OEKO-TEX® ACCREDITATION AGREEMENT

Annex II

Quality Assurance System

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1. Introduction

ANNEX II defines the quality assurance system of the OEKO-TEX® CERTIFICATION SYSTEM in terms of the comparability and harmonisation of the OEKO-TEX® INSTITUTES.

ANNEX II sets out the requirements and obligations to be fulfilled by the INSTITUTE in order to ensure effective quality assurance within the OEKO-TEX® CERTIFICATION SYSTEM. It establishes the framework for the implementation of quality assurance measures and defines the INSTITUTES responsibilities in relation to these measures. Compliance with the provisions of this ANNEX II is essential for maintaining the CERTIFICATE OF ACCREDITATION and the rights and obligations under the ACCREDITATION AGREEMENT.

2. Definitions

Unless otherwise defined hereinafter the Definitions of the ACCREDITATION AGREEMENT apply to this ANNEX II.

3. References

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

4. Round Robin Tests

4.1 Requirements

The INSTITUTE must register to the relevant ROUND ROBIN TEST for analyses which are commercially offered in the framework of OEKO-TEX® SERVICES. Proactive, timely and successful participation is required as per the requirements defined in the relevant OEKO-TEX® GUIDANCE.

4.2 Validation

Compliance with the ROUND ROBIN TEST and the permission to perform CONFORMITY ASSESSMENT ACTIVITIES is described in detail in the relevant OEKO-TEX® GUIDANCE. As a general guidance, outliers are defined through z-scores based on ISO 13528 if not stated otherwise. Missed participation, late submission, non-compliant methodology, false positive findings and insufficient analysis of key analytes are also defined as outlier. The OEKO-TEX® GUIDANCE defines actions to regain permission to perform CONFORMITY ASSESSMENT ACTIVITIES and specifies the relevant quality assurance measures that need to be implemented.

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5. Product Control

5.1 Requirements

The INSTITUTE must carry out product controls in accordance with the applicable OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE. This contains, in particular, proper sampling, documentation, testing and follow-up measures in the event of non-conformities, as well as strict compliance with the number of annual product control amount required by OEKO-TEX®. The INSTITUTE must ensure that product controls are carried out in a consistent, traceable and timely manner.

5.2 Validation

OEKO-TEX® reserves the right to review, validate and assess the INSTITUTES product control activities at any time. For this purpose, the INSTITUTE must provide all relevant information, records and access required to verify compliance with applicable requirements.

6. Audits

6.1 Institute Audit

6.1.1 Requirements

The INSTITUTE is regularly audited concerning their compliance with the OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE. The audit is organized by OEKO-TEX®. The INSTITUTE must proactively support the audit and grant the auditors access to all the areas they may require. The INSTITUTE must ensure that auditors have access to all the information they need. The result of the audit will be provided to the INSTITUTE in form of a report, which can include obligations and recommendations to ensure compliance with OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE. The obligations must be implemented within the timelines provided in the report. OEKO-TEX® may request proof of implementation, which the INSTITUTE must then provide. If the auditor observes the need for additional training, the training effort must be supported by the INSTITUTE. Special audits can be performed if necessary. OEKO-TEX® commits to ensure that the documentation of the audits including, in particular, KNOW-HOW of the INSTITUTE, remain protected under the confidentiality provisions set out in the ACCREDITATION AGREEMENT.

6.1.2 Validation

OEKO-TEX® may determine if and when an audit is necessary and may proactively contact the INSTITUTE about the necessity of an audit. It is the INSTITUTES responsibility to support the auditing efforts and to implement the obligations ensuring the compliance with the OEKO-TEX® STANDARD and OEKO-TEX® GUIDANCE within the provided timelines and improve non-conforming certificates and processes.

