

International Cooperation on Cosmetics Regulation (ICCR) - Standard Operating Procedures

Document Change Control

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1. INTRODUCTION

ICCR is a voluntary international group of cosmetics regulatory authorities whose mission is to maintain the highest level of global consumer protection, while minimizing regulatory barriers to international trade. As part of its portfolio of activities, the ICCR may engage in information sharing, regulatory cooperation, training, and other activities aimed at advancing science and knowledge internationally in this area.

ICCR's focus is primarily on cosmetics, but will also include some quasi-drugs, over-the-counter (OTC) drugs and natural health products marketed for cosmetic purposes (by virtue of their national or jurisdictional legal definition). In addition, ICCR will address advances in technology as they relate to cosmetics safety.

Further to the Terms of Reference (ToR) for ICCR, this document is intended to describe operating principles of ICCR, the roles and responsibilities of its participants, and its activities. Many principles are clearly outlined in the Terms of Reference and are not repeated here, unless elaborated upon.

2. ICCR OPERATIONAL STRUCTURES¹

ICCR Members² consist of regulators from Brazil³, Canada, European Union, Japan and the United States. While each Member holds the ultimate responsibility for implementation of ICCR initiatives, it is recognized that successful implementation requires a constructive dialogue with the regulated community, represented by the cosmetics industry trade associations and other stakeholders, as appropriate.

The operational structures under ICCR are described in detail throughout this document, and are as follows:

- Steering Committee (SC)
- Industry Group (IG)
- Observers
- Working Groups (WGs)

2.1 Steering Committee (SC)

2.1.1 Membership

The ICCR SC is composed of individuals from the regulatory authorities that make up the ICCR Members as outlined in the ToR.

¹ More detailed information can be found under section 5 on Deliverables.

² As new countries transition to be member of the SC based on the criteria, the SC members will be updated.

³ Brazil (ANVISA) transitioned to a member of the SC in 2014.

The collective participants' expertise should reflect the range of products that are within the scope of the ICCR. The inclusion of other members and their appropriate status can be decided by consensus of the SC.

2.1.2 Responsibilities

The Steering Committee (SC) will provide overall strategic guidance and direction to the activities of ICCR, will define subject areas for ICCR, and decide on future topics of work.

The responsibilities of the SC members include, but are not limited to:

- Chair the SC by rotation, providing direct staff support as secretariat during chairmanship period
- Enter into dialogue with industry and other stakeholders
- Communicate via email, teleconferences, and in-person as necessary, in order to efficiently manage ICCR work
- Participate in the development of ICCR policy and management
- Where appropriate, seek prior approval or positions from regulators in their home jurisdiction
- Contribute to decision making by consensus, on behalf of their jurisdictions
- Appoint experts to Working Groups
- Participate in all meetings including teleconference calls
- Adopt policies and guidelines of ICCR as applicable
- Share information and experiences on issues of common concern
- Produce and review documents, review project proposals, commit to completing action items and provide progress updates

2.1.3 Chair

The SC Chair leads the proceedings of the SC, including facilitating face-to-face meetings, teleconferences, or videoconferences. The SC Chair works closely with the SC Secretariat, SC members, Observers, the Industry Group and its Chair, and other stakeholders as necessary.

The SC Chair is from the jurisdiction that will host the ICCR annual meeting. The Chair rotates amongst jurisdictions each year starting at the end of the previous meeting and concludes at the adjournment of the meeting held in their jurisdiction.

The SC Chair will also communicate the efforts and accomplishments of the ICCR initiative and inform interested stakeholders of ICCR activities and outcomes.

The Chair will be allowed to represent his or her member regulatory body with full decision-making privileges.

2.1.4 Secretariat

The SC will be supported by the Secretariat, whose function will be to act as an administrative point of contact to facilitate and coordinate work of the ICCR SC and its Chair by undertaking such tasks as disseminating information and coordinating meetings.

The SC Chair may identify one or more individuals from their regulatory body to hold the role of the ICCR SC Secretariat. The SC Secretariat will receive instructions from and report directly to the SC Chair and his/her staff.

2.1.5 Meetings

The SC will conduct work mainly via e-mail, teleconference, and an annual face-to-face meeting, but may alter the frequency of meetings if considered necessary to ensure progress.

In order to efficiently advance work, the SC will engage in quarterly regulator teleconferences hosted by the SC Chair, throughout the year. In addition, the SC will have joint quarterly teleconferences with the Industry Group. ICCR Observers can participate in these teleconferences after the initial attendance of ICCR annual meeting.

To allow ample time for review, any document, work item, progress report, update or proposed agenda item to be discussed at the meeting should be received by the SC Chair a minimum of three (3) weeks before the meeting or teleconference.

