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RULES OF PROCEDURE

of the certification body HyCert of the Hygiene Institut des Ruhrgebiets for certification of materials and products in contact with drinking water

1. Purpose

These rules of procedure serve to carry out the conformity assessment procedures of materials and products in contact with drinking water within the framework of the assessment principles laid down by the Federal Environment Agency (UBA) for the harmonisation of the hygienic requirements according to § 17 paragraph 2 and paragraph 3 of the Drinking Water Ordinance as well as the UBA recommendation "Conformity confirmation of the drinking water hygienic suitability of products" (UBA recommendation conformity confirmation). The current versions of the assessment principles and the UBA recommendation "Conformity confirmation" can be viewed at the homepage of the Federal Environment Agency (www.umweltbundesamt.de)

In the following text, the term "assessment basis(s)" is used collectively to refer to the assessment basis and the UBA recommendation Conformity Confirmation.

If the assessment basics are updated or extended to other materials/products by the Federal Environment Agency, these Rules of Procedure shall also apply to them.

The Rules of Procedure describe the general principles and procedures for implementing

- the certification of materials and products according to the above-mentioned UBA recommendation for conformity confirmations,
- tests on the basis of the above-mentioned assessment principles,
- assessments, as described in the recommendation of the Confirmation of Conformity.
- as well as the issuance of the certificate

1.1 Abbreviations

The following abbreviations apply:

- HyCert for certification body of the Hygiene Institute of the Ruhr Area, Gelsenkirchen
- Recommendation on conformity confirmation for "Conformity confirmation of the drinking water hygienic suitability of products".
- TrinkwV for Drinking Water Ordinance,
- UBA for Federal Environment Agency,
- EC for European Community,
- CE for Communauté Européenne (French: European Community),

- GO for Rules of Procedure
- QM for quality management,
- DIN for German Institute for Standardization,
  EN for European Standard
  - IEC for International Electronic Commission,
  - ISO for International Organization for Standardization,
  - DVGW for Deutscher Verein des Gas- und Wasserfaches.

2. Scope

These rules of procedure regulate the relationship between the client (see point 6f.) and the certification body of the Hygiene Institute of the Ruhr Area, Gelsenkirchen (HyCert), with regard to the testing and external monitoring of materials and products in contact with drinking water in accordance with the UBA assessment principles and the UBA recommendation Confirmation of Conformity.

HyCert undertakes to provide access to the certification procedure to all clients who wish to have their materials, products certified in accordance with the UBA Recommendation Confirmation of Conformity and the UBA Assessment Principles for Plastics, Metals and Enamels or Ceramics in Contact with Drinking Water, unless there are important reasons against access to the certification procedure. An important reason exists, in particular, if the access impaired the maintenance of impartiality or financial independence, if access resulted in unreasonable risks for the certification body or if legal requirements prevent access to certification.

To simplify the readability of the Rules of Procedure, persons are always indicated in the masculine form, irrespective of their gender.

3. Independence and impartiality of the certification body

HyCert performs its certification and surveillance tasks independently, free from instructions and free from any internal or external commercial, financial or other influence.

The independence and freedom from instructions of the certification body is regulated and documented by written instructions and declarations of the Hygiene Institute of the Ruhr Area, Gelsenkirchen.
The personnel involved in testing, inspection and certification are not influenced by secondary activities and other tasks, so that their decisions, assessments and the results of their work remain independent and confidentiality is guaranteed.
The management personnel shall provide assurance that, in addition to their management duties, they will perform other activities only to such an extent as to ensure the proper performance of their duties as head/deputy head of the certification body, including product and manufacturing surveillance.

The managing personnel shall ensure that there is no influence by third parties, i.e. by persons and/or groups of persons or institutions interested in the results of his and their employees.

Before submitting a bid, new customers are screened for potential conflicts of interest.

Compliance with the independence and impartiality of HyCert is monitored by an independent body (Committee for Ensuring Impartiality).

