Department of Biological Standardisation, OMCL Network & HealthCare (DBO)
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Terms of Reference of the European Network of Official Cosmetics Control Laboratories (OCCLs)

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Introduction

Since 01 January 2009, the EDQM has been engaged in efforts to strengthen consumer health protection in Europe, with a focus on the safe use and quality of cosmetics. To foster cross-border collaboration, share technical expertise and enhance quality management in each laboratory in accordance with international standards, the European Network of Official Cosmetics Control Laboratories (OCCL) was initiated in June 2010, following the positive outcome of a survey of market surveillance authorities in 18 European countries. Their willingness to engage in scientific and technical collaboration in the field of cosmetics testing and 15 years of experience of the EDQM with the Network of Official Medicines Control Laboratories (OMCL) were the main assets for building a network of official cosmetics control laboratories.

Achievements 2011-2020

Proficiency Testing Scheme (PTS)

Conducting PTS studies is part of a quality management programme to ensure an appropriate level of performance in the different testing laboratories. The OCCL PTS study programme 2011-2020 included the following analytes: hydroquinone in skin bleaching creams, formaldehyde in hair products, thioglycolic acid and *p*-phenylenediamine in hair products, diethylene glycol in toothpaste, phthalates in eaux de toilette, allergens in eaux de toilette, body lotion, shampoo and shower gel, UV filters including titanium dioxide in sunscreens, fluorides in toothpaste, hydrogen peroxide in tooth whitening products, parabens in lipsticks and metals in face cream. These studies are planned and coordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM).

Market Surveillance Studies (MSS)

The Network of OCCLs organises Europe-wide product sampling and testing to check their compliance with European and national regulations as well as to identify risks for consumer safety. With a focus on metals that may give rise to health concerns, several countries collected samples in 2011 of decorative cosmetics (make-up, eye shadow, eye liner, lip gloss, etc.) to measure the content of antimony, cadmium, chromium, lead, mercury and nickel. Traces of some of these metals may be unavoidable for technical reasons.

Furthermore, a specific product group is being closely monitored every year: bubble bath, shampoo, toothpaste and other kinds of products for use by children; the results are then taken up in a database (restricted access). Tooth whitening products were the subject to a dedicated Network campaign. More recently, cosmetics sold as ‘perfume-free’ were checked in several countries for the presence of any allergenic substances. Summaries of the findings for various product groups and overall compliance have been published.

Standardisation of analytical methods

In accordance with Article 12 of Regulation (EC) No 1223/2009, cosmetics are tested with "reliable and reproducible" methods when official methods are not available. To this end, the OCCL Network established the modalities for the proper conduct of validation studies for analytical methods, the so-called "peer reviews".

Successful peer reviews performed according to this procedure led to the publication of methods for the determination of free formaldehyde in cosmetic products (2016) and of hydrogen peroxide in cosmetic products (2016). A peer review of the method for the determination of nitrosamines in nail polish was completed (2020) and publication of the method is imminent.

Resources

Participation in the OCCL Network is open to all Council of Europe States having signed the Convention on the Elaboration of a European Pharmacopoeia[1], which includes the member States of the European Union. Observers to the aforementioned Convention may join the Network and become *associated* members.

In 2020, more than 50 official laboratories follow the network activities.

The work in this Network is accomplished thanks to the voluntary contributions to the overall costs by the Member States' competent authorities. However, scarce resources do not allow all OCCLs to offer the same technical expertise. One of the Network's goals is to promote specialisation (centres of excellence) as an effective strategy to increase the Network capacity to respond to multiple testing needs. Sample exchange between OCCLs and mutual recognition of results build on the trust in each other and in the quality of the work.

External relations

Co-operation with the European Commission, Platform of European Market Surveillance Authorities in Cosmetics (PEMSAC), Joint Research Centre (JRC), European Chemicals Agency (ECHA) and CEN.

[1] States concerned: Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Republic of North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom.

Participation in annual conferences of the General network of Official Medicines Control Laboratories (OMCLs).

Exchange of information with the Health Sciences Authority (HSA), Singapore, National Institute of Food and Drug Safety Evaluation South Korea (NIFDS) under the Korean Food and Drug Administration (KFDA) and the Taiwan FDA (TFDA).

