



FORM 1: PROPOSAL FOR A NEW FIELD OF TECHNICAL ACTIVITY

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Proposer ISO Copolco	ISO/TS/P 302

A proposal for a new field of technical activity shall be submitted to the ISO Central Secretariat, which will assign it a reference number and process the proposal in accordance with the [ISO/IEC Directives Part 1, Clause 1.5](#). The proposer may be a member body of ISO, a technical committee, subcommittee or project committee, the Technical Management Board or a General Assembly committee, the Secretary-General, a body responsible for managing a certification system operating under the auspices of ISO, or another international organization with national body membership. Guidelines for proposing and justifying a new field of technical activity are given in the [ISO/IEC Directives Part 1, Annex C](#).

Proposal (to be completed by the proposer)

Title of the proposed new committee (The title shall indicate clearly yet concisely the new field of technical activity which the proposal is intended to cover).
Menstrual products
Scope statement of the proposed new committee (The scope shall precisely define the limits of the field of activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned).
Standardization in the field of menstrual products, covering all products intended for both single and multiple use, regardless of material.
<input checked="" type="checkbox"/> The proposer has checked whether the proposed scope of the new committee overlaps with the scope of any existing ISO committee
<input type="checkbox"/> If an overlap or the potential for overlap is identified, the affected committee has been informed and consultation has taken place between proposer and committee on i. modification/restriction of the scope of the proposal to eliminate the overlap, ii. potential modification/restriction of the scope of the existing committee to eliminate the overlap.
<input type="checkbox"/> If agreement with the existing committee has not been reached, arguments are presented in this proposal (under question 7) as to why it should be approved.

Proposed initial programme of work. (The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall, therefore, show the relationship between the subject proposed. Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, characteristics, other requirements, data to be supplied, test methods, etc.). Supplementary justification may be combined with particular items in the programme of work. The proposed programme of work shall also suggest priorities and target dates.)

In terms of suggesting a priority among the different aspects of menstrual products we suggest that the first standard proposal to be developed is a general requirement standard focusing on the general safety, performance, and health requirements from the user's perspective. Following that other aspects should be handled, such as environmental aspects, disposal, and manufacturing.

We suggest that all manufactured menstrual products intended for collecting or absorbing menstrual blood or discharge during the menstrual cycle are to be covered by this new standardisation field. This includes pads, tampons, cups, panty liners ect.

Attached to this form is an outline of the first new work item proposal, which will serve as discussion base at the first meeting with the new TC.

We anticipate the 36 months track to develop this first standard.

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal (This may be combined with the "Proposed initial programme of work" if more convenient).

See above.

A listing of relevant existing documents at the international, regional and national levels. (Any known relevant document (such as standards and regulations) shall be listed, regardless of their source and should be accompanied by an indication of their significance.)

Africa				
Country/Region	Authority	Standard Name	Parameters Covered	Others
East African Community (Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda)	East African Standards Committee	EAS 96-1:2008 Sanitary towels Specification- Part 1: Disposable	Construction, performance, hygiene	Uganda standard for reusable pads DUS 1782: 2017 Kenya KS 507: Sanitary towels
Ethiopia	Ethiopian Standards Agency	ES 6345:2018 Part 2: Disposable	Construction, performance, hygiene	ES 6346:2018 Part 2: Reusable
UNECA and AU	African Organization for Standardization	DARS 653:2017 Sanitary towels		DARS 1575 Textiles — Reusable sanitary towels
South Africa	South Africa Bureau of Standards	SANS 1043:2010	Size and construction, performance, hygiene, sterility and autoclavability	SANS Draft for Reusable pads
Zimbabwe	Standards Association of Zimbabwe	ZWS 730:2015 Manufacture of Sanitary Pads		ZWS 1023: Reusable sanitary pads

Asia				
Country/Region	Authority	Standard Name	Parameters Covered	Others
India	Bureau of Indian Standards	IS 5405:2019	Construction, performance, hygiene, biocompatibility, compostability	Reusable pads, menstrual cups under development
Sri Lanka	Sri Lanka Standards Institution	SLS 111 Sanitary Towels		
Pakistan	Pakistan Standards and Quality Control Authority	PS: 1449-1979		
Bangladesh	Bangladesh Standards and Testing Institute	BDS 1261:2016 Sanitary Towels Mandatory		
Nepal	Nepal Bureau of Standards and Metrology	Under development with recent advocacy		
Cambodia, Vietnam	Institute of Standards of Cambodia; Vietnam Standards and Quality Institute			

Others - Reference				
Country/Region	Authority	Standard Name	Parameters Covered	Others
United States	US FDA	Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) Classified as non-significant risk (NSR) medical devices	Materials, performance, Hygiene (staph, TSST-1 for tampons, normal vaginal flora), Toxicology	Includes disposable pads, tampons, washable cloth pads and intra-labial pads
Japan	Pharmaceuticals and Medical Devices Agency	The Standards for Marketing Approval of Sanitary Napkins Notification PFSB No.0325-17, March 2015 Sanitary napkins classified as 'Quasi-drugs'	Colour fastness, pH, fluorescence, absorption, exudation, adhesion etc., Safety profile of 150 materials used in a sanitary napkin (including those that should not come in contact with skin or mucosa)	
China	Bureau of Standards, Metrology and Inspection	CNS 9324:2004 Feminine sanitary napkins		

Additionally published national standards:

SANS 1812, the manufacture of washable, reusable sanitary towels was published 2020.

AS 2869:2008 Tampons – Menstrual. This standard is also referenced in the national regulation (see below).

GB/T 8939-2018 Sanitary absorbent pads (panty liner)

TIS 295-2560 (2017) Sanitary napkins as a national standard covering the aspects of menstrual health or products

Within the EU there is a voluntary label manufacturers can apply for, called the ECOlable. In Europe there is also an association of the nonwovens and related industries (EDANA) who has developed a code of practice for tampon manufacturers and a guide for supply chain information for absorbent hygiene care products.

There are no ISO/IEC standards that address this issue specifically. There are, however, as stated above a number of national, regional and industry level standards that address the issue to an extent, albeit, on a level that arguably is insufficient both in terms of scope of the standards and their areas of application (the types of products they include), the reach of the standards themselves (what and how they guide) and geographically (the number of consumers they protect worldwide).

Regulations: Menstrual products are mostly categorised as Medical device, therapeutic goods or consumer products in different countries and regions. For example, in most European countries they fall under the General Product Safety Directive which means there is no obligation for manufactures to list the composition of the product or perform biocompatible testing. Whereas in the USA menstrual products are considered a medical device, with additional testing requirements. There are also countries that classify menstrual products in other categories, for example the legislation in Thailand covering this area is the Ministry of Public Health’s Cosmetic Act. In Australia there are specific legislation for tampons, where all tampons on the internal market need to comply with Therapeutic Goods (Standards for Tampons) (TGO 103). In Japan menstrual products are included in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

Given the complex and different classification situation around the world, and in many instances lack of clear requirements international standards in this field can help bridge the gap where regulations are not clear or strong enough.

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables. (The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized. If seemingly similar or related work is already in the scope of other committees of the organization or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)

There is no ISO/IEC committee working specifically with menstrual products. The material used in menstrual products, for example nonwoven, cotton, plastic, silicone and the adhesives used are subjects in international standardization work but there is no group working in ISO/IEC directly with menstrual products as their focus.

It is noteworthy that there is a current momentum regarding both the matter of menstruation, especially in terms of destigmatizing it and raising it to the public agenda as an important question to discuss, as well as in terms of standardization. For example, menstrual product standardization is discussed within and between organizations, both non-governmental and corporations around the globe(Reproductive Health Supplies Coalition, 2020)¹.

We do not see there is an overlap with any existing ISO/IEC committee and propose to create a new TC for menstrual products.

¹ Reproductive Health Supplies Coalition. 2020. Standards for Disposable Sanitary Pads (Menstrual Health Standards Webinar Series). Available online: <https://www.rhsupplies.org/activities-resources/webinars/standards-for-disposable-sanitary-pads-menstrual-health-standards-webinar-series-149/>.

A listing of relevant countries where the subject of the proposal is important to their national commercial interests.

Menstrual products are used by half of the world's population, everyday 300 million people menstruate.

Most people who menstruate do so between three to seven days each month for about 40 years,² which amounts to around 2400 days in a lifetime, meaning a person is expected to use between 12,000 and 15,000 sanitary pads, tampons, and panty liners in a lifetime. Having access to safe products is a prerequisite to being able to participate and contribute to society fully, which benefits the individual and society at large.

In the committee internal ballot within ISO Copolco the following 55 countries approved to proceed with the suggested new field, showing a strong support. Only 1 country disapproved.

Algeria (IANOR)
Argentina (IRAM)
Australia (SA)
Bahrain (BSMD)
Barbados (BNSI)
Bolivia, Plurinational State of (IBNORCA)
Botswana (BOBS)
Brazil (ABNT)
Canada (SCC)
China (SAC)
Colombia (ICONTEC)
Congo, The Democratic Republic of the (OCC)
Costa Rica (INTECO)
Denmark (DS)
Ecuador (INEN)
Ethiopia (ESA)
Fiji (DNTMS)
France (AFNOR)
Germany (DIN)
India (BIS)
Indonesia (BSN)
Jamaica (BSJ)
Kazakhstan (KAZMEMST)
Kenya (KEBS)
Korea, Republic of (KATS)
Malawi (MBS)
Malaysia (DSM)
Mali (AMANORM)

² Friedmann, I. 2017. Mens. 1177 *Vårdguiden*. Available online: <https://www.1177.se/Skane/Fakta-och-rad/Sjukdomar/Mensbesvar/>.