4. Disclosure of information to third parties

HyCert publishes on its homepage only those products in a certification directory that have been certified by it. As a rule, the consent is obtained with the certification contract.

The scope of the published data is limited to the content of the respective certificate/confirmation of conformity.

HyCert undertakes to treat any further information with regard to the product to be certified and the production or manufacturing process as strictly confidential and not to pass on or publish any information to third parties without the written consent of the client or the owner.

5. External testing laboratories, assessors and samplers

HyCert cooperates, if required, with selected external testing laboratories and inspection bodies with regard to product-related tests and the assessment of quality assurance systems, in particular with regard to their product-related characteristics. These external testing laboratories and inspection bodies are accredited for these specific tasks and/or have a proven qualification and valid comparable recognition.
These testing laboratories, assessors and samplers are only subcontractors of HyCert and they are not authorized, unless otherwise agreed, to submit offers, statements or information on behalf of HyCert. Furthermore, they are not allowed to issue registration certificates, certificates, test certificates, etc. in the name of HyCert.

6. Application

6.1 General

The client commissions HyCert in the form of a written application with the conformity assessment and certification of the product as well as, if necessary, changes, extensions, summaries of conformity assessment procedures and the resulting attestations, test reports, certificates or conformity confirmations.

With his application, the client authorizes HyCert to use other qualified third-party institutes, assessors and samplers for the testing of a product, the product production and the determination of selected test parameters.

If the conformity assessment procedure also includes the inspection of the production of the product and the control of the customer's self-monitoring, the application shall also specify the relevant manufacturing plant and, if applicable, the contact persons authorized by the company.

An application may relate to a single product or to a product group or product series, but the individual types may differ from each other only in terms of size or appearance and certain design variants or surfaces in contact with water; but not in their chemical composition (formulation) and in the manufacturing process. Multiple models (trade names) and distributors of a product may be considered. A separate application must be submitted for each certificate to be issued.

Prior to the start of the actual certification process, a certification contract is concluded between HyCert and the client, which defines the further rights and obligations between the client and the certification body.

The certification procedure in the sense of the assessment principles as well as the UBA recommendation for conformity confirmation begins with assigning a process number. The process number forms the reference for the following correspondence and other exchange of data.

6.2 Takeover of a product by a third party (distributor certificate)

If a company incorporates another clients material or product into its manufacturing or sales program under its own name, it may also apply to conduct conformity assessment procedures itself.

6.3 Change or extension of certifications

The client notifies HyCert of any modifications to its products that are relevant for certification. HyCert decides on the necessity of an additional conformity assessment.

7. Inspections and tests

7.1 General

Inspections and/or tests of a product are only carried out if a certification agreement has been concluded beforehand between the client and the certification body and a process number has been generated by HyCert.

7.2 Product-related tests

The client, testing laboratory and certification body work together within the framework of an independent contractual relationship. These tests are based on the assessment principles in the respective current edition and the UBA recommendation for conformity confirmation.

7.3 Verification quality-assured product manufacture

The inspectors of HyCert have to check within the scope of the external surveillance whether a suitable quality assurance system is in place at the client that guarantees a quality-assured production of the products/product groups to be certified.

Product-related tests may be required to verify the effectiveness of a quality system.

Verification of quality-assured manufacture shall be carried out in accordance with the requirements of the Recommendation on Confirmation of Conformity, unless other specifications and regulations make it mandatory.

8. Production monitoring

8.1 General

Depending on the selected procedure, inspections of the quality-assured production, external monitoring of the manufacturing plant, tests on products as well as, if necessary, unannounced visits to check and carry out corresponding tests / assessments take place. (For all assessments, tests and, if necessary, detected deviations, point 8 ff. applies).

Changes to the certification requirements are communicated via the homepage of the certification body. HyCert informs the client by e-mail about the changes on the homepage. For this purpose, the client informs HyCert of an e-mail address which can be contacted for this.

purpose and which must be permanently reachable. Changes of this e-mail address have to be communicated to HyCert immediately. The client is obliged to inform himself continuously about the current status of certification requirements and to take necessary measures if necessary.