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6.2 Spot Visits

6.2.1 Requirements

Spot visits are either announced or unannounced visits conducted by an OEKO-TEX® auditor at and/or of an OBJECT OF CONFORMITY ASSESSMENT. These visits ensure ongoing compliance with OEKO-TEX® STANDARDS throughout the year and validate the accuracy of the information provided in reports. They can be conducted in any country and at any facility holding an OEKO-TEX® CERTIFICATE which includes a visit or audit in the respective OEKO-TEX® STANDARD. The primary focus is on the implementation of obligations that have been imposed to the EXISTING CUSTOMER and have been identified during the previous visit, as well as the overall evaluation of the production site. The visits must be documented with a report. They are not billed to the EXISTING CUSTOMER. The INSTITUTE must support OEKO-TEX® by providing the necessary information and support during the visit.

6.2.2 Validation

If the INSTITUTE is not proactively supporting the spot visits (incl. providing the necessary information, sharing the reports from the previous spot visits to the EXISTING CUSTOMER and monitoring the implementation of the obligations imposed to him) and is not performing the defined follow-up activities or if significant discrepancies between the INSTITUTES report and the situation on-site are observed or if the quality of the last performed company visit is not sufficient, the INSTITUTE must investigate the situation and provide proof that adequate corrective and preventive actions were taken. The outcome of the investigation as well as the defined corrective and preventive actions must be provided to OEKO-TEX®.

In accordance with the OEKO-TEX® TERMS OF USE if an EXISTING CUSTOMER does not comply with their obligation to support the audit, grant access to all the areas the auditor requires and provide access to all the information needed, the issuing of the OEKO-TEX® CERTIFICATE must be refused or an already issued OEKO-TEX® CERTIFICATE may be withdrawn by the INSTITUTE.

6.2.3 Consequences

If access for an audit is refused by the EXISTING CUSTOMER or if significant non-conformities with the applicable OEKO-TEX® STANDARD are observed, the OEKO-TEX® CERTIFICATE may be refused or may be withdrawn.

7. User Management

7.1 Requirements

The qualification and competency requirements for the employees of the INSTITUTE is defined in the OEKO-TEX® GUIDANCE. The INSTITUTE must ensure that only qualified employees are part of the CONFORMITY ASSESSMENT ACTIVITIES. The INSTITUTE must ensure that employees that are not yet trained according to the requirements are supervised accordingly. The INSTITUTE must also ensure that employees that do not have the required competencies and training are

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excluded from CONFORMITY ASSESSMENT ACTIVITIES. It is essential that employees involved in the CONFORMITY ASSESSMENT ACTIVITIES possess deep knowledge of the OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE and that they demonstrate integrity, ethical conduct, and freedom from conflicts of interest. Any compliance breaches must be reported through the OEKO-TEX® WHISTLEBLOWING SYSTEM.

Employees which are working within the OEKO-TEX® CERTIFICATION SYSTEM must be registered in the OEKO-TEX® SYSTEMWIDE DIGITAL PLATFORM. If the OEKO-TEX® STANDARD and OEKO-TEX® GUIDANCE is describing participation in specific training and approval by OEKO-TEX®, the INSTITUTE must ensure that the relevant employees are able to participate.

OEKO-TEX® must keep an internal up to date register of approved employees and limits the access of employees not approved to the OEKO-TEX® CERTIFICATION SYSTEM.

Regular staff evaluations are necessary. OEKO-TEX® must provide trainings. The INSTITUTE must ensure that employees participate and that the INSTITUTE performs internal trainings as well.

7.2 Validation

Employees which do not have the appropriate status cannot participate in the OEKO-TEX® CERTIFICATION SYSTEM. If the INSTITUTE or OEKO-TEX® observes that not suitable employees is part of the OEKO-TEX® CERTIFICATION SYSTEM, immediate corrective action must be taken. The list of employees involved with the OEKO-TEX® CERTIFICATION SYSTEM at the INSTITUTE and the training documentation of these employees must be made available to OEKO-TEX® upon request.

7.3 Consequences

If employees without the correct status are performing CONFORMITY ASSESSMENT ACTIVITIES, the INSTITUTE must immediately take corrective action. The employee must be removed from the CONFORMITY ASSESSMENT ACTIVITIES and the OEKO-TEX® CERTIFICATES that this person has been involved with must be reviewed and reassessed.