Mauritius (MSB)
Mexico (DGN)
Mongolia (MASM)
Morocco (IMANOR)
Nigeria (SON)
Norway (SN)
Panama (COPANIT)
Philippines (BPS)
Romania (ASRO)
Russian Federation (GOST R)
Rwanda (RSB)
Serbia (ISS)
Singapore (SSC)
Slovenia (SIST)
South Africa (SABS)
Sri Lanka (SLSI)
Sudan (SSMO)
Sweden (SIS)
Switzerland (SNV)
Thailand (TISI)
Trinidad and Tobago (TTBS)
Tunisia (INNORPI)
Turkey (TSE)
Uganda (UNBS)
United Kingdom (BSI)
United States (ANSI)
Zimbabwe (SAZ)

A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s). (In order to avoid conflict with, or duplication of efforts of, other bodies, it is important to indicate all points of possible conflict or overlap. The result of any communication with other interested bodies shall also be included.)

There are different organisations around the world that work extensively with breaking stigma around menstruation, highlighting the importance of talking about this openly, the right for all to access safe products and being able to participate fully in society. To mention a few, UNFPA³, UNICEF⁴, UNHCR⁵, Plan International⁶ and WASH United⁷ work with such matters. By bringing the issue to ISO we lift the status and take the next step in the process of making a practical difference for consumers around the world. Work is also being conducted in specific countries where the issues of the lack of rules and standards have surfaced. We see the importance to invite these global advocacy organizations to the work.

From the manufacturer side:

- EDANA– association for the nonwovens and related industries that develop industry standards. It is important to invite them and collaborate to avoid conflicting recommendations.

These ISO committees have been identified as possible collaboration partners, however not overlapping in scope:

- ISO/PC 243, ISO 10377 Consumer product safety – Guidelines for suppliers
- ISO/TC 173, Assistive products for persons with disability, Subcommittee SC 3, Aids for ostomy and incontinence – as they deal with products that are very similar to some menstrual products, they most likely have a lot of knowledge to be gained for the standardization of menstrual products such as testing methods on materials and their effects on vaginal health, so communication is important to avoid overlap and inefficiency.
- ISO/TC 157, Non-systemic contraceptives and STI barrier prophylactics – the relevance of this committee is dependent on the degree to which the standards pertains to condoms' effects on the vagina.
- ISO/PC 325 Sex Toys- Design and safety requirements for products in direct contact with genitalia, the anus, or both – As this group also deals with a consumer product in sensitive parts of the body.
- ISO/TC 194 Biological and clinical evaluation of medical devices – and especially parts of the ISO 10993-series.
- ISO/TC 61/SC 11 Products, especially related to ISO 19699-1 Superabsorbent polymer -- Sodium polyacrylate resin for absorbing blood -- Part 1: Test methods
- ISO/TC 210 Quality management and corresponding general aspects for medical devices especially relating to ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes

³ UNFPA. (2019). Menstruation is not a girls' or women's issue – it's a human rights issue. Available online:

<https://www.unfpa.org/news/menstruation-not-girls-or-womens-issue-%E2%80%93-its-human-rights-issue>

⁴ UNICEF. (2019). Guidance on Menstrual Health and Hygiene. Available online:

<https://www.unicef.org/wash/files/UNICEF-Guidance-menstrual-health-hygiene-2019.pdf>

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) and how they will each benefit from or be impacted by the proposed deliverable(s).

A wide range of stakeholders should be involved in this work, we see it as important that both industry, NGOs, international organisations, testing institutes, governmental agencies, medical professions, and consumer organizations are represented.

Manufacturers - both large and small can by participating in this work show transparency and respect to their consumers. Standards can facilitate innovation by providing a foundation of safety requirements on which to build new products, enabling for companies to spend their resources more efficiently on product development rather than figuring out how to deal with product safety.

Consumers - it will be easier for consumers to distinguish between products that hold certain quality. Consumers must assess whether products suit one's needs in terms of access to privacy, time and hygienic possibilities to change and dispose of alternatively empty one's product. Standards would facilitate such an assessment.

NGO and international aid organizations - international standards can facilitate the procurement of menstrual products by for instance relief organizations. Today, a lack of such standards instead inhibits efficient procurement thereof, placing menstruators in especially vulnerable positions without proper access to menstrual products.

Governments - at the moment there are several countries who have decided to supply menstrual products for free to their citizens (e.g. Scotland, New Zealand). A clear international standard could support this too, as there would be clear quality requirements for governmental procurement bodies to request.

Another instance where an international standard can alleviate procurement issues is by simply specifying the nature and use of products, which enables countries to import them. There have been occurrences where countries have burned menstrual products at border customs due to the lack of standards.

An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.

The Swedish Institute for Standards (SIS) commits to provide the necessary secretariat support and leadership for this TC if approved.
We also propose Mrs Gerda Larsson as chair for the future TC.

⁵ UNHCR. (2019). Institutional Survey on Menstrual Hygiene Management. Available online: <https://wash.unhcr.org/download/institutional-survey-on-menstrual-hygiene-management/>.

⁶ Plan International. (2020). *Menstruation*. Available online: <https://plan-international.org/sexual-health/menstruation>

⁷ Wash United. (2020). WASH advocacy and education, with a focus on menstrual hygiene and human rights. Available online: <https://www.wash-united.org/>.

Purpose and justification for the proposal. (The purpose and justification for the creation of a new technical committee shall be made clear and the need for standardization in this field shall be justified. Clause C.4.13.3 of [Annex C](#) of the ISO/IEC Directives, Part 1 contains a menu of suggestions or ideas for possible documentation to support and purpose and justification of proposals. Proposers should consider these suggestions, but they are not limited to them, nor are they required to comply strictly with them. What is most important is that proposers develop and provide purpose and justification information that is most relevant to their proposals and that makes a substantial business case for the market relevance and the need for their proposals. Thorough, well-developed and robust purpose and justification documentation will lead to more informed consideration of proposals and ultimately their possible success in the ISO IEC system.)

Please see the attached justification, submitted, and approved by ISO Copolco.

Signature of the proposer

Dan Nilsson, Head of Standardization, SIS dan.nilsson@sis.se

Dana Kissinger-Matray, Secretary of ISO/COPOLCO, kissinger@iso.org

Further information to assist with understanding the requirements for the items above can be found in the [Directives, Part 1, Annex C](#).

ISO/TC /SC N

Date: 2021-04-14

ISO/WD :2021(E)

ISO/TC /SC /WG

Secretariat:

Menstrual products — General safety, performance, and health requirements

Élément introductif — Élément central — Élément complémentaire

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Document type: International Standard
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Document stage: (20) Preparatory
Document language: E

STD Version 2.9p

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Contents	Page
Foreword.....	3
Introduction	4
1 Scope.....	4
2 Normative references	4
3 Terms and definitions.....	5
4 Risk analysis.....	6
5 Health and safety requirements	6
5.1 General.....	6
5.2 Materials.....	6
5.2.1 Material safety	6
5.2.2 Chemicals	6
5.2.3 Scents, bleach, and, dyes	6
5.3 Biocompatibility.....	6
5.4 Material release.....	6
5.5 Sterilization and contamination	6
6 Performance requirements.....	6
6.1 Fitness to purpose.....	6
6.2 Performance evaluation and labelling.....	6
7 User information.....	6
7.1 General.....	6
7.2 Packaging and labelling.....	6
7.3 Instructions of use	6
7.4 Ingredient disclosure.....	6
7.5 Information of disposable	6
7.6 Cleaning and maintenance of multi-use products	6
Bibliography.....	7

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee [or Project Committee] ISO/TC [or ISO/PC] ###, [name of committee], Subcommittee SC ##, [name of subcommittee].

This second/third/... edition cancels and replaces the first/second/... edition (ISO #####:#####), which has been technically revised.

The main changes compared to the previous edition are as follows:

— xxx xxxxxxxx xxx xxxx

A list of all parts in the ISO ##### series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Most people who menstruate do so between three to seven days each month for about 40 years, which amounts to around 2400 days in a lifetime meaning a person is expected to use between 12,000 and 15,000 sanitary pads, tampons, and panty liners in a lifetime. To manage menstruation menstrual products, exist to enable menstruators to carry on with their normal lives, as much as possible. Menstrual products are used on or inside the body by those who have access to and can afford them. However, important to remember is that access is not guaranteed anywhere in the world, including developing countries.

While most other products that are intended for such intimate use, such as incontinence products, condoms, plasters and wound dressings, are highly regulated, tested and monitored, there is a lack of regulation and standards that ensure the safety of the contents and physical properties of menstrual products for both people and the planet.

This international standard is one step among other initiatives worldwide to ensure consumers have the possibility to make informed choices when choosing the products which fit their purpose the best, always knowing it is safe to use.