Interruptions in production do not in principle reduce the frequency of measures for third-party and production monitoring. However, if a measure cannot be carried out in the planned period as a result of a longer production interruption, the client shall inform the certification body of the interruption and the planned resumption of production.

The time intervals between two measures for third-party / production monitoring must not exceed the specifications given in the assessment basis and the UBA recommendation for conformity confirmation by more than three months.

8.2 Suspension of certification

If the certification body has objective evidence from whatever source that certified products, the process or the service are no longer in conformity with the certification requirements, HyCert may issue a written warning to the client to suspend certification and impose conditions (e.g. increased surveillance) until the certification requirements are again met.

Possible conditions are:

- a recall of the products already on the market,
- a comprehensive rework of all affected products,
- comprehensive education of all affected users to point out potential hazards and the possibilities to control them,
- Limitation of the scope of certification,
- Suspension of certification until cessation of the non-conformity by the by the client.

If the client does not provide the mentioned evidence within the period set by HyCert with the reminder to establish the contractual condition, HyCert assumes that the conformity with the requirements of the assessment basis and the UBA recommendation for conformity confirmation is permanently violated (see point 8.3, point 13 and point 14). This may lead to a suspension of the certification.

If HyCert has not granted a certification or has withdrawn a granted certification, the client is not entitled to label the affected products with a reference to the certification. He may no longer place products already marked on the market.
Suspension of certification may also occur if the certificate holder exceeds the surveillance period by more than 90 days in accordance with the requirements of the recommendation for confirmation

of conformity. The client will be notified of the suspension by the certification body in writing, stating the reasons. The client can file a written objection against this measure within 4 weeks.

The suspension of certification will be retracted as soon as the certificate holder has proven that all requirements for the use of the certification mark (file number) are fulfilled. The client will be informed about this measure in writing by the certification body.

If serious deviations in products from which health hazards are to be expected are detected during third-party inspections, certifications or product tests, the respective supervisory authority must be notified by the certification body.

8.3 Special test

If there are well-founded objective indications and/or HyCert has doubts about the conformity of the products placed on the market with the requirements of the assessment basis and the UBA recommendation on conformity confirmation, it may initiate a special test. The decision whether a special test is to be carried out is incontestable for the certificate holder.

The special test is carried out on behalf of HyCert by a test laboratory and/or inspector appointed by HyCert.

The testing laboratory or the inspector informs HyCert about the course and results of the special test.

If the special audit shows that the requirements of the assessment basis and the UBA recommendation for conformity confirmation are not met, HyCert can terminate the production surveillance, withdraw the certificate and inform the public (homepage) about the withdrawal of the certificate.

The certificate holder shall bear all costs of the special audit.

8.4 Cancellation of Production Supervision, Certificate Withdrawal

Production monitoring by HyCert can be terminated in writing by either party. Further details are specified in the certification contract

Subject to corresponding contractual provisions in the certification contract, HyCert may terminate the production surveillance with an immediate effect and withdraw the certificate in particular if:

Vorbehaltlich entsprechender vertraglicher Regelungen im Zertifizierungsvertrag kann die HyCert die Produktionsüberwachung mit sofortiger Wirkung kündigen und das Zertifikat insbesondere entziehen, wenn:

- die Konformität der überwachten Produkte mit den Anforderungen der Bewertungsgrundlagen und der UBA-Empfehlung zur Konformitätsbestätigung dauerhaft verletzt ist,
- Abweichungen nicht fristgerecht behoben werden,
- Änderungen am Produkt oder Qualitätssicherungssystem vorgenommen werden, die zur Folge haben, dass das zertifizierte Produkt nicht mehr den Anforderungen der Zertifizierung entspricht,
- Nachweise für fristgerecht durchgeführte Korrekturmaßnahmen bei festgestellten Abweichungen im Rahmen von Überwachungen / Begutachtungen nicht erbracht werden,
- die Durchführung von Maßnahmen zur Produktionsüberwachung bei Begutachtungen oder Überprüfungen nicht ermöglicht wird,
- die Kennzeichnung (Aktenzeichen) der HyCert missbräuchlich verwendet wird, der Auftraggeber seine finanziellen Verpflichtungen gegenüber der HyCert nicht erfüllt.