The **ICCR Annual Meeting** format may include the following types of sessions:

- SC only
 - Each ICCR jurisdiction is normally allowed up to 3 representatives at the table during the annual meeting; however, if product jurisdictions cross more than one regulatory body, an additional representative may be seated at the table. In addition, according to the agenda topics, each jurisdiction may bring additional representatives, knowledgeable in the topics to be discussed.
- SC and ICCR Observers - Regulators
 - Observing regulators – allowed up two (2) seats at the table
- SC, Observers and IG meeting (Dialogue Meeting):
 - ICCR Members - for each jurisdiction, a total of three (3) IG seats at the dialogue table are allocated per ICCR jurisdiction. Jurisdictions with more than one participating Industry Trade Associations (ITA) in the IG will be allocated four (4) seats at the table during annual meetings. Other IG representatives may attend the meeting at the discretion of the SC Chair.
 - ICCR Observers - regulators and respective ITA(s) may participate in the Dialogue Meeting and will be allocated up to two (2) seats each at the table for both the regulatory jurisdiction and ITA (total of 4 seats).
- Other possible dialogue between SC and other stakeholders.

It is strongly encouraged that Observer representatives from both the Regulator and the Industry be present at the Annual Meeting. In the event that only one party can attend, it is

appropriate that only the Regulators participate. It would not be appropriate that the Industry side is solely present at the Annual Meeting.

The ICCR SC will determine, by consensus, the agenda and duration of the annual meeting.

The meeting venue will rotate among the Members' jurisdictions on an annual basis.

Additional face-to-face meetings may be considered and could be held on the borders of another international conference, provided that there is a consensus of the ICCR SC.

2.2 Industry Group (IG)

2.2.1 Membership

The IG is composed of Industry Trade Associations (ITAs)⁴ of each ICCR jurisdiction. The ITA(s) of the Observers jurisdiction may also participate and be engaged in the activities of the IG.

2.2.2 Responsibilities

The role of the IG is to gather input in order to represent all affected industry sectors on specific issues during meetings or teleconferences with the SC. The IG may suggest work items for priority actions to be considered by the ICCR SC and will provide information on those potential work items well in advance of meetings or teleconferences as requested. Items should be submitted to the Chair and Secretariat, a minimum of three (3) weeks before the meeting or teleconference.

When specific topics warrant the need, IG membership may be extended to other relevant associations, provided that there is agreement by the ICCR SC.

The IG may nominate, where requested by the SC, representatives for Joint Working Groups.

2.2.3 Chair

The IG Chair leads the proceedings of IG meetings and works closely with the SC Chair and Secretariat, IG members, the ITA(s) and other stakeholders as necessary.

The IG Chair rotates among the ICCR jurisdictions on an annual basis, from the same jurisdiction as the SC Chair. The IG Chair must be an IG member. The IG Chair is allowed to represent his or her ITA.

⁴ If the IG is composed of multiple ITAs, it is understood that there is "one voice" per IG per jurisdiction.

2.2.4 Meetings

The frequency and content of IG meetings are at the Group's discretion. The IG participates in the Dialogue Meeting during the annual face-to-face ICCR meetings and in quarterly joint teleconferences with the SC.

2.3 Observers

2.3.1 Membership

ICCR Observers are representatives from the regulatory and ITA(s) of the jurisdiction who meet the criteria outlined in "Requirements for ICCR Observers" available on the ICCR website.

A cosmetic regulatory authority that would like to be an ICCR Observer must make an official request to participate to ICCR activities by contacting the respective ICCR Chair (please consult <https://www.iccr-cosmetics.org/>).

Once an observer request is accepted, the corresponding ITA representatives can participate to the IG activities.

2.3.2 Responsibilities

ICCR Observers are expected to actively participate in ICCR Working Group(s), as appropriate.

Observers do not participate in the ICCR decision making process.

Reference documents for ICCR Observers are available on the ICCR website:

- 1) Process for ICCR Observer to transition to ICCR Steering Committee Member
- 2) Requirements for ICCR Observers

2.3.3 Meetings

The principal regulatory representative(s) of the Observer country will actively participate in the quarterly teleconferences and Annual Meeting of ICCR.

2.4 Working Groups (WG)

2.4.1 Creation/Termination/Renewal

The SC establishes WGs to undertake specific activities, which shall be described in a WG Terms of Reference (WG ToR), following the structure in Annex I. In creating a WG, the SC shall consider whether the proposed activities fit the goals of the ICCR. Topics and work of the WGs are not expected to require regulatory changes to ICCR's jurisdictions.

