Department of Biological Standardisation, OMCL Network & HealthCare (DBO)

Consumer Health Protection

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Terms of Reference of the European Network of Official Cosmetics Control Laboratories (OCCLs)

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FACT SHEET

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 set up in June 2010. 15 years of experience of the EDQM with the network of Official Medicines Control Laboratories (OMCL) were an asset in the set up phase.

In 2010, the EDQM had surveyed 18 European countries on their willingness to engage in collaboration to exchange scientific and technical expertise in the field of cosmetics testing and received significant support for building a network of official control laboratories.

In 2015, more than 30 official laboratories participate in regular network activities including laboratories in 19 Member States of the European Union. Participation is open also to other Council of Europe States having signed the Convention on the Elaboration of a European Pharmacopoeia[1].

Achievements 2011-2014:

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 2011-2014 included the following analytes: hydroquinone in skin bleaching creams, formaldehyde in hair products, thioglycolic acid in hair products, diethylene glycol in toothpaste, allergens and phthalates in eaux de toilettes and UV filters in sunscreens. These studies are carried out under the aegis of the European Directorate for the Quality of Medicines and HealthCare (EDQM). Participants are based in 31 national laboratories in Austria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Ireland, Luxembourg, the Netherlands, Portugal, Serbia, Slovakia, Slovenia, Sweden and Turkey.

Market Surveillance Studies (MSS)

Following a discussion in the network in 2011, several countries collected samples of decorative cosmetics (make-up, eye-shadow, eye liner, lip gloss, etc.) to measure the content of certain metals that may give rise to health concerns: antimony, cadmium, chromium, lead, mercury and nickel. Traces of some of these metals may be unavoidable for technical reasons but, in most countries, maximum tolerable limits have not been set.

Products for use by children (bubble bath, shampoo, toothpaste, etc): various products were sampled and tested; the results have been taken up in a database (restricted access). A summary of results and conclusion will be published.

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

The above achievements have been made possible thanks to the voluntary contribution 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), exchange samples and results between OCCLs and build on mutual trust and recognition of results.

External relations

Cooperation with the European Commission, PEMSAC-AM, Joint Research Centre (JRC) and CEN.

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

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

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 and performing Europe-wide market surveillance studies.
The following steps are needed to build a network and to keep it operational:

- → *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.*
- → *Inventory the analytical resources and competences and create a database (EDQM).*
- → *Make available suitably validated analytical methods on cosmetics for use by testing laboratories.*
- → *Disseminate knowledge and expertise among the members.*
- → *Share competences and test results.*
- → *Conduct PTS and training sessions as described below under Quality Management System.*
- → *Harmonise the approach to market surveillance across Europe.*
- → *Carry out common campaigns across Europe.*
- → *Move towards a system for mutual recognition of results.*

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.
Competent Authorities for the market surveillance of cosmetic products may also become members (see under "2. Objectives").
Laboratory membership of the Network is based on having an independent status (publicly-funded only, absence of conflicts of interest, suitable rules when sub-contracting certain types of work) and the fulfilment of the requirements of *ISO/IEC 17025:2005*.
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, Morocco, Canada, Singapore or USA). Associated members do not have the right to vote or to request defrayal of expenses.

3. DEFINITIONS

An *Official Cosmetics Control Laboratory* is a public institution, which performs laboratory testing of cosmetic and other products as appropriate for a Competent Authority for the purpose of market surveillance, independently from a manufacturer. The Competent Authority provides the laboratory with a clear mandate, ensures the absence of any conflicts of interest and specifies their responsibilities and specific duties.

Each laboratory is 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.
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. NETWORK STRUCTURES AND RULES OF PROCEDURE

The OCCL Network consists of laboratories as defined under paragraph 3 above.
The EDQM provides the Secretariat and co-ordinates all the Network activities.
Regular plenary meetings of the OCCL Network are organised and decisions are taken based on consensus.
The creation of advisory committees may be considered in the future as necessary to account for greater complexity of Network tasks and activities (*e.g.* with a focus on policy issues, technical guidelines, *etc.*). In this case, a specific document will define the terms of reference for each of those groups.
All elaborated documents (position papers, guidelines referring to policy issues, technical documents) or their revisions must be agreed on and adopted during the plenary meetings before their implementation.
The rules of procedures for the Network address the practical organisation of plenary meetings, the frequency of meetings, responsibilities of the Network members, the organisation of dedicated seminars to enhance technical progress in certain areas, working language (English), voting and appointment procedures, deadlines, reimbursement of expenses, archiving, *etc.* are presented in PART II [will soon be made available from the EDQM as a separate document].