Standards can facilitate innovation by providing a foundation of safety requirements on which to build new products, enabling for companies to spend their resources more efficiently and focus on other aspects of product development than product safety. In turn this enables new companies and products to access the market.

Additionally, international standards can facilitate the procurement of menstrual products by for instance relief organizations. Today, a lack of such standards instead inhibits efficient procurement thereof, placing menstruators in especially vulnerable positions without proper access to menstrual products.

Menstrual products — General safety, performance and health requirements

1 Scope

This document specifies safety, performance, and health requirements for menstrual products from a user perspective.

This document covers products intended both for single and multiple use, regardless of material.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO ab-c:201x, General title of series of parts — Part c: Title of part

ISO xyz (all parts), General title of the series of parts

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

menstrual product

manufactured products intended for collecting or absorbing menstrual blood or discharge during the menstrual cycle

3.2

menstrual health

state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity, in relation to the menstrual cycle

3.3

user

text of the definition

[SOURCE: EN xyz:199x, term number]

4 Risk analysis

5 Health and safety requirements

5.1 General

5.2 Materials and physical properties

5.2.1 Material safety

5.2.2 Chemicals

5.2.3 Scents, bleach, sensation, and dyes

5.3 Biocompatibility

5.4 Material release

5.5 Sterilization and contamination

6 Performance requirements

6.1 Fitness to purpose

6.2 Performance evaluation and labelling

7 User information

7.1 General

7.2 Packaging and labelling

7.3 Instructions of use

7.4 Ingredient disclosure

7.5 Information of disposable

7.6 Cleaning and maintenance of multi-use products

Bibliography

- [1] Lättöppnade förpackningar
- [2] Julie Hennegan, Inga T. Winkler, Chris Bobel, Danielle Keiser, Janie Hampton, Gerda Larsson, Venkatraman Chandra-Mouli, Marina Plesons & Thérèse Mahon (2021) Menstrual health: a definition for policy, practice, and research, *Sexual and Reproductive Health Matters*, 29:1



Annex B – Template for new key area submissions

New Suggestions for ISO/COPOLCO Activity

Template

SUBJECT:

ISO COPOLCO welcomes all suggestions for topics of consumer concern which might be addressed by International Standardization.

This template allows us to more easily consider these.

It may be that, at this stage, not all aspects are relevant to your proposal. However, the more you complete, the better. If you are unsure or need help, please contact the ISO COPOLCO Secretariat who will assist you.

Please fill Part B if you would like the project to become a new COPOLCO Key Area.

Please submit the template to the ISO COPOLCO Secretariat (copolco@iso.org).

Thank you



SUGGESTING NEW ISO COPOLCO ACTIVITY – GUIDANCE

A. Complete a pre-submission check to ensure that:

- ✓ All sections of the form are complete as far as practicable.
- ✓ The need for the standard and its benefit to the public interest are fully articulated.
- ✓ Personnel, resources and timeline are shown.
- ✓ Any supporting documentation is attached to the proposal.

B. Seek guidance from the ISO/COPOLCO Secretariat to ensure all sections of the template have been completed to requirements.

C. Submit the completed proposal with all supporting documents by e-mail to the ISO/COPOLCO Secretariat.

TEMPLATE

Part A. New suggestions for COPOLCO activity

Standard for menstrual product safety

1. Proposer's Details

Name: Anna Sjögren
Email: anna.sjogren@sis.se
Telephone: +46855552087
Associated National Standards Body (NSB)/Organization: Swedish Institute for Standards, SIS

2. Description of consumer issue

What is the consumer issue?
What evidence do you have (for example: statistics, consumer detriment)
What is the consumer interest(s), such as: safety and health, performance, fitness for purpose, likely stakeholders (for example children, older persons and persons with disabilities), information, environment, and developing countries?
Does this issue require action at the international level?

In short, the consumer issue is that a lack of standards limits consumers' ability to determine the safety and health, performance and fitness of purpose of menstrual products. This consumer group is substantial, as half of the world's population are potential menstruators and are likely to be users of commercially manufactured menstrual products. And estimated 300 million people menstruate every day. Menstrual products are manufactured products intended for collecting or absorbing menstrual blood or discharge during the menstrual cycle.



COPOLCO WG 2 Key areas

- A. Product safety and health: The safety of these products is of significant concern, as they are intended for use inside the body in contact with mucous membranes, alternatively in contact with sensitive skin for long periods of time and for repeated use for up to 40 years. Today there are no overarching standards that address all the different types of menstrual products available on the global market although the market is made up of a few (1-4) large producers who sell their products all over the world¹. Due to the lack of a global standard, consumers have limited or no ability to make an informed choice regarding the safety, performance or fitness to purpose of the products. It is highly noteworthy that such products are not standardized.²
- B. Product performance and fitness for purpose: Menstruators require products that ensure that menstruation does not interfere with one's regular life when menstruating. Otherwise menstruators will be subject to inequalities such as limited attendance at school or decreased income due to absence from work. Consumers must assess whether products suit one's needs in terms of access to privacy, time and hygienic possibilities to change and dispose of, alternatively empty one's product. Standards would facilitate such an assessment, as the only option currently is trial and error. Since 'error' may imply that the product leaks causing visible staining, which can lead to public disgrace due to the unfortunate stigma on menstruation, this is a large social risk to take.
- C. Destigmatization and gender equality: The stigma on menstruation and menstrual products has detrimental effects on menstruators both mentally and structurally, as the discovery of a person as menstruating often causes them to be seen as discredited³. According to for instance Carvalho (1997), "[...] the very fact that women were menstruating was used to keep them 'in their place'" Furthermore, research shows that standardization can have a destigmatizing effect on stigmatized products⁴. Thus, standardization can contribute to destigmatization, which in turn can facilitate greater gender equality.
- D. Environmental considerations and benefits: with growing awareness of the environmental impact of our everyday behavior, consumers continuously search for more sustainable alternatives including in the area of menstrual products. There are a large number of environmental concerns regarding especially disposable menstrual products, which hold around 97 % of the world market. To name a few, these include the chemicals used in the development process, in plastic applicators and polyester linings, including pesticides in cotton plantations (25 % of all pesticides in the USA are used on cotton), which have harmful long-term effects on the ecosystem. Further, the vast amount of resources that go into a product used for 5-8 hours and that is thereafter thrown out for good are overwhelming⁵. Additionally, in order to stimulate the development of more sustainable menstrual products, disposable and re-usable alike, and to facilitate for consumers to distinguish between more or less sustainable alternatives, a standard that incorporates comparison in terms of sustainability parameters would be beneficial.

¹ Euromonitor International. 2020. Sanitary Protection in World – Datagraphics. Available Online: <https://www.portal.euromonitor.com/portal/analysis/tab>

² The Swedish Chemicals Agency. 2018. Survey of hazardous chemical substances in feminine hygiene products. Available Online: <https://www.kemi.se/en/publications/reports/2018/report-8-18-survey-of-hazardous-chemical-substances-in-feminine-hygiene-products>

³ Carvalho. 1997. The Social Construction of Menstruation: A Historical Study of Menstrual Product Advertising. Available Online: http://journals.cambridge.org/abstract_S0165115300023299.

⁴ Clair, Daniel & Lamont. 2016. Social Science & Medicine Destigmatization and health: Cultural constructions and the long- term reduction of stigma. Available Online: https://scholar.harvard.edu/files/lamont/files/destigmatization_and_health_lamont_clair_daniel.pdf

⁵ Especially when considering that takes 20,000 liters of water to grow 1kg of cotton and that it takes 500-800 years for a disposable menstrual product to decompose while more than 12 billion pads and tampons are disposed of annually. Not to mention the huge number of menstrual products that are flushed down the toilet, blocking sewers and ending up along coastlines or as microplastics contaminating the sea. According to a study performed by Anglian Water, 41 % of UK women flush their tampons down the toilet without knowing that they should not. Newman, L. & Cogdell, C. (2018). Raw Materials in Sanitary Pads, *Design Lifecycle*, Available Online: <http://www.designlife-cycle.com/sanitary-pads/>.



COPOLCO WG 2 Key areas

- E. Access and innovation: because of the homogeneity among menstrual products on the market today, for those with access to menstrual products at all, it is not uncommon that they are dissatisfied by available options. Large companies tend to develop products for the greater mass, thus those consumers with needs that go beyond the general public have difficult time finding such options. Hence, innovation in order to meet smaller, more specific consumer segments is needed. Standards can facilitate innovation by providing a foundation of safety requirements on which to build new products, enabling for companies to spend their resources more efficiently on product development rather than figuring out how to deal with product safety.



3. Need for an international standard

Why do you think an international standard might be useful in addressing the issue?

An international standard would be useful in addressing the issues identified above, as requirements of testing and transparency can reduce the information asymmetry between producers and consumers regarding product safety (pertaining to health as well as environmental safety), performance and fitness to purpose. This should increase consumers' ability to make an informed choice, with the fundamental principle that all consumers should have this right. Additionally, standardizing menstrual products can have a destigmatizing effect, which can increase gender equality. These matters should be addressed on an international level, since, as previously mentioned, they apply to all consumers of these products, globally.