1. OBJECTIVES OF THE NETWORK

The overall objective of the Network is to maximise the protection of consumers by means of strengthening the surveillance of the quality and/or efficacy (*e.g.* sun protection) of cosmetic products at the European level. This is possible by pooling the resources of the Network's laboratories, building capacity and performing Europe-wide market surveillance studies.

The following steps are taken to build and consolidate the network:

- → *Create a link between official control laboratories in different countries that have responsibility for cosmetic products.*
- → *Define basic working methods and develop the necessary tools for an efficient network.*
- → *Disseminate knowledge and best practices among the members.*
- → *Inventory the analytical resources and specialised competences and create a database (EDQM).*
- → *Make available suitably validated analytical methods on cosmetics for use by testing laboratories.*
- → *Share test results.*
- → *Conduct PTS and training sessions as described under Quality Management System (item 6 below).*
- → *Harmonise the approach to market surveillance across Europe.*
- → *Carry out common campaigns across Europe.*
- → *Move towards a system for mutual recognition of results.*
- → *Combine efforts and minimise the presence of harmful substances in cosmetics, even at trace levels.*
- → *Share product safety data in a harmonised and secure manner.*
- → *Respond to emerging risks in the field of cosmetics.*

2. THE NETWORK MEMBERS

The Network is composed primarily of Official Cosmetics Control Laboratories (OCCLs) that are based in member states of the Council of Europe that are signatory parties to the Convention on the Elaboration of a European Pharmacopoeia [1].

Laboratory membership of the Network is based on having an independent status (publicly funded only, absence of conflicts of interest, suitable rules when subcontracting certain types of work) and the fulfilment of the requirements of ISO/IEC 17025:2017 [2].

Other countries may designate an OCCL to become an associated member of the network if they have been granted observer status to the European Pharmacopoeia Commission (e.g. Australia, Canada, Morocco, Singapore, Taiwan FDA, Tunisia or the USA).

3. DEFINITIONS

An *Official Cosmetics Control Laboratory* is a public institution, which performs laboratory testing of cosmetic and other products on behalf of competent authorities and in fulfilment of other national obligations for the purpose of market surveillance, independently from manufacturers.

These laboratories are part of a structure under the aegis of the respective national Ministry of Health (or equivalent) or an independent governmental body.

In the European Union, *cosmetic products* are defined by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 [3]. According to the aforementioned Regulation (Art. 22), “Member States shall monitor compliance with the Regulation via in-market controls” and “shall perform appropriate (…) laboratory checks on the basis of adequate samples.”

4. ROLE OF THE NETWORK MEMBERS, PRACTICAL AGREEMENTS AND DOCUMENTATION

- Role of the Network members

The OCCL Network consists of laboratories as defined above. The Network members define and participate in the activities, carry out experimental work and share their expertise. A competent authority may exceptionally act as a Network member when the testing facilities are not part of the same public services.

The Network members may decide on the creation of advisory committees as necessary to account for greater complexity of Network tasks and activities. Furthermore, ad hoc working groups may be tasked with the elaboration of technical or policy guidance related to PTS schemes, market surveillance or method validation. Terms of reference may be defined for such groups when needed.

The EDQM provides the Secretariat and co-ordinates all the Network activities.

- Practical agreements

Regular (about 2 per year) plenary meetings of the OCCL Network are organised and decisions are taken based on consensus. The working language is English. *The Network members bear the travel and subsistence expenses related to their participation in meetings and events*.

Associated members do not have the right to vote.

- Documentation

Documents such as position papers, guidelines referring to policy issues, technical documents or their revisions must be approved before their implementation, in a written procedure or at the occasion of a plenary or remote meeting.

The EDQM Quality Management System includes instructions and procedures for the Network activities such as the practical organisation of campaigns and collaborative studies (MSS, PTS, peer reviews). These instructions are available at the Secretariat [4, 5, 6] and referenced in the individual study protocol.

5. RELATIONS WITH OTHER ORGANISATIONS, STAKEHOLDERS AND COMMUNICATION

The OCCL Network was established under the aegis of the former Consumer Health Protection Committee (CD-P-SC, dissolved end of 2017) and in accordance with the following goals, set out in their terms of reference: to foster co-operation between the member States and in particular, promoting technical collaboration in the field of market surveillance by Official Cosmetics Control Laboratories (e.g. implementing a quality management system according to international standards, setting up an analytical competence inventory and conducting surveys).