HyCert reserves the right to proceed accordingly also in case of other violations of the agreed conditions after setting an appropriate deadline. Furthermore, HyCert may refuse the processing of further orders/applications of this client in the aforementioned cases.

9. Certificates / confirmations of conformity

9.1 Issuance of certificates / confirmations of conformity

HyCert evaluates the incoming test reports or monitoring protocols and issues corresponding certificates / confirmations of conformity if the result is positive.

A certificate or confirmation of conformity contains the essential characteristics of the product, information in accordance with the specifications of the evaluation criteria and the UBA recommen-

dation for confirmation of conformity, including the test and assessment procedures, test bases used and any comments (e.g. instructions for use).

A certificate/confirmation of conformity is always issued in the name of the client, who thus becomes the owner of the certificate/confirmation of conformity.

Separate certificates with different file numbers can be issued for different models of the same product series (matching formulation and production process, different design features) or different distributors of the same product series. Alternatively, the certificate can be issued to the certificate holder and contains separate supplementary sheets in which the different models (article numbers), trade names and distributors are listed in detail. These supplementary sheets are part of the overall certificate. They have the same file number.

In case of withdrawal or suspension of the accreditation of HyCert according to DIN EN ISO/IEC 17065 by the Deutsche Akkreditierungsstelle GmbH (DAkkS), all current certification projects are suspended, as a continuation of the project processing is no longer possible in this case. The certification body informs the respective clients about the situation and initiates the corresponding corrective measures. Upon withdrawal of accreditation as a certification body, the certification contract may be terminated. After the DAkkS has reissued the accreditation, all certification procedures still open at that time will be resumed and processing will be continued.

9.2 Duration of validity of certificates / confirmations of conformity

The validity of certificates / conformity confirmations is based on the up-to-dateness of the data on which they are based (see also point 7) and fulfillment of conformity.

Certificates / confirmations of conformity expire:

- after return by the client, e.g. in case of cessation of production or gross deviations from the specifications of the assessment basis and the UBA recommendation for confirmation of conformity and reclaim by HyCert (see also item 8.2),

- in case of changes in the composition of the material / product or in the processing conditions, which result in non-compliance with the conformity requirements,

- upon termination of the certification agreement between the certification body and the client.

After a certificate/confirmation of conformity has expired, the contracting entity or the distributor no longer affixes the marking or file number to the products concerned (see also points 10 and 11). Goods already marked may no longer be placed on the market. The client or distributor shall not use expired certificates / conformity confirmations and the file number for advertising purposes and shall return these documents to HyCert.

The client shall notify HyCert of the cessation of production or distribution of the products concerned within the scope of the assessment basis and the UBA recommendation for confirmation of conformity.

10. Product identification (file number, HyCert mark)

In case of successful confirmation of conformity by HyCert, the client is entitled to mark his material / product and packaging including product descriptions and technical leaflets with a HyCert marking (file number or HyCert mark with file number).

The file number and the HyCert mark can be withdrawn again by the certification body if

- the certificate has expired in accordance with clause 9.2,

- the marking or the file number or the HyCert mark are misused,

- the client does not fulfill his financial obligations towards the certification body of the Hygiene Institute of the Ruhr Area, Gelsenkirchen or the testing laboratory and/or the auditor/sampler.

11. Registration

HyCert archives electronically and/or on file all accruing data from the issuance of the process number, including the application documents. With the process number, this data can be searched upon request in case of justified interest. The archiving obligations of the client remain unaffected by this.