Simultaneously, specifying the requirements for producers to place safe products on the market might contribute to lowered entry barriers for producers wanting to enter the market and stimulate innovation by reducing the resources they need to spend on searching for safety requirements. This further reduces the time to market, which is likely to increase the profitability and ability for producers to place more products on the market, that are increasingly adapted and segmented to different user groups' needs and preferences. Hence, international standards can be beneficial for consumers, not least directly through increased product safety, but also indirectly through a potentially increased number and variation of products on the market that suit them better.⁶

Further, international standards can facilitate the procurement of menstrual products by for instance relief organizations. Today, a lack of such standards instead inhibits efficient procurement thereof, placing menstruators in especially vulnerable positions without proper access to menstrual products⁷. Another instance where an international standard can alleviate procurement issues is by simply specifying the nature and use of products, which enables countries to import them. There have namely been occurrences where countries have burned menstrual products at border customs due to the lack of standards. While national standards can address this, it can be argued that it is much less efficient that each and every country, alternatively region, around the world creates its own standard.

Furthermore, due to the stigma on menstrual products and historical neglect of issues pertaining to this product category, it is unlikely that countries, regions or producers will in fact initiate such a process, further reinforcing the lack of standards and ability for consumers to assess and access product safety, performance, and fitness to purpose.

Finally, standards on menstrual products can aid both companies and governments in their work toward a number of the Sustainable Development Goals (SDGs). Unfortunately, menstruation is not mentioned, specifically, under any of the SDGs, nonetheless, the matter can be connected to several of them and standards on menstrual products can drive the sustainable development in these areas. The most significant points include SDGs 1 (no poverty), 3 (health and well-being), 4 (quality education), 5 (gender equality), 6 (clean water and sanitation), 10 (reduced inequalities) and 12 (responsible consumption and production)⁸. Increasing all consumers' access to safe menstrual products and helps to reduce period poverty⁹ and/or inequality.

⁶ Klintner. Forthcoming in 2021. Normalizing the Natural: A study of menstrual product destigmatization (Unpublished doctoral dissertation. Lund University. Lund. Sweden. Available from <https://www.lub.lu.se/en/lund-university-libraries>.

⁷ Roedel, Cabrera-Clerget, Yamakoshi. 2019. Guide to menstrual hygiene materials. Online Access: <https://www.unicef.org/wash/files/UNICEF-Guide-menstrual-hygiene-materials-2019.pdf>.

⁸ ISO. 2020. How ISO Standards Help Meet the SDGs. *ISO: Standards*. Available online: <https://www.iso.org/sdgs.html>.

⁹ 'Period poverty' means being unable to access menstrual products and having poor knowledge of menstruation often due to financial constraints. In the UK, 1 in 10 girls cannot afford to buy menstrual products, while 1 in 7 have struggled to afford them, according to a representative survey of 1,000 girls and young women aged 14-21 (Plan International UK, 2017).



4. Benefit to consumers or the public interest

What is the added value for consumers/public interest of the work? Check that your proposal fits COPOLCO's terms of reference:

- *Terms of reference*
 - To study means of helping consumers to benefit from standardization, and means of improving consumer participation in national and international standardization.
 - To provide a forum for the exchange of information on the experience of consumer participation in the development and implementation of standards in the consumer field, and on other questions of interest to consumers in national and international standardization.
 - To advise ISO Council as to the consolidated viewpoints of consumers on matters relevant to ISO's current and potential standardization and conformity assessment work.
 - To advise ISO Council on the need for new or revised policies or actions within ISO as they relate to consumers' needs.

Most people who menstruate do so between three to seven days each month for about 40 years,¹⁰ which amounts to around 2400 days in a lifetime meaning a person is expected to use between 12,000 and 15,000 sanitary pads, tampons, and panty liners in a lifetime. In order to manage menstruation these (and other) products exist to enable menstruators to carry on with our normal lives, as much as possible. Menstrual products are used on or inside the body by those who have access to and can afford them. What may be important to remember is that access is not guaranteed anywhere in the world, including developing countries. For example, one in ten menstruators in the UK lack such access¹¹. While most other products that are intended for such intimate use, such as incontinence products, condoms, plasters and wound dressings, are highly regulated, tested and monitored, there is a lack of regulation or standards that ensure the safety of the contents and physical properties of menstrual products for both people and the planet.¹²

A major problem with this is the lack of information about the relation between vaginal health and the use of menstrual products, due to the limited third-party testing and research conducted, which could be rectified with appropriate standards in place. Furthermore, the vaginal mucous membranes are much more absorbent, and hence, sensitive to exposure than the traditionally tested manners of exposure such as airways, skin and oral intake.¹³ Therefore, leaving it up to each country and producer to determine e.g. which methods of testing are needed and what limit values of different chemicals are acceptable can be considered inefficient and rather unusual for products used so intimately.

Furthermore, some of the existing industry standards are in need of updating with regards to e.g. the labels of absorption capacity of mini, normal/regular and super/super plus etc. These labels tend to inhibit proper usage of tampons, as the majority of women want to be "normal". Labelling in a way that encourages the use of different sized tampons during for instance different days of the period in accordance with the heaviness of the flow would be more beneficial. Incorrect use of tampons, namely using too absorbent a tampon when not bleeding enough that it is filled before it needs to be changed in relation to the recommended time, can result in issues such as yeast infections, as they can dry out the mucous membranes causing a bacterial imbalance.¹⁴

The public interest and added value for consumers of menstrual product standardization lays in, as mentioned, their increased ability to assess product safety, performance and fitness for purpose. This will in turn facilitate for consumers to compare products and select a most suitable product for their needs, which can be difficult in the current status of the marketplace. Further this will increase consumers' general comfort when menstruating, which can contribute to increased participation by

¹⁰ Friedmann, I. 2017. Mens. 1177 *Vårdguiden*. Available online: <https://www.1177.se/Skane/Fakta-och-rad/Sjukdomar/Mensbesvar/>.

¹¹ Plan International UK. 2017. Plan International UK's Research on Period Poverty and Stigma. Available online: <https://plan-uk.org/media-centre/plan-international-uks-research-on-period-poverty-and-stigma>.

¹² Nicole, W. (2014). A Question for Women's Health: Chemicals in Feminine Hygiene Products and Personal Lubricants, *Environmental Health Perspectives*, vol. 122, no. 3, pp.70–75.

¹³ Ibid.

¹⁴ Hanssoon, M. (2010). Forskare: 'Tamponger Absorberar För Bra', Testfakta.



COPOLCO WG 2 Key areas

menstruators in school and in the workforce. Research shows that by increasing the number of girls who graduate secondary school by one per cent, GDP in that country can increase by a corresponding 0.3 % per capita¹⁵.

Moreover, as increased comfort is likely to contribute to greater confidence regarding menstruation, these aspects are together also likely to contribute to destigmatization¹⁶ of menstruation and menstrual products, which enables greater gender equality.

Finally, it is noteworthy that there is a current momentum regarding both the matter of menstruation, especially in terms of destigmatizing it and raising it to the public agenda as an important question to discuss, as well as in terms of standardization. For example, menstrual product standardization is discussed within and between organizations, both non-governmental and corporations around the globe (Reproductive Health Supplies Coalition, 2020)¹⁷. This momentum has been going on for a number of years, most markedly since 2015, which was deemed the year of the period¹⁸. The same year WASH United established the international Menstrual Hygiene Day and since then several large international organizations have emphasized the importance of taking menstrual health seriously including the Bill and Melinda Gates Foundation¹⁹, the 2019 UN Commission on Human Rights²⁰ the World Bank^{21,22} and the UN has started a Sanitation and Hygiene fund which will include a focus on menstruation²³.

¹⁵ Chaaban, J. & Cunningham, W., 2011. Measuring the Economic Gain of Investing in Girls – the girl effect dividend. *The World Bank Human Development Network Children and Youth Unit*. Available online:

<http://documents1.worldbank.org/curated/en/730721468326167343/pdf/WPS5753.pdf>

¹⁶ Mirabito, Otnes, Crosby, Wooten, Machin, Pullig, Ross Adkins, Dunnet, Hamilton, Thomas, Yeh, Davis, Gollnhofer, Grover, Matias, Mitchell, Ndichu, Sayarh and Velagaleti. 2016. The Stigma Turbine: A Theoretical Framework for Conceptualizing and Contextualizing Marketplace Stigma. Available

Online: <http://journals.ama.org/doi/10.1509/jppm.15.145>.

¹⁷ Reproductive Health Supplies Coalition. 2020. Standards for Disposable Sanitary Pads (Menstrual Health Standards Webinar Series). Available online: <https://www.rhsupplies.org/activities-resources/webinars/standards-for-disposable-sanitary-pads-menstrual-health-standards-webinar-series-149/>.

¹⁸ Gharib, M. (2015, December 31). Why 2015 Was The Year Of The Period, And We Don't Mean Punctuation. NPR, 1–9. <http://www.npr.org/sections/health-shots/2015/12/31/460726461/why-2015-was-the-year-of-the-period-and-we-dont-mean-punctuation>.

¹⁹ Amaya, L., Marcatili, J., & Bhavaraju, N. (2020). *Advancing Gender Equity by Improving Menstrual Health*.

