complaint Mechanism

The INSTITUTE must have a documented procedure for receiving, evaluating and deciding on complaints in respect to OEKO-TEX® SERVICES provided. The INSTITUTE must record and track complaints, appeals and the actions taken to resolve them:

- after receiving a complaint, the INSTITUTE must confirm whether the complaint relates to CONFORMITY ASSESSMENT ACTIVITIES for which the INSTITUTE is responsible;
- the INSTITUTE must acknowledge receipt of the complaint and provide a written response to the complainant;
- the INSTITUTE must investigate the complaint and must take appropriate corrective action;
- the INSTITUTE must document the results of the investigation and the corrective action taken;

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- the decision resolving the complaint must be made and approved by a person who is not involved in the CONFORMITY ASSESSMENT ACTIVITIES related to the complaint;
- the complainant must be informed about the results of the complaint process;
- the complainant must be able to remain anonymous during the complaint process.

7. Resource Requirements

7.1 Sales and Distribution System

The INSTITUTE must have a sales and distribution system to sell and market OEKO-TEX® SERVICES.

7.2 Staff Requirements, Capacity and Training

The INSTITUTE must have clear separation regarding employees working on laboratory testing / certification and employees working in research and development (see section 5).

7.3 Mandatory Support for OEKO-TEX® Requests

The INSTITUTE must have adequate response time for information requests coming from OEKO-TEX® regarding CONFORMITY ASSESSMENT ACTIVITIES.

7.4 Laboratory / Audit Capacity

The INSTITUTE must have enough laboratory capacity to guarantee the seamless transition of an OEKO-TEX® CERTIFICATE about to expire into a new OEKO-TEX® CERTIFICATE. It is in the responsibility of the INSTITUTE to guarantee that the OEKO-TEX® CERTIFICATE remains valid at all times if the re-certification process is done correctly by the EXISTING CUSTOMER (see section 8.2).

8. Process Requirements

8.1 Certification

8.1.1 Application

The INSTITUTE must ensure that the customer must provide the INSTITUTE in the application with all necessary information to complete the CONFORMITY ASSESSMENT ACTIVITIES. The application form of the corresponding OEKO-TEX® STANDARD must be used.

The INSTITUTE must evaluate the information received in the application. The INSTITUTE makes sure that the following points are complete and adhered to before starting with the DETERMINATION ACTIVITIES:

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- the information about the customer and the product is sufficient to carry out the respective OEKO-TEX® SERVICE(S);
- there is no discrepancy of understanding between the INSTITUTE and the customer in relation to the OEKO-TEX® SERVICE(S);
- the scope of the intended certification is defined;
- the means to carry out all DETERMINATION ACTIVITIES are available (e.g. testing materials);
- the CERTIFICATION AGREEMENT (see section 8.1.2 "contracting") is concluded.

8.1.2 Contracting

The INSTITUTE must establish a contractual basis with the customer. Integral part of this CERTIFICATION AGREEMENT must include in the minimum:

- the application of the customer;
- the offer issued by the INSTITUTE based on the application of the customer;
- the INSTITUTE General Terms and Conditions, if available;
- the OEKO-TEX® TERMS OF USE;
- data protection provisions (see section 4.5),
- declaration of conformity by the customer, if according to the relevant OEKO-TEX® STANDARD applicable.

The contract must furthermore include clauses such as applicable law and jurisdiction, force majeure, liability, clause for re-certification (see section 8.2) etc.

The INSTITUTE is responsible for the contract management with their EXISTING COSTUMERS.

8.1.3 DETERMINATION ACTIVITIES

DETERMINATION ACTIVITIES must provide a complete set of information regarding the fulfilment of the applicable OEKO-TEX® STANDARD by the OBJECT OF CONFORMITY ASSESSMENT. The output of the DETERMINATION ACTIVITIES is the sum of both the input to the determination function (application, evaluation and contracting) and all the information created by the DETERMINATION ACTIVITY.