The CD-P-SC was succeeded by the European Committee for Cosmetics and Consumer Health (CD-P-COS). The CD-P-COS was established in January 2018 as intergovernmental steering committee with a dedicated mandate to enhance the control of cosmetics, to identify emerging health risks related to the use of cosmetics and to promote technical collaboration and provide guidance to national authorities. Joint sessions of the representatives of the CD-P-COS and the Network are organised to foster cross-border co-operation of authorities, to identify emerging health threats related to the use of cosmetics, to decide on actions and to monitor their effectiveness.

The OCCL Network is represented at relevant meetings of the European Commission and the Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC), the Joint Research Centre (JRC) and when appropriate, consults the European Chemicals Agency (ECHA) on specific questions in order to safeguard the quality of cosmetic products in the European market.

On questions related to medicines or products on the borderline with medicines (“borderline products”), members of the OCCL Network or the Secretariat contact the

network of Official Medicines Control Laboratories (OMCL), the GEON Advisory Group, and participate to the annual OMCL Network Meeting.

When necessary, contact may also be made with the European Medicines Agency (EMA).

International Organisation for Standardization (ISO) and European Committee for Standardization (CEN) commissions, dedicated to cosmetic products, have led to the development of some new standards on testing methods to help authorities in this work. The OCCL Network may collaborate with CEN and ISO working groups on specific questions.

Consumer organisations such as the European Consumers' Organisation BEUC, or stakeholder organisations such as Cosmetics Europe, may be approached on specific questions when necessary.

It is widely accepted that efforts should be made to avoid conflicts of interest and breaches of independence or confidentiality in relations with the cosmetics industry, wholesalers, importers, other stakeholders or any other partners that may be defined at a later stage.

6. QUALITY MANAGEMENT SYSTEM

Each member laboratory documents its competence and implements an appropriate quality management system. It is the responsibility of the laboratory to carry out its testing activities in such a way as to meet the requirements of ISO/IEC 17025 and the specific guidelines (if any) of the OCCL Network. ISO/IEC 17025 requires that the laboratory uses as much as possible methods published as national, regional or international standards by reputable organisations or in relevant scientific texts or journals. Analytical methods having undergone a successful peer review in the OCCL Network are established as official standards.

For the purpose of testing cosmetics, the laboratory takes into account the guidelines for the selection and/or validation of analytical methods for cosmetics elaborated by the Joint Research Centre (JRC) [5] and decides on the best-fitted analytical approach.

When specific technical competences or resources are not available, the competent authority may request another official control laboratory (OCCL, OMCL) or suitable supplier to carry out certain tasks, ensuring that technical and confidentiality agreements are in place and there are no conflicts of interest. Only laboratories with a suitable quality management system are eligible to perform testing upon authority request.

6.1 Analytical testing methods

6.1.1 Official and standard methods

At the European level, (a small number of) official and standard methods for cosmetic product testing are available from the EDQM and shall be applicable for cosmetics testing,

after verification of their performance under real conditions, taking into account the relevant sample matrices.

Certain other analytical methods have been included in European Directives (e.g. 80/1335/EEC, 82/434/EEC, 83/514/EEC, 85/490/EEC, 93/73/EEC, 95/32/EC, 96/45/EC) or published as “harmonised standard”, the reference of which have been stated in the Official Journal of the European Union (e.g. CEN standard methods).

As a general rule, sampling and analysis shall be performed in a reliable and reproducible manner as laid down for example, in Article 12 of Regulation (EC) No 1223/2009.

When no methods are available from the sources stated above, any methods that have been suitably validated by a reputable technical organisation including reproducibility of the results may be used by suitably equipped network members.

In all cases, OCCLs must ensure that they use the most up-to-date version of the method.

6.1.2 Modified official methods

Considering the great number of prohibited or restricted substances, only few official methods are available for cosmetic product testing. Some of the analytical methods stated in European Directives are no longer considered state-of-the-art and require modification in order to meet pre-established acceptance criteria and to allow the use of improved techniques and equipment.

Where modifications to the original validated method are necessary, these modifications should be justified and some parameters may need revalidation.

6.1.3 In-house methods

In-house methods are developed and validated as appropriate and documented by a single laboratory to show that the methods concerned (quantitative, qualitative determination or screening methods) are fit for purpose. The OCCL network provides an inventory of analytical competences. In-house methods and method descriptions may be shared with other members of the network.