<https://www.fsg.org/publications/advancing-gender-equity-improving-menstrual-health>

²⁰ WASH United. (2020). *Significant new language on MHM in Human Rights Council resolution*. Menstrual Hygiene Day.

<https://menstrualhygieneday.org/significant-new-language-mhm-human-rights-council-resolution-ahrc39l-11/>

²¹ Kiefer, T., Sara, J., Davis, J., & Ljungberg, C. (2019, May 24). #ItsTimeForAction: Invest in Menstrual Hygiene Management. *The World Bank*, 1–8. <https://www.worldbank.org/en/news/feature/2019/05/24/menstrual-hygiene-day-2019.print>

²² Plesons *et al.* *Reprod Health* 2021. The state of adolescent menstrual health in low-and middle-income countries and suggestions for future action and research. Available online: <https://doi.org/10.1186/s12978-021-01082-2>

²³ Stenghtening the Weakest Link. The Sanitation and hygiene fund investment case.

<https://www.shfund.org/sites/default/files/2020-11/SHF%20Investment%20Case%20Nov20.pdf>



5. Possible existing relevant standards work

Include any existing standards or standards development activity which is – or could be – relevant to the issue, such as:

1. Are there any relevant national, regional, international standards or ISO/IEC deliverables?
2. Are any Technical Committees (TCs) of ISO/IEC already addressing this issue?
2-1 If yes, is this issue properly addressed by the TC in your opinion? 2-2 If, no, how should the TC address the issue?
3. Can any Technical Committee of ISO/IEC address this issue?
3-1 If so, why should they do so?
4. Should there be consumer participation in the TC to raise the issues?
5. Is there any other organization besides ISO/IEC which addresses the issue?
6. Is there any relevant regulation related to this issue?

There are no ISO/IEC TCs currently addressing this issue and no international standards that address this specific issue. There are, however, a number of national, regional and industry level standards that address the issue to an extent, albeit, on a level that arguably is insufficient both in terms of scope of the standards and their areas of application (the types of products they include), the reach of the standards themselves (what and how they guides) and geographically (the number of consumers they protect worldwide). A list of relevant standards and groups can be seen below:

- ISO/PC 243, ISO 10377 *Consumer product safety – Guidelines for suppliers*
<https://isotc.iso.org/livelink/livelink/Open/16474221>
- ISO/TC 173, *Assistive products for persons with disability, Subcommittee SC 3, Aids for ostomy and incontinence* – as they deal with products that are very similar to some menstrual products they most likely have a lot of knowledge to be gained for the standardization of menstrual products such as testing methods on materials and their effects on vaginal health, so communication is important to avoid overlap and inefficiency.
- ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics* – as previously mentioned, the relevance of this committee is dependent on the degree to which the standard pertains to condoms' effects on the vagina.
- ISO/PC 325 *Sex Toys- Design and safety requirements for products in direct contact with genitalia, the anus, or both* – As this group also deals with a consumer product in sensitive parts of the body.
- ISO/TC 194 Biological and clinical evaluation of medical devices – and especially parts of the ISO 10993-series.

Africa				
Country/Region	Authority	Standard Name	Parameters Covered	Others
East African Community (Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda)	East African Standards Committee	EAS 96-1:2008 Sanitary towels Specification- Part 1: Disposable	Construction, performance, hygiene	Uganda standard for reusable pads DUS 1782: 2017 Kenya KS 507: Sanitary towels
Ethiopia	Ethiopian Standards Agency	ES 6345:2018 Part 2: Disposable	Construction, performance, hygiene	ES 6346:2018 Part 2: Reusable
UNECA and AU	African Organization for Standardization	DARS 653:2017 Sanitary towels		DARS 1575 Textiles — Reusable sanitary towels
South Africa	South Africa Bureau of Standards	SANS 1043:2010	Size and construction, performance, hygiene, sterility and autoclavability	SANS Draft for Reusable pads
Zimbabwe	Standards Association of Zimbabwe	ZWS 730:2015 Manufacture of Sanitary Pads		ZWS 1023: Reusable sanitary pads



COPOLCO WG 2 Key areas

Asia				
Country/Region	Authority	Standard Name	Parameters Covered	Others
India	Bureau of Indian Standards	IS 5405:2019	Construction, performance, hygiene, biocompatibility, compostability	Reusable pads, menstrual cups under development
Sri Lanka	Sri Lanka Standards Institution	SLS 111 Sanitary Towels		
Pakistan	Pakistan Standards and Quality Control Authority	PS: 1449-1979		
Bangladesh	Bangladesh Standards and Testing Institute	BDS 1261:2016 Sanitary Towels Mandatory		
Nepal	Nepal Bureau of Standards and Metrology	Under development with recent advocacy		
Cambodia, Vietnam	Institute of Standards of Cambodia; Vietnam Standards and Quality Institute			

Others - Reference				
Country/Region	Authority	Standard Name	Parameters Covered	Others
United States	US FDA	Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) Classified as non-significant risk (NSR) medical devices	Materials, performance, Hygiene (staph, TSST-1 for tampons, normal vaginal flora), Toxicology	Includes disposable pads, tampons, washable cloth pads and intra-labial pads
Japan	Pharmaceuticals and Medical Devices Agency	The Standards for Marketing Approval of Sanitary Napkins Notification PFSB No.0325-17, March 2015 Sanitary napkins classified as 'Quasi-drugs'	Colour fastness, pH, fluorescence, absorption, exudation, adhesion etc., Safety profile of 150 materials used in a sanitary napkin (including those that should not come in contact with skin or mucosa)	
China	Bureau of Standards, Metrology and Inspection	CNS 9324:2004 Feminine sanitary napkins		

Source: Webinar on standardization of disposable menstrual products hosted by Reproductive Health Supplies Coalition, Menstrual Hygiene Day – WASH United and Menstrual Health Alliance India

Additionally, published standards:

SANS 1812, the manufacture of washable, reusable sanitary towels was published 2020.

AS 2869:2008 Tampons – Menstrual. This standard is also referenced in the national regulation²⁴.

Regulations: Menstrual products are categorised as Medical device, therapeutic goods or consumer products in different countries and regions. For example, in most European countries they fall under the General Product Safety Directive which means there is no obligation for manufacturers to list the composition of the product or perform biocompatible testing. Whereas in the USA menstrual products are considered a medical device, with additional testing requirements. International standards can help bridge the gap were regulations are not clear or strong enough.

A wide range of stakeholders should be involved in this work, we see it as important that both industry, NGOs, international organisations, testing institutes, governmental agencies, medical

²⁴ Guidance on the regulation of tampons in Australia” <https://www.tga.gov.au/book/export/html/4403>



COPOLCO WG 2 Key areas

professions and consumer organizations are represented. There are different organisations around the world that work extensively with breaking stigma around menstruation, highlighting the importance of talking about this openly, the right for all to access safe products and being able to participate fully in society. To mention a few, UNFPA²⁵, UNICEF²⁶, UNHCR²⁷, Plan International²⁸ and WASH United²⁹ work with such matters. By bringing the issue to ISO we lift the status and take the next step in the process of making a practical difference for consumers around the world. Work is also being conducted in specific countries where the issues of the lack of rules and standards have surfaced³⁰.

6. Personnel & Resources

If ISO/COPOLCO approves the proposal, would you be able to contribute to the work?

1. Mention any consumer representatives, technical experts or national standards bodies who you think may wish to be involved.

National Standards bodies: SIS

Consumer representatives: The Swedish Consumers' Association,

Technical Experts: The experts part of drafting this proposal are: Gerda Larsson, Louise Klintner, Magnus Fransson, Louise Berg, Linda Bergh Kristina von Dolwitz, Marie Walleberg, Jessica Laneborg, Jens Henriksson and Catrin Lindblad. Representing manufacturers, consumers, academia, testing institute and advocacy organization. In addition, we hope and expect that national experts from all participating members will contribute. We also see the need and possibility to liaison with international organizations such as UNFPA and of course other relevant ISO groups.

2. What kinds of resources (time, talent, research, funds and expertise) are needed?

We think it is important that this standardization area is initiated by COPOLCO so that the consumer perspective is clearly highlighted.

In order to make this work of as high quality and of as great a global relevance as possible, a wide range of stakeholders should be involved. This includes preferably a diverse group where many different varieties of menstrual products are represented, medical experts, public health experts, consumer representatives, NGOs, researchers, material experts and manufacturers.

The future TC/PC secretariat needs funding. We may be of assistance in finding potential solutions but are not in a position to fund it on our own.

²⁵ UNFPA. (2019). Menstruation is not a girls' or women's issue – it's a human rights issue. Available online:

<https://www.unfpa.org/news/menstruation-not-girls-or-womens-issue-%E2%80%93-its-human-rights-issue>

²⁶ UNICEF. (2019). Guidance on Menstrual Health and Hygiene. Available online:

<https://www.unicef.org/wash/files/UNICEF-Guidance-menstrual-health-hygiene-2019.pdf>

²⁷ UNHCR. (2019). Institutional Survey on Menstrual Hygiene Management. Available online:

<https://wash.unhcr.org/download/institutional-survey-on-menstrual-hygiene-management/>.

²⁸ Plan International. (2020). *Menstruation*. Available online: <https://plan-international.org/sexual-health/menstruation>

²⁹ Wash United. (2020). WASH advocacy and education, with a focus on menstrual hygiene and human rights.