5. RELATIONS WITH OTHER ORGANISATIONS, STAKEHOLDERS AND COMMUNICATION

The OCCL Network has been established under the aegis of the Consumer Health Protection Committee (CD-P-SC) 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 supports the work of the OCCL Network and monitors the work progress. The OCCL Network reports to the Committee of Experts on Cosmetic Products (P-SC-COS), the subordinate body of the CD-P-SC, which is dedicated to cosmetics.
The OCCL Network interacts and co-operates with the European Commission and the Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC) and the Joint Research Centre's Institute for Reference Materials & Measurements (IRMM) 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, contact is made with the network of Official Medicines Control Laboratories (OMCL) through the Advisory Group GEON, the annual OMCL Network Meeting or the OMCL Network Secretariat.
When necessary, contact may also be made with the European Medicines Authority (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 uniformly 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 should document its competence and implement 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.
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)[2] and decides on the best fitted analytical approach:

6.1 Official and standard methods

When analytical methods are included in a European Directive (e.g. 80/1335/EEC, 82/434/EEC, 83/514/EEC, 85/490/EEC, 93/73/EEC, 95/32/EEC, 96/45/EEC), they are considered 'official' and shall be applicable for cosmetics testing without any further method validation.

According to Article 12 of Regulation (EC) No 1223/2009, sampling and analysis shall be performed in a reliable and reproducible manner. In the absence of any applicable Community legislation, reliability and reproducibility shall be presumed if a method used is in accordance with relevant harmonised standards that have been published in the Official Journal of the European Union (e.g. CEN standard methods).
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 procedures may be used by suitably equipped network members. (*e.g.* peer-reviewed OCCL test procedures).
Prior to cosmetic product testing, the laboratory verifies performance under real conditions, taking into account the relevant sample matrices.
In all cases, OCCLs must ensure that they use the most up-to-date version of the method.

[2] the document will soon become available on the JRC website.

6.2 Modified official methods

Considering the great number of prohibited or restricted substances, only few official methods are stated in European legislation on cosmetic products. Some of these methods 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.

6.3 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 in-house methods and method descriptions may be shared with other members of the network.

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

6.4 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 terms and conditions of these participations are laid down in PART III [will be made available by the EDQM as a separate document].
Collaborative studies pursue the following aims:

- To determine the competency of the laboratories to carry out certain analyses.
- To study new methods and to compare the relevance of them with existing ones.
- To validate the suitability of methods by studying the performance parameters (such as the robustness of the method and the precision and accuracy of the results).
- To investigate the quality of a group of certain cosmetic products marketed across Europe (and in the countries concerned).
- To diagnose any need for specific technical laboratory training in certain fields of testing.

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.
There are two types of inter-laboratory studies performed within the activities of the OCCL Network, *i.e.* Proficiency Testing Scheme (PTS) and Market Surveillance Studies (MSS).

6.4.1 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. A detailed procedure for planning and conducting PTS studies can be found in PART III [will be made available by the EDQM as separate document].

6.4.2 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.

A detailed general procedure which can be found in PART III [will be made available by the EDQM as separate document], describes the performance of an MSS from the planning stage to the presentation and dissemination of results (and the ownership of the data produced).

6.5 Audits and mutual visits

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

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 usually subjected to Mutual Joint Audits (MJA) within the OMCL Network. These audits cover the quality management system and, also, the technical competence of the laboratory to perform analytical testing of pharmaceuticals.
Note: For such laboratories, efforts should be made to ensure consistent application of these ISO guidelines to medicines and cosmetics where appropriate. In this way, additional specific audits for the testing of cosmetic products may be omissible if the testing competence of a laboratory has been readily subjected to an MJA by suitably trained technical auditors.

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 or address any such activities as part of MJA/MJV of the OMCL Network.

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 and OMCL networks to develop a quality system that meets the requirements of ISO/IEC 17025.
A detailed procedure for requesting assistance may be added in PART III.

Note: The MJA/MJV Program of the OMCL Network may facilitate the implementation of a new quality management system for OCCL laboratories and provides external evidence that the requirements according to established standards are met.

6.6 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, the estimation of measurement uncertainty and validation of analytical methods.
To this end, the need for training on specific topics should be evaluated regularly and tutors for specific topics identified amongst the members of the OCCL Network.
Training sessions may be held at the EDQM premises or at an OCCL or any other institution. 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. Depending on the need, workshops on specific themes, presented as case studies, may be organised by the Secretariat. The number of participants, the location of the meeting, *etc*., can be decided on an ad hoc basis by the Secretariat or a member may raise the issue during a scheduled meeting of the OCCL Network.
- 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, specialised platforms of at least two or three reference laboratories could be created to pool analytical resources and expertise (*e.g*. allergen testing platforms, preservative testing platforms, *etc*.).
When one laboratory is faced with technical difficulties concerning a specific analytical method, it may consult the specialists for solutions. It would also be possible to ask for assistance when faced with analytical challenges related to certain products.

Finally, specialised laboratories may perform testing in the context of market surveillance studies that are coordinated at the European level. The advantage of this approach would be that specific concerns could be addressed at a Europe-wide level in a very short time, based on reproducible results for samples from different origins that were obtained by only two or three laboratories.

8. MUTUAL RECOGNITION OF TEST RESULTS

Mutual recognition of test results is based on common rules amongst 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 acceptance criteria are defined in order to facilitate comparison of analytical findings of cosmetic products on the market.