8. Review Activities

8.1 Requirements

OEKO-TEX® reserves the right to perform reviews of the documentation made by the INSTITUTE. OEKO-TEX® may request full documentation at any time and without providing a reason to the INSTITUTE. The full documentation must be provided within a reasonable time frame according to the OEKO-TEX® STANDARD and OEKO-TEX® GUIDANCE. The data entry to the OEKO-TEX® SYSTEMWIDE DIGITAL PLATFORM must be performed according to the rules described in the OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE.

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8.2 Validation

The documentation must be evaluated against the OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE which were valid at the time of issuance of the OEKO-TEX® CERTIFICATE. Deviations will be communicated to the INSTITUTE.

9. Cooperation and Information Obligations

9.1 Requirements

The INSTITUTE must cooperate fully with OEKO-TEX® in connection with any reviews, assessments, inquiries or investigations relating to OEKO-TEX® SERVICES and the protection of CONTRACT TRADEMARKS as well as any other contractual obligations towards OEKO-TEX®. The INSTITUTE must provide OEKO-TEX® without delay with all relevant information, documentation and records required for such purposes. Additionally, the INSTITUTE must further inform OEKO-TEX® without delay of any significant events that may affect the integrity of the OEKO-TEX® CERTIFICATION SYSTEM, including, but not limited to, OEKO-TEX® CERTIFICATE withdrawals, limitations of scope, serious non-compliances or other critical findings. Upon request, the INSTITUTE must support OEKO-TEX® in the clarification of cases and the implementation of follow-up measures.

9.2 Validation

In order to ensure effective monitoring within the OEKO-TEX® CERTIFICATION SYSTEM, OEKO-TEX® may request and review relevant information and documentation, review the INSTITUTES handling of certification matters and evaluate the adequacy of the measures taken by the INSTITUTE. To this end, OEKO-TEX® must be granted access to relevant documents and, if necessary, demand appropriate measures and improvements to ensure that the integrity of the OEKO-TEX® CERTIFICATION SYSTEM and the OEKO-TEX® STANDARDS is maintained.

10. Complaint Management

10.1 Requirements

The INSTITUTE must establish, implement and maintain effective procedures for the systematic receipt, documentation, assessment and handling of complaints related to OEKO-TEX® SERVICES. Complaint management must be performed in accordance with the applicable OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE. The INSTITUTE must ensure that complaints are addressed in a timely, consistent and traceable manner and that appropriate corrective and preventive measures are initiated where necessary.

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10.2 Validation

OEKO-TEX® operates a central complaints management and monitoring system to ensure uniform processing and appropriate handling of complaints within the OEKO-TEX® CERTIFICATION SYSTEM. The INSTITUTE must cooperate with OEKO-TEX® in this regard and provide all relevant information, documentation and access requested by OEKO-TEX® that are necessary for the review, evaluation and follow-up of complaints. To ensure the proper functioning of the entire cross-INSTITUTE complaint management, operated by OEKO-TEX®, OEKO-TEX® may review the INSTITUTES complaint management processes and, if necessary, require appropriate measures and improvements to ensure that the complaint management is maintained according to the OEKO-TEX® STANDARD and OEKO-TEX® GUIDANCE.

11. Compliance with Standards, Guidebooks, Guidelines and Directives

11.1 Requirements

The INSTITUTES CERTIFICATION ACTIVITIES must be at all times compliant with the currently valid OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE. The INSTITUTE must follow any instructions or directions to ensure its compliance with OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE issued by OEKO-TEX®, irrespective of the manner in which they are communicated. It is their responsibility to implement updates within the described timelines. This obligation does not affect the independence of the OEKO-TEX® INSTITUTE'S CERTIFICATION ACTIVITIES.

11.2 Validation

The compliance of the INSTITUTES CERTIFICATION ACTIVITIES with the currently valid OEKO-TEX® STANDARDS and OEKO-TEX® GUIDANCE is checked through several measures described in earlier chapters of ANNEX II.

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