Available online: <https://www.wash-united.org/>.

³⁰ ANSES (Agence Nationale Sécurité Sanitaire Alimentaire Nationale - National Food and Health Security Agency) on « Sécurité des produits de protection intime » (Safety of intimate protection products)

<https://www.anses.fr/fr/content/evaluation-de-la-s%C3%A9curit%C3%A9-des-produits-deprotections-intimes>

A Parliamentary information report (N° 2691 By Mme Romeiro-Dias et Mme Taurine on menstruations)

<http://www.assemblee-nationale.fr/15/pdf/rap-info/i2691.pdf>

- An article of ALLDC (Association Léo Lagrange pour la défense des consommateurs) on « Couches, protection intime: des produits sous surveillance! » (Nappies, intimate protection: products under surveillance) <https://www.leolagrange-conso.org/couches-protection-intime-des-produits-sous-surveillance/>



COPOLCO WG 2 Key areas

3. Other information

We are able to nominate a chairperson for the future ISO group.



Next steps

What do you propose as the next steps for COPOLCO? For example;

- *Conduct a feasibility/justification study*
- *Prepare a scoping document/paper summarizing the project or project objectives with appropriate references and facts*
- *Propose a new area of work for ISO*

Given the complexity, the specific nature of the topic, the number of standards that may be needed and the potential impact standardisation can have within the topic of menstrual products we suggest creating a new area of technical work, a new TC/PC. In terms of suggesting a priority among the different aspects of menstrual products we suggest that the first standard proposal to be developed is a general requirement standard focusing on the safety and health of the consumers. Following that other aspect should be handled, such as for example environmental aspects, disposal, and manufacturing.

- *A specific recommendation for ISO to address the problem*
- *Monitor the technical work (If you think monitoring is the next step, please go to Part B).*

Recommendation – To be completed by the Chair's Group

Date submitted: _____

Date of initial review: _____

Date of recommendation: _____

Part B. PROPOSAL FOR KEY AREA

1. Do you wish this suggestion to be considered a new Key Area?

If so, why do you believe this should be added to the list of Key Areas?

Note: Once the subject is approved as a new Key Area within COPOLCO, monitoring by COPOLCO will start. To become a Key Area, the subject has to be an area of standards work within the ISO/IEC fora and of interest to consumers. In effect, the Key Areas for Consumers WG will propose the Key Areas and Key Persons for decision by COPOLCO.

The Key areas for consumers WG's mandate is, in effect, to inform on key areas of work in standardization relevant to consumers, working towards continuous improvement in the delivery of this mandate, while taking account of the needs of developing countries and emerging economies:

- *To identify and monitor key areas of standards work in ISO and IEC of interest to consumers including emerging areas, horizontal issues, and mature technical committee work;*
- *To raise awareness of these areas and disseminate information to the ISO membership, the ISO/COPOLCO members, consumer organizations and consumer representatives, standards development organizations, and members of technical committees and subcommittees;*



COPOLCO WG 2 Key areas

- *To facilitate networking amongst individuals interested in areas of consumer interest.*

2. Do you wish to revise or delete the existing area? If so, why do you wish to do so?

Potential Key Person



COPOLCO WG 2 Key areas

Recommendation – To be completed by COPOLCO WG 2 Key Areas for consumers

Date submitted: _____

Date of initial review: _____

Date of recommendation: _____

Result of voting

Ballot Information

Ballot reference	COPOLCO N605
Ballot type	CIB
Ballot title	Safety and performance of menstrual products
Opening date	2021-05-19
Closing date	2021-06-16
Note	This CIB is to invite COPOLCO members to indicate their position on this proposal (submitted as a COPOLCO template), and if applicable, to cite relevant national examples of standards and/or regulations affecting menstrual products.

Member responses:

Votes cast (73)	Algeria (IANOR) Argentina (IRAM) Australia (SA) Austria (ASI) Bahrain (BSMD) Bangladesh (BSTI) Barbados (BNSI) Bolivia, Plurinational State of (IBNORCA) Botswana (BOBS) Brazil (ABNT) Bulgaria (BDS) Canada (SCC) Chile (INN) China (SAC) Colombia (ICONTEC) Congo, The Democratic Republic of the (OCC) Costa Rica (INTECO) Czech Republic (UNMZ) Denmark (DS) Ecuador (INEN) Ethiopia (ESA) Fiji (DNTMS) France (AFNOR) Germany (DIN) Ghana (GSA) India (BIS) Indonesia (BSN) Iran, Islamic Republic of (INSO) Ireland (NSAI)
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Israel (SII)
Italy (UNI)
Jamaica (BSJ)
Japan (JISC)
Kazakhstan (KAZMEMST)
Kenya (KEBS)
Korea, Republic of (KATS)
Malawi (MBS)
Malaysia (DSM)
Mali (AMANORM)
Malta (MCCAA)
Mauritius (MSB)
Mexico (DGN)
Mongolia (MASM)
Morocco (IMANOR)
Netherlands (NEN)
Nigeria (SON)
Norway (SN)
Panama (COPANIT)
Peru (INACAL)
Philippines (BPS)
Portugal (IPQ)
Romania (ASRO)
Russian Federation (GOST R)
Rwanda (RSB)
Saudi Arabia (SASO)
Serbia (ISS)
Singapore (SSC)
Slovenia (SIST)
South Africa (SABS)
Spain (UNE)
Sri Lanka (SLSI)
Sudan (SSMO)
Sweden (SIS)
Switzerland (SNV)
Thailand (TISI)
Trinidad and Tobago (TTBS)
Tunisia (INNORPI)
Turkey (TSE)
Uganda (UNBS)
United Arab Emirates (ESMA)
United Kingdom (BSI)
United States (ANSI)
Zimbabwe (SAZ)

Comments submitted (3)

ANEC
CI
Jordan (JSMO)

Votes not cast (6)

Egypt (EOS)
Finland (SFS)
Namibia (NSI)
Oman (DGSM)
Pakistan (PSQCA)
Uruguay (UNIT)

Questions:

Q.1	"Do you support the proposal for standardization of menstrual products?"
Q.2	"Do you have national standards covering any aspects of menstrual health or products? "
Q.3	"Is there any legislation in your country covering this area?"
Q.4	"Have you had resistance to this project from national stakeholders? "
Q.5	"Do you have any additional comments?"

Votes by members	Q.1	Q.2	Q.3	Q.4	Q.5
Algeria (IANOR)	Yes	Yes	Yes	No	No
Argentina (IRAM)	Yes	Yes	Yes	Abstain	No
Australia (SA)	Yes	Yes	Yes	No	Yes
Austria (ASI)	Abstain	Abstain	Abstain	Abstain	Abstain
Bahrain (BSMD)	Yes	No	No	No	No
Bangladesh (BSTI)	Abstain	Abstain	Abstain	Abstain	Abstain
Barbados (BNSI)	Yes	No	No	No	No
Bolivia, Plurinational State of (IBNORCA)	Yes	No	No	No	No
Botswana (BOBS)	Yes	Yes	No	No	No
Brazil (ABNT)	Yes	No	Yes	No	No
Bulgaria (BDS)	Abstain	Abstain	Abstain	Abstain	Abstain
Canada (SCC)	Yes	No	Yes	No	No
Chile (INN)	Abstain	No	No	No	No
China (SAC)	Yes	Yes	Yes	No	Yes
Colombia (ICONTEC)	Yes	Yes	No	No	No
Congo, The Democratic Republic of the (OCC)	Yes	Yes	No	No	No
Costa Rica (INTECO)	Yes	Abstain	Abstain	Abstain	No
Czech Republic (UNMZ)	Abstain	Abstain	Abstain	Abstain	Abstain
Denmark (DS)	Yes	No	No	No	No
Ecuador (INEN)	Yes	Yes	Abstain	Abstain	No
Ethiopia (ESA)	Yes	Yes	No	No	No
Fiji (DNTMS)	Yes	No	No	No	No
France (AFNOR)	Yes	No	Abstain	No	No
Germany (DIN)	Yes	No	No	No	No
Ghana (GSA)	Abstain	Yes	No	Abstain	Abstain