The WG will be responsible to prepare and draft the WG ToR. WGs shall have narrow mandates and specific activities that must be approved by the SC. The SC may discharge a WG, instruct it to redefine its mandates, charge it with a new task, redefine the deliverable, or request that a new chair be appointed by the WG. WGs shall be disbanded upon completion of their mandate.

2.4.2 Membership

The SC shall determine the size and overall composition of the WG. At the discretion of the SC, a WG may be composed of regulators, industry representatives, observers and/or interested stakeholders. Examples of WG types are:

- WG-Regulators only
- WG-Industry only
- WG- Regulators and Industry: Joint WG (JWG)

Members should be considered and selected based upon their expertise in the specific subject matter and should be nominated by their respective jurisdiction, and, where appropriate, the ITA. Nominations are provided to the SC Chair and/or Secretariat. The Members will be equally represented on a WG, unless this right is waived by the SC member for a specific jurisdiction. If no expert is nominated from a specific regulatory jurisdiction, the SC member representing that jurisdiction will by default become a member, and thus be notified of all communications from that group.

Membership of WGs shall generally be small in number and shall provide a balance of regulators and industry and geographic jurisdictions, as appropriate. Members shall represent their respective nominating organization, and reflect those policies in the WG, not their personal opinions. The number of experts per industry group is not limited, but each party's experts count as one voice, and are expected to express the same opinion.

Observers can participate in WGs, as appropriate. Observing ITA of a given jurisdiction can send an expert to WGs as appropriate, provided that their Regulator counterparts also participates in that WG.

In exceptional cases and upon endorsement of the SC, a WG may allow other individuals with appropriate knowledge and expertise to participate in a WG meeting(s) as an external observer/expert.

2.4.3 Responsibilities

In conjunction with the WG ToR, participants' responsibilities include, but are not limited to:

- Participating in meetings, working via email, teleconferences, and in-person meetings, as necessary in order to most efficiently conduct ICCR work,
- Liaising with their home organization or constituency in order to communicate the efforts and accomplishments of the WG initiative, and
- Producing papers and reviewing project proposals, committing to completing action items and reporting on progress made.

2.4.4 Co-Chairs

WG participants appoint their Co-Chairs (one from the regulators and one from industry) and develop a work plan based on the ToR of the specific WG. The SC will be informed of the proposed WG Co-Chairs and reserves the right to make an alternate recommendation for the appointment. The Co-Chairs of a WG must be endorsed by the SC.

The WG Co-Chairs will lead activities of the WG, including running of teleconferences, videoconferences and any face-to-face meetings, if required, and prepare a short summary of key action items for all WG members following each call. The Co-Chairs will work closely with the SC, IG, Observers and other stakeholders as necessary.

WG Co-Chairs are responsible for the development of the WG workplan, and for obtaining agreement from WG members, for endorsement by the SC. The WG Co-Chairs should provide periodic reports on the progress of the group's work, or more frequently upon request by the ICCR SC. WG Co-Chairs should be prepared to respond to SC questions or concerns with the direction or function of a WG. Additionally, Co-Chairs will inform WG members of any SC feedback or decisions regarding the WG's activities. Should a WG Co-Chair be unable to fulfill his/her term, he/she should promptly notify the SC.

2.4.5 Meetings

WGs shall generally give preference to electronic communication tools (e.g. e-mail, teleconferencing or videoconferencing) but in exceptional cases, WG may meet to carry out the tasks assigned to them when SC approves. Meetings, as well as their specific format are at the option of the WG Co-Chairs. All WG members or their alternates must participate in WG meetings. In the absence of representation by all ICCR jurisdictions, a quorum of the WG is not convened and no official recommendations can be made. Presentations, status updates and progress report shall be prepared and forwarded to the SC Chair and Secretariat a minimum of three (3) weeks prior to ICCR Annual meeting, teleconferences or upon request. Reports will then be forwarded to the members of the SC. All decisions and subsequent work actions must be done on a consensus basis.

Other Stakeholders

Other stakeholders, and/or designated subject matter experts may be invited to ICCR meetings at the discretion of the SC Chair, in consultation with the SC.

Interested stakeholders may propose new items of work under ICCR. For each item, a project proposal form must be submitted to the SC Chair. A template entitled "New Work Item Proposal Form (Annex II)" can be obtained from the SC Chair or Secretariat. Work items proposed must align with the goals of ICCR, must have relevance to all ICCR jurisdictions and must not require legislative and/or regulatory amendments to effect changes.

3. QUALIFICATIONS

Participants in the ICCR process must be comprised of individuals committed to its success, have the qualifications and experience needed to adequately represent their jurisdictional body, and have the willingness and authority to devote the time and energy required to see these goals to fruition.