12. Costs and charges

Grants, amendments, extensions, summaries, of certificates / conformity confirmations are charged according to the HyCert fee list valid at the time of receipt of the application. There is no entitlement to non-payment or repayment of advance payments already transferred if it is determined during the examination and/or the assessment that the procedure will not be concluded positively.

The current list of fees and the General Terms and Conditions (GTC) of the Hygiene Institute of the Ruhr Area, Gelsenkirchen, are taken into account for the HyCert monitoring fees including production monitoring and certificate issuance.

The client shall bear the costs of the entire procedure unless otherwise expressly agreed in writing.

13. Complaint/appeal procedure

An appeal is a request by the applicant or a certificate holder to review the decision made by the certification body with respect to its sought certification status.

Objections must be submitted in writing to HyCert within four weeks of receipt of the certification decision, stating the reasons. HyCert will confirm receipt of formal objections in writing in a timely manner.

A complaint is an expression of dissatisfaction awaiting a response - but in a different sense than an objection, by any person or organization to the certification body regarding the activities of that body or a certificate holder.

An complaintmay be filed by the party directly affected by HyCert's decision as well as by any other party. The complainant must submit the complaint to HyCert in writing, stating the reasons. HyCert will acknowledge receipt of formal complaints in writing in a timely manner.

The certification body is responsible for gathering and verifying all necessary information (as far as possible) to reach a decision on the complaint or appeal. In doing so, results from previous similar processes are taken into account.

At HyCert, there is an Objections and Appeals Committee, which decides on the complaint or appeal within a period of no more than three months and informs the objector or complainant of the decision. The supplier of the product (appellant) has the right to be heard by the Appeals and Complaints Committee.

All proceedings will be handled in a constructive, impartial and timely manner. Persons will not be disadvantaged by the filing, investigation, and resolution of appeals and complaints. Appeals and complaints will be documented, including actions taken to resolve them. If applicable, appropriate corrective action will be taken from the submitted appeals and complaints.

As far as possible, the certification body will inform the complainant or the objector about the result and the termination of the procedure in writing. If the certification body is not the correct contact for a complaint and an appeal, HyCert will inform the appellant or complainant of this, taking into account the above requirements.

14. Disclaimer

The Hygiene Institut des Ruhrgebiets, Gelsenkirchen, the certification body HyCert established with it and its sponsor, Verein des Hygiene-Instituts e.V., are not liable - except in cases of intent and gross negligence - for damages incurred by an applicant, certificate holder or third party due to the granting or non-granting or the extension or modification of certificates due to the termination of production monitoring or due to erroneous or incorrect information in certificates or attestations.

This also applies to pecuniary losses and indirect damages, such as procedural costs or fees arising from disputes under competition law or trademark law. The information in the certificates is based on the information provided by the applicants. Certificate holders use the certificates on their own responsibility.

The certificate holder releases the Hygiene Institut des Ruhrgebiets, Gelsenkirchen, the certification body HyCert established at the Institute and its sponsor, the Verein des Hygiene-Instituts e.V. from any liability arising from or in connection with its use of the certification.

The Hygiene Institut des Ruhrgebiets, Gelsenkirchen, the certification body HyCert established with it and its sponsor, the Verein des Hygiene-Instituts e.V., are not liable for damage resulting

from modifications of certified products that were not brought to the attention of HyCert and reported for inspection.

If it is disputed whether a modification of a product has been made before or after the issuance of a certificate/confirmation of conformity, the burden of proof in this regard rests with the certificate holder or applicant.

15. Quality management manual of the certification body

The quality management (QM) system of HyCert is a part of the QM system of the Hygiene Institute of the Ruhr Area, Gelsenkirchen. The QM system of the Hygiene Institute of the Ruhr Area, Gelsenkirchen, is regulated, documented and archived.

The certification body HyCert maintains a quality management manual (QMHZ) in which the procedures carried out are integrated and updated.

16. Coming into effect

These Rules of Procedure shall come into effect on 02.05.2023
(5th version)