India (BIS)	Yes	Yes	Abstain	No	No
Indonesia (BSN)	Yes	Yes	Yes	No	Yes
Iran, Islamic Republic of (INSO)	No	Yes	Yes	Abstain	No
Ireland (NSAI)	Abstain	Abstain	Abstain	Abstain	Abstain
Israel (SII)	Abstain	Abstain	Abstain	Abstain	Abstain
Italy (UNI)	Abstain	Abstain	Abstain	Abstain	Abstain
Jamaica (BSJ)	Yes	Yes	No	Abstain	Abstain
Japan (JISC)	Abstain	No	Yes	No	Yes
Kazakhstan (KAZMEMST)	Yes	No	No	Abstain	No
Kenya (KEBS)	Yes	Yes	Yes	No	No
Korea, Republic of (KATS)	Yes	No	No	No	No
Malawi (MBS)	Yes	Yes	No	No	No
Malaysia (DSM)	Yes	No	No	No	No
Mali (AMANORM)	Yes	No	Abstain	Abstain	Abstain
Malta (MCCAA)	Abstain	No	No	No	No
Mauritius (MSB)	Yes	No	No	No	No
Mexico (DGN)	Yes	No	No	No	No
Mongolia (MASM)	Yes	No	No	No	No
Morocco (IMANOR)	Yes	Yes	No	No	No
Netherlands (NEN)	Abstain	Abstain	Abstain	Abstain	Abstain
Nigeria (SON)	Yes	No	No	No	No
Norway (SN)	Yes	No	No	No	No
Panama (COPANIT)	Yes	No	No	No	No
Peru (INACAL)	Abstain	Abstain	Abstain	Abstain	Abstain
Philippines (BPS)	Yes	Yes	Yes	Abstain	No
Portugal (IPQ)	Abstain	Abstain	Abstain	Abstain	Abstain
Romania (ASRO)	Yes	No	Abstain	Abstain	No
Russian Federation (GOST R)	Yes	Yes	No	No	No
Rwanda (RSB)	Yes	Yes	No	No	Abstain
Saudi Arabia (SASO)	Abstain	Abstain	Abstain	Abstain	Abstain
Serbia (ISS)	Yes	No	No	No	Abstain
Singapore (SSC)	Yes	No	No	No	No
Slovenia (SIST)	Yes	No	No	No	No

South Africa (SABS)	Yes	Yes	No	No	No
Spain (UNE)	Abstain	Abstain	Abstain	Abstain	Abstain
Sri Lanka (SLSI)	Yes	Yes	Yes	No	No
Sudan (SSMO)	Yes	Yes	No	No	Yes
Sweden (SIS)	Yes	No	Yes	Yes	Yes
Switzerland (SNV)	Yes	Abstain	Abstain	Abstain	No
Thailand (TISI)	Yes	Yes	Yes	No	Yes
Trinidad and Tobago (TTBS)	Yes	No	No	No	No
Tunisia (INNORPI)	Yes	No	No	No	No
Turkey (TSE)	Yes	Abstain	Yes	Abstain	No
Uganda (UNBS)	Yes	Yes	Abstain	No	No
United Arab Emirates (ESMA)	Abstain	Yes	Abstain	Abstain	Abstain
United Kingdom (BSI)	Yes	No	Abstain	No	No
United States (ANSI)	Yes	Yes	No	Abstain	Yes
Zimbabwe (SAZ)	Yes	No	No	No	No

Answers to Q.1: "Do you support the proposal for standardization of menstrual products?"

55 x	Yes	Algeria (IANOR) Argentina (IRAM) Australia (SA) Bahrain (BSMD) Barbados (BNSI) Bolivia, Plurinational State of (IBNORCA) Botswana (BOBS) Brazil (ABNT) Canada (SCC) China (SAC) Colombia (ICONTEC) Congo, The Democratic Republic of the (OCC) Costa Rica (INTECO) Denmark (DS) Ecuador (INEN) Ethiopia (ESA) Fiji (DNTMS) France (AFNOR) Germany (DIN) India (BIS) Indonesia (BSN) Jamaica (BSJ) Kazakhstan (KAZMEMST) Kenya (KEBS) Korea, Republic of (KATS) Malawi (MBS) Malaysia (DSM) Mali (AMANORM)
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		Mauritius (MSB) Mexico (DGN) Mongolia (MASM) Morocco (IMANOR) Nigeria (SON) Norway (SN) Panama (COPANIT) Philippines (BPS) Romania (ASRO) Russian Federation (GOST R) Rwanda (RSB) Serbia (ISS) Singapore (SSC) Slovenia (SIST) South Africa (SABS) Sri Lanka (SLSI) Sudan (SSMO) Sweden (SIS) Switzerland (SNV) Thailand (TISI) Trinidad and Tobago (TTBS) Tunisia (INNORPI) Turkey (TSE) Uganda (UNBS) United Kingdom (BSI) United States (ANSI) Zimbabwe (SAZ)
1 x	No	Iran, Islamic Republic of (INSO)
17 x	Abstain	Austria (ASI) Bangladesh (BSTI) Bulgaria (BDS) Chile (INN) Czech Republic (UNMZ) Ghana (GSA) Ireland (NSAI) Israel (SII) Italy (UNI) Japan (JISC) Malta (MCCA) Netherlands (NEN) Peru (INACAL) Portugal (IPQ) Saudi Arabia (SASO) Spain (UNE) United Arab Emirates (ESMA)

Answers to Q.2: "Do you have national standards covering any aspects of menstrual health or products? "

27 x	Yes	Algeria (IANOR) Argentina (IRAM) Australia (SA) Botswana (BOBS) China (SAC) Colombia (ICONTEC)
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		<p>Congo, The Democratic Republic of the (OCC) Ecuador (INEN) Ethiopia (ESA) Ghana (GSA) India (BIS) Indonesia (BSN) Iran, Islamic Republic of (INSO) Jamaica (BSJ) Kenya (KEBS) Malawi (MBS) Morocco (IMANOR) Philippines (BPS) Russian Federation (GOST R) Rwanda (RSB) South Africa (SABS) Sri Lanka (SLSI) Sudan (SSMO) Thailand (TISI) Uganda (UNBS) United Arab Emirates (ESMA) United States (ANSI)</p>
31 x	No	<p>Bahrain (BSMD) Barbados (BNSI) Bolivia, Plurinational State of (IBNORCA) Brazil (ABNT) Canada (SCC) Chile (INN) Denmark (DS) Fiji (DNTMS) France (AFNOR) Germany (DIN) Japan (JISC) Kazakhstan (KAZMEMST) Korea, Republic of (KATS) Malaysia (DSM) Mali (AMANORM) Malta (MCCAA) Mauritius (MSB) Mexico (DGN) Mongolia (MASM) Nigeria (SON) Norway (SN) Panama (COPANIT) Romania (ASRO) Serbia (ISS) Singapore (SSC) Slovenia (SIST) Sweden (SIS) Trinidad and Tobago (TTBS) Tunisia (INNORPI) United Kingdom (BSI) Zimbabwe (SAZ)</p>
15 x	Abstain	<p>Austria (ASI) Bangladesh (BSTI) Bulgaria (BDS) Costa Rica (INTECO)</p>

Czech Republic (UNMZ)
 Ireland (NSAI)
 Israel (SII)
 Italy (UNI)
 Netherlands (NEN)
 Peru (INACAL)
 Portugal (IPQ)
 Saudi Arabia (SASO)
 Spain (UNE)
 Switzerland (SNV)
 Turkey (TSE)

Answers to Q.3: "Is there any legislation in your country covering this area?"

15 x	Yes	Algeria (IANOR) Argentina (IRAM) Australia (SA) Brazil (ABNT) Canada (SCC) China (SAC) Indonesia (BSN) Iran, Islamic Republic of (INSO) Japan (JISC) Kenya (KEBS) Philippines (BPS) Sri Lanka (SLSI) Sweden (SIS) Thailand (TISI) Turkey (TSE)
36 x	No	Bahrain (BSMD) Barbados (BNSI) Bolivia, Plurinational State of (IBNORCA) Botswana (BOBS) Chile (INN) Colombia (ICONTEC) Congo, The Democratic Republic of the (OCC) Denmark (DS) Ethiopia (ESA) Fiji (DNTMS) Germany (DIN) Ghana (GSA) Jamaica (BSJ) Kazakhstan (KAZMEMST) Korea, Republic of (KATS) Malawi (MBS) Malaysia (DSM) Malta (MCCAA) Mauritius (MSB) Mexico (DGN) Mongolia (MASM) Morocco (IMANOR) Nigeria (SON) Norway (SN) Panama (COPANIT) Russian Federation (GOST R) Rwanda (RSB)

		Serbia (ISS) Singapore (SSC) Slovenia (SIST) South Africa (SABS) Sudan (SSMO) Trinidad and Tobago (TTBS) Tunisia (INNORPI) United States (ANSI) Zimbabwe (SAZ)
22 x	Abstain	Austria (ASI) Bangladesh (BSTI) Bulgaria (BDS) Costa Rica (INTECO) Czech Republic (UNMZ) Ecuador (INEN) France (AFNOR) India (BIS) Ireland (NSAI) Israel (SII) Italy (UNI) Mali (AMANORM) Netherlands (NEN) Peru (INACAL) Portugal (IPQ) Romania (ASRO) Saudi Arabia (SASO) Spain (UNE) Switzerland (SNV) Uganda (UNBS) United Arab Emirates (ESMA) United Kingdom (BSI)

Answers to Q.4: "Have you had resistance to this project from national stakeholders? "

1 x	Yes	Sweden (SIS)
46 x	No	Algeria (IANOR) Australia (SA) Bahrain (BSMD) Barbados (BNSI) Bolivia, Plurinational State of (IBNORCA) Botswana (BOBS) Brazil (ABNT) Canada (SCC) Chile (INN) China (SAC) Colombia (ICONTEC) Congo, The Democratic Republic of the (OCC) Denmark (DS) Ethiopia (ESA) Fiji (DNTMS) France (AFNOR) Germany (DIN) India (BIS) Indonesia (BSN) Japan (JISC)