4. DECISION MAKING

A consensus-based approach is also expected for the deliverables of the WGs among members, observers and industry.

The SC is the ultimate decision maker of ICCR. All decisions are reached by SC members using a consensus-based approach, which means general support and an absence of any major objection. Each ICCR SC jurisdiction will have one voice, regardless of the number of participants representing a given ICCR jurisdiction.

5. DELIVERABLES

Depending upon the deliverable, each member will decide upon the applicability and potential implementation within its respective jurisdiction, according to its own jurisdictional processes. Following acceptance by the SC and posting of the final deliverable to the ICCR website, each member may take further steps (i.e. publish a guideline, initiate regulatory adoption). The ICCR logo will be displayed on final deliverables. See Annex III for an example of the report template.

6. WORKING LANGUAGE

The working language of ICCR is English.

Annex ITemplate for Terms of Reference for Joint Working Groups⁵

ICCR-XX⁶ TERMS of REFERENCE <i>Joint Working Group Name</i>

1. Background**2. Mandate****3. Deliverable****4. Membership**

Each of the five jurisdictions will have the option to nominate experts, at least one representing regulators and one representing industry, as well as Observers who have expressed their interest in participating to the JWG (regulators and industry representatives). In the case of multiple industry nominations, members are to speak with a united voice. Additional subject matter experts may be invited to participate at the discretion of the JWG Co-Chairs.

Overall expertise for the JWG membership should include those with knowledge and experience in some of the following: *to be completed accordingly*.

Subject matter experts should have company/association/government/university commitment to support active participation in the JWG.

The work of the group will be completed primarily by teleconference or e-mail. Should there be a need for a face-to-face meeting, it will be agreed beforehand amongst JWG members and subsequently endorsed by ICCR Steering Committee.

5. Costs

Members are responsible for the costs of conference calls and any associated travel.

⁵ Template also applies to Regulators only or Industry only Working Groups

⁶ Cycle to be added

6. Joint Working Group Participants

Regulators – Members

<i>Jurisdiction</i>	<i>Institution</i>	<i>Name</i>	<i>E-Mail</i>
<i>Brazil</i>			
<i>Canada</i>			
<i>Europe</i>			
<i>Japan</i>			
<i>United States</i>			

Industry - Members

<i>Jurisdiction</i>	<i>Industry Trade Association</i>	<i>Name</i>	<i>E-Mail</i>
<i>Brazil</i>			
<i>Canada</i>			
<i>Europe</i>			
<i>Japan</i>			
<i>United States</i>			

*Co-Chairs

Regulators - Observers

<i>Jurisdiction</i>	<i>Institution</i>	<i>Name</i>	<i>E-Mail</i>

Industry - Observers

<i>Jurisdiction</i>	<i>Industry Trade Association</i>	<i>Name</i>	<i>E-Mail</i>

Annex II



New Item Proposal Form

Date of proposal:
1. Contact information:
2. Brief overview (no more than 50 words) of the proposed new item: e.g. Identifying common key criteria for what are considered nanomaterials in cosmetics for the purposes of the cosmetics regulation.
3. Is this topic new to ICCR? NEW ESTABLISHED
4. Does this topic meet the Terms of Reference for ICCR⁷ ? YES NO Explain:
5. Rationale 5.1 <i>Describe issue in detail</i> 5.2 <i>Describe applicability to all ICCR jurisdictions</i> 5.3 <i>Describe anticipated outcomes</i>
6. Accepted by ICCR Steering Committee YES NO Rationale:

⁷ICCR Terms of Reference are available here: <https://www.iccr-cosmetics.org/about-us/>

Annex III
Report template

1. Cover



**REPORT FOR THE
INTERNATIONAL COOPERATION ON COSMETICS REGULATION**

REPORT TITLE

Authors:

XXX (1), XXX(2); *XXX (3), XXX(4)#, ...⁸

1. Name of Regulator⁹
2. Name of Industry Trade Association
- 3.

#Co-chairs

*Former Joint Working Group member

⁸The order of the authors should be the same as the list with the respective Regulators and Industry Trade Associations.

⁹Include the Regulators of the ICCR member in alphabetical order, followed by the Regulators of the Observers in alphabetical order. Follow the same structure to list the Industry Trade Association.

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5. TITLE RELATED TO THE SPECIFIC CONTENT.....X

 5.1 Subtitle (if necessary).....X

 5.1.1 Subtitle (if necessary).....X

6. DISCUSSION.....X

 6.1 Subtitle (if necessary)..... X

 6.1.1 Subtitle (if necessary).....X

7. CONCLUSION (to include next steps, recommendations, etc. if necessary).....X

8. REFERENCES.....X