OCCLs perform formal validation studies on newly developed (in-house) methods or when existing methods require modification. The extent of validation studies may vary depending on the test procedure.

6.2 Collaborative studies

Inter-laboratory studies are performed by OCCL Network members and coordinated by the EDQM. Other cosmetics control laboratories that are not members of the OCCL Network may participate, on a voluntary basis, if certain conditions are fulfilled. The applicable terms and conditions are laid down as instructions and operational procedures and are available at the Secretariat. Reference to these quality documents is provided in

the test protocols that are distributed to the participants in corresponding studies (peer review, COS PTS, MSS).

There are three types of collaborative studies performed within the OCCL Network, *i.e.* Proficiency Testing Scheme (PTS), peer review of an analytical test protocol and Market Surveillance Studies (MSS). These inter-laboratory studies pursue the following aims:

- To determine the competency of the laboratories to carry out certain analyses (PTS);
- To diagnose any need for specific technical laboratory training in certain fields of testing (PTS);
- To study the performance parameters of new methods (peer review) and compare them with parameters of well-established methods when appropriate;
- To investigate the quality of a group of certain cosmetic products marketed across Europe (MSS).

Inter-laboratory studies also provide a tool for building trust between laboratories in the OCCL Network and allow moving towards harmonised approaches to cosmetic product surveillance and mutual recognition of test results.

6.2.1 Proficiency Testing Scheme (PTS) studies

Proficiency testing is an external quality control and covers the overall performance of a laboratory. This includes the entire process from reception and storage of samples, the experimental work in the laboratory, the interpretation of results and the transcription of the data and conclusions to the reporting sheets.

The performance of PTS studies within the OCCL Network is an essential tool to demonstrate technical competence of the participant laboratories and, furthermore, to identify steps that need harmonisation (e.g. sample preparation, analysis) or technical improvement.

The scope and frequency of PTS studies are decided during plenary Network meetings and in accordance with the needs of the OCCLs.

The EDQM coordinates the conduct of PTS studies and ensures that the requirements of ISO standard 17043 are met. Statistical evaluation of the analytical results is performed by the EDQM. Instruction IS17/01 provides a detailed operational procedure on the conduct of PTS studies [4].

6.2.2 Peer reviews

Peer reviews aim to establish reproducibility of non-official analytical methods by means of interlaboratory comparison. The principles of method validation are laid down in the JRC guidelines for the validation of analytical methods to test cosmetic products [5].

To respond to the great need for reproducible analytical methods that are accessible to quality control laboratories of health authorities, private testing institutions and industry, results from collaborative analytical trials are used to confirm that a method is fit for purpose and can be recommended for use by suitably equipped and experienced laboratories.

Where a validated in-house method is available from a single laboratory and no official reference method exists, it may be peer reviewed by three or more participants. If reproducibility can be established, the corresponding method description may be published or otherwise made available for quality control purposes by official and private control laboratories as well as the industry.

If there is more than one method, the peer review would be preceded by a selection process to identify the best suited test protocol. Instruction IS17/02 describes an operational procedure for the conduct of peer reviews in the OCCL Network [6].

6.2.3 Market surveillance studies (MSS)

The aims of Market Surveillance Studies (MSS) include:

i) an investigation of the quality of certain cosmetic products or groups of products marketed in several countries or Europe-wide;

ii) an investigation of practical aspects of an analytical approach in use for cosmetics testing.

MSS are performed on the basis of an MSS study programme decided by the Network members in advance during the OCCL plenary meetings. Usually, the study programme covers two years and describes the objective, type of products to be tested, timetables, scientific advice, etc.

A request to conduct a certain MSS can be made by the EDQM or the OCCLs.

Protocols for individual studies and a summary of analytical results are made available on the EDQM extranet. PROC/PR10 of 13/02/2017 provides an operational procedure on the conduct of market surveillance studies for cosmetic products, from the planning stage to the presentation and dissemination of results [7].

6.3 Audits and mutual visits

There are three different types of laboratories recognised within the OCCL Network, depending on their quality system.

6.3.1 Laboratories that are part of the OCCL Network and the OMCL Network

These laboratories have a quality system based on ISO/IEC 17025. They are subjected to Mutual Joint Audits (MJA) within the OMCL Network (and may additionally be accredited,

see below). An MJA covers the laboratory's quality management system, which is checked for compliance with the quality management guidelines established in the OMCL Network and with the requirements laid down in ISO/IEC 17025.