The INSTITUTE must have a plan for the DETERMINATION ACTIVITIES in place to enable the CONFORMITY ASSESSMENT ACTIVITIES of OEKO-TEX® STANDARDS.

The INSTITUTE must appoint at least one person responsible to assess and evaluate all information and results related to the DETERMINATION ACTIVITIES. The DETERMINATION ACTIVITIES must be carried out by persons who were not involved in the standard setting procedure of the OEKO-TEX® STANDARDS.

8.1.4 REVIEW ACTIVITIES

The INSTITUTE must appoint at least one person to review and evaluate all information and results related to the DETERMINATION ACTIVITIES. The review must be carried out by persons who were not involved in the DETERMINATION ACTIVITIES.

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REVIEW ACTIVITIES must provide recommendations based on the DETERMINATION ACTIVITIES for the CERTIFICATION ACTIVITIES.

8.1.5 CERTIFICATION ACTIVITIES

The INSTITUTE must appoint at least one person to provide the CERTIFICATION ACTIVITIES based on all information relating to the DETERMINATION ACTIVITIES.

The CERTIFICATION ACTIVITIES must be made by a person or group of persons who were not involved in the DETERMINATION ACTIVITIES.

REVIEW ACTIVITIES and CERTIFICATION ACTIVITIES may be done by the same person.

Upon completion of the CERTIFICATION ACTIVITIES, an OEKO-TEX® CERTIFICATE is issued which includes all means of communicating that fulfilment of the specified requirements of the OEKO-TEX® STANDARD has been demonstrated.

8.1.6 Documentation

The INSTITUTE must provide the customer with certification documentation that clearly conveys or allows for the identification of the following elements:

- the name and address of the certification body;
- the date on which the OEKO-TEX® CERTIFICATE is granted (the date must not be earlier than the date on which the CERTIFICATION ACTIVITIES were concluded);
- the name and address of the customer;
- the test and/or audit report;
- the scope of OEKO-TEX® CERTIFICATE;
- the period or expiry date of the OEKO-TEX® CERTIFICATE.

The formal certification documentation must include the signature of the person(s) at the INSTITUTE that is responsible for the CERTIFICATION ACTIVITIES. To guarantee independence, OEKO-TEX® does not sign this formal certification documentation.

The INSTITUTE must maintain records to demonstrate that all requirements of the certification process have been effectively fulfilled and treat such records as confidential.

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OEKO-TEX® provides a registry of certified customers free of charge that allows for the verification of:

- the date of the OEKO-TEX® CERTIFICATE;
- the validity date of the current OEKO-TEX® CERTIFICATE;
- the identification of the product;
- the identification of the customer;
- the scope of the OEKO-TEX® CERTIFICATE; and
- the current version of the OEKO-TEX® STANDARD under which the product or facility has been certified.

8.1.7 Monitoring

The monitoring function can involve verification audits, unannounced audits or spot-checks in the market by the Institute. The monitoring function depends on the applicable OEKO-TEX® STANDARD.

8.2 Re-Certification

The EXISTING CUSTOMER must issue an application for re-certification 90 days before the OEKO-TEX® CERTIFICATE expires.

The EXISTING CUSTOMER must provide the INSTITUTE with all necessary documentation and testing materials 90 days before the OEKO-TEX® CERTIFICATE expires.

If the EXISTING CUSTOMER fails to do so, the INSTITUTE shall have no liability as defined in the OEKO-TEX® TERMS OF USE if the certificate is not renewed on time and the label-check is set to "expired".

The INSTITUTE must ensure that it has sufficient resources in place (see section 7) to, provided that the EXISTING CUSTOMER has fulfilled their obligations, guarantee that the OEKO-TEX® CERTIFICATE is renewed on time and, if re-certification is successful, the OEKO-TEX® CERTIFICATE remains valid.

Furthermore, the certification process requirements will apply (see section 8.1).

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