Note: Efforts should be made to implement ISO requirements in a consistent manner for all tested products (medicines, cosmetics, other) when appropriate so that additional audits for the testing of, for example, cosmetic products may be omissible.

6.3.2 Laboratories that have been accredited by a national accreditation body

Some OCCLs are accredited for compliance with ISO/IEC 17025 by a national accreditation body and accreditation includes cosmetics testing.

Where accreditation covers the entire spectrum of a laboratory's cosmetic testing activities, no additional external evaluation is needed.

Note: If the scope of accreditation does not cover all its activities, a laboratory can request that the accreditation body extend the scope. For laboratories that also belong to the OMCL Network, any such activities may be addressed as part of an MJA/MJV.

6.3.3 Laboratories in the process of implementing a quality management system based on ISO/IEC 17025

Laboratories in the process of implementing a quality system based on ISO/IEC 17025 can request assistance (e.g. information, pre-audit visits) from the OCCL Network to develop a quality system that meets the requirements of ISO/IEC 17025.

Note: Laboratories testing medicines in addition to testing cosmetics may be included in the MJA/MJV Programme of the OMCL Network, which provides external evidence that the requirements according to established standards are met.

6.4 Training

The OCCL Network organises training sessions for its members aimed at harmonising the work carried out in the OCCL laboratories, sharing technical expertise among the members and responding to training needs identified e.g. in the proficiency testing scheme.

Work-sharing is an important goal of the Network and is based on availability of appropriate technical expertise when needed.

Furthermore, the requirements of ISO 17025 need to be well understood and implemented in the same manner in all OCCLs; for example, new requirements of ISO 17025:2017 that address risk and opportunities, decision rules or the estimation of measurement uncertainty and the validation of analytical methods.

Participation in OMCL Network training programmes that are relevant to OCCLs (and no restrictions apply) should be pursued. OMCL Network Guidelines (QM, Technical and Policy) that are available on the EDQM website may be applied or suitably adapted.

Training sessions may be organised on site or as webinars. Participation in training sessions is voluntary.

Training may include:

- Tutorials on specific subjects such as QA issues, technical aspects, methodologies, etc.
- Workshops with case studies.
- Site visits dedicated to demonstrating a specific analytical methodology.

7. SPECIALISED LABORATORIES

Market surveillance of cosmetic products in Europe is a challenge due to the great variety of products and substances to be investigated and the diversity of matrices. To optimise surveillance, two or more specialised laboratories pool their analytical resources and expertise (e.g. metal trace testing platforms, nitrosamine testing platforms, etc.).

When a Network member is faced with technical difficulties concerning a specific analytical method or cosmetic product, it may consult the specialists for solutions.

Specialised laboratories may perform testing in the context of market surveillance studies that are coordinated at the European level. The advantage of this approach is that specific concerns could be addressed at a Europe-wide level in a very short time, based on reproducible results for samples of various origins.

8. MUTUAL RECOGNITION OF TEST RESULTS

Mutual recognition of test results is based on common rules among Network members and confidence in each other's competence and quality of the work. Duplication of work can be avoided if information on national activities and results are shared that form the basis for surveillance decisions.

Where no official reference exists for analytical methods, common technical acceptance criteria are defined in order to facilitate comparison of analytical findings of cosmetic products on the market.

9. REFERENCES

[1] European Treaty Series (ETS) – No. 50 – Convention on the Elaboration of a European Pharmacopoeia, Strasbourg, 22.VII.1964

[2] ISO/IEC 17025:2017. General requirements for the competence of testing and calibration laboratories

[3] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009

[4] Instruction IS17/01 of 18 September 2017 (as amended) on the Management of the Proficiency Testing Scheme for cosmetic products (COS PTS)

[5] Report EUR 27284. JRC Guidelines for 1 – Selecting and/or validating analytical methods for cosmetics 2 – Recommending standardization steps for analytical methods for cosmetics, 2015. ISBN 978-92-79-48534-3 (PDF)

[6] Instruction IS17/02 (as amended). Plan, implement and coordinate a peer review of an analytical method to test cosmetic products *(in preparation*)

[7] Procedure PROC/PR10 of 13/02/2017 (as amended). Plan, implement and coordinate Market Surveillance Studies for cosmetic products (COS MSS)