		Kenya (KEBS) Korea, Republic of (KATS) Malawi (MBS) Malaysia (DSM) Malta (MCCAA) Mauritius (MSB) Mexico (DGN) Mongolia (MASM) Morocco (IMANOR) Nigeria (SON) Norway (SN) Panama (COPANIT) Russian Federation (GOST R) Rwanda (RSB) Serbia (ISS) Singapore (SSC) Slovenia (SIST) South Africa (SABS) Sri Lanka (SLSI) Sudan (SSMO) Thailand (TISI) Trinidad and Tobago (TTBS) Tunisia (INNORPI) Uganda (UNBS) United Kingdom (BSI) Zimbabwe (SAZ)
26 x	Abstain	Argentina (IRAM) Austria (ASI) Bangladesh (BSTI) Bulgaria (BDS) Costa Rica (INTECO) Czech Republic (UNMZ) Ecuador (INEN) Ghana (GSA) Iran, Islamic Republic of (INSO) Ireland (NSAI) Israel (SII) Italy (UNI) Jamaica (BSJ) Kazakhstan (KAZMEMST) Mali (AMANORM) Netherlands (NEN) Peru (INACAL) Philippines (BPS) Portugal (IPQ) Romania (ASRO) Saudi Arabia (SASO) Spain (UNE) Switzerland (SNV) Turkey (TSE) United Arab Emirates (ESMA) United States (ANSI)

Answers to Q.5: "Do you have any additional comments?"		
8 x	Yes	Australia (SA)

		<p>China (SAC) Indonesia (BSN) Japan (JISC) Sudan (SSMO) Sweden (SIS) Thailand (TISI) United States (ANSI)</p>
47 x	No	<p>Algeria (IANOR) Argentina (IRAM) Bahrain (BSMD) Barbados (BNSI) Bolivia, Plurinational State of (IBNORCA) Botswana (BOBS) Brazil (ABNT) Canada (SCC) Chile (INN) Colombia (ICONTEC) Congo, The Democratic Republic of the (OCC) Costa Rica (INTECO) Denmark (DS) Ecuador (INEN) Ethiopia (ESA) Fiji (DNTMS) France (AFNOR) Germany (DIN) India (BIS) Iran, Islamic Republic of (INSO) Kazakhstan (KAZMEMST) Kenya (KEBS) Korea, Republic of (KATS) Malawi (MBS) Malaysia (DSM) Malta (MCCAA) Mauritius (MSB) Mexico (DGN) Mongolia (MASM) Morocco (IMANOR) Nigeria (SON) Norway (SN) Panama (COPANIT) Philippines (BPS) Romania (ASRO) Russian Federation (GOST R) Singapore (SSC) Slovenia (SIST) South Africa (SABS) Sri Lanka (SLSI) Switzerland (SNV) Trinidad and Tobago (TTBS) Tunisia (INNORPI) Turkey (TSE) Uganda (UNBS) United Kingdom (BSI) Zimbabwe (SAZ)</p>
18 x	Abstain	<p>Austria (ASI) Bangladesh (BSTI)</p>

Bulgaria (BDS)
Czech Republic (UNMZ)
Ghana (GSA)
Ireland (NSAI)
Israel (SII)
Italy (UNI)
Jamaica (BSJ)
Mali (AMANORM)
Netherlands (NEN)
Peru (INACAL)
Portugal (IPQ)
Rwanda (RSB)
Saudi Arabia (SASO)
Serbia (ISS)
Spain (UNE)
United Arab Emirates (ESMA)

Comments from Voters		
Member:	Comment:	Date:
Australia (SA)	Comment File	2021-06-10 00:42:03
CommentFiles/COPOLCO N605_SA.doc		
Brazil (ABNT)	Comment	2021-06-15 22:12:12
<i>Currently, we already have an Anvisa regulation dealing specifically with these products, so it would not be interesting to have standards that compete with the same scope. However, if this discussion opens, the CB-57 wishes to lead and contribute to the development of standards.</i>		
Canada (SCC)	Comment	2021-06-16 22:07:35
There are no National Standards of Canada covering menstrual health or products (below for additional information in response to question 3 for government regulation). Legislation and regulation is managed by Health Canada under their medical devices regime. In Canada, menstrual tampons are regulated as medical devices . Health Canada makes sure that the tampons sold in Canada are safe, effective, and of high quality based on requirements for licensing , quality manufacture, and post-market surveillance. Before a device license is given to a manufacturer, tampon-package labelling must contain specific information about absorbency. Labels must also provide details about the risks and symptoms of Toxic Shock Syndrome, and instructions on what to do if you have these symptoms		
China (SAC)	Comment File	2021-06-02 04:31:52
CommentFiles/COPOLCO N605_SAC.docx		
Denmark (DS)	Comment	2021-05-25 16:26:26
We do not have national standards but one of our stakeholders (test and marking) have informed us that they use the EN/ISO12625 series regarding tissue paper and tissue products		
France (AFNOR)	Comment	2021-06-11 09:02:01
Not identified at this stage.		

Indonesia (BSN)	Comment File	2021-06-16 12:07:08
CommentFiles/COPOLCO N605_BSN.doc		
Iran, Islamic Republic of (INSO)	Comment File	2021-06-16 09:42:55
CommentFiles/COPOLCO N605_INSO.docx		
Japan (JISC)	Comment	2021-06-15 05:19:37
Not resistance but there was a reaction that ISO standards in this field is not necessary because of related legislation already exists.		
Japan (JISC)	Comment File	2021-06-15 05:19:37
CommentFiles/COPOLCO N605_JISC.docx		
Sudan (SSMO)	Comment File	2021-06-15 13:56:20
CommentFiles/COPOLCO N605_SSMO.docx		
Sweden (SIS)	Comment File	2021-06-11 15:43:55
CommentFiles/COPOLCO N605_SIS.doc		
Thailand (TISI)	Comment File	2021-06-16 06:15:41
CommentFiles/COPOLCO N605_TISI.doc		
United States (ANSI)	Comment File	2021-06-16 16:37:40
CommentFiles/COPOLCO N605_ANSI.docx		

Comments from Commenters		
Member:	Comment:	Date:
ANEC	Comment	2021-05-27 15:17:33
ANEC submits the attached positive comments.		
ANEC	Comment File	2021-05-27 15:17:33
CommentFiles/COPOLCO N605_ANEC.doc		
CI	Comment	2021-06-15 13:51:25
Consumers International support the development of a standard for menstrual product safety		
Jordan (JSMO)	Comment	2021-06-15 07:59:51
JSMO support the proposal for standardization of menstrual products The safety of these products is of significant concern, as they are intended for use inside the body in contact with mucous membranes,		

alternatively in contact with sensitive skin for a long and repeated periods of time, regarding to what mentioned an international standard would be useful to regulate the product globally (pertaining to health as well as environmental safety and product performance)

We Have Jordanian Standard no. 1732:2013 Hygienic paper Ladies sanitary pads, based on the Gulf standard GSO 751:1997 SANITARY PADS FOR LADIES.

the Jordanian Standard covering the aspects of menstrual products is JS 1732:2013 Hygienic paper Ladies sanitary pads, and as an addition SMIC recently published a new standard covering this topic : OIC/SMIC 16: 2020 Disposable Sanitary Pads – Specifications and Test Methods.

Template for comments and secretariat observations

Date:2021-06-17

Document:

Project:

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Observations of the secretariat
TH- 001					<ul style="list-style-type: none"> - We have developed TIS 295-2560 (2017) Sanitary napkins as a national standard covering the aspects of menstrual health or products. - The legislation in Thailand covering this area is the Ministry of Public Health's Cosmetic Act of B.E. 2558 (2015). 		
AU- 002				ge	Tampons are required to comply with Therapeutic Goods (Standards for Tampons) (TGO 103) Order 2019 before they can be supplied in Australia. This order states that the Australian Standard "AS 2869:2008 Tampons - Menstrual" is currently the applicable standard for menstrual tampons in Australia. This standard is currently undergoing revision with an expected publication date in 2021		
JISC- 003				ge	<p>Japan abstained from the vote, for the following reasons</p> <p>As a result of enquiries made to domestic stakeholders, the majority of respondents were in favour of the direction of the project itself. However, there were some problems</p> <ul style="list-style-type: none"> a) The scope of the proposal is not clear. b) If the proposal is for a product standard, there is no need for an international standard because national legislation already exists. <p>Detailed explanation</p> <p>Details about a)</p> <p>The scope of the standard is too broad to be clearly understood.</p> <p>The following specific points are unclear</p> <p>Is it a technical standard (standards for hygienic quality, absorption, retention, etc.)?</p> <p>Is it a guideline that focuses on the "consumer perspective" (i.e. product labelling, consideration for people with disabilities, ease of choice, gender</p>		

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

Template for comments and secretariat observations

Date:2021-06-17

Document:

Project:

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Observations of the secretariat
					<p>equality, environmental considerations, etc.)? If the above two criteria are included, the proposal should be divided into "technical standards" and "consumer issues arising from the product". A TC instead of a PC shall be proposed.</p> <p>The number of product types is also quite large if peripheral products are included. Do the products covered include 'liners', 'sanitary panties', 'wash water' and 'washers'?</p> <p>b) Links Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices PMD Act : Pharmaceutical and Medical Device Act https://www.jhpia.or.jp/product/napkin/napkin5.html https://www.jhpia.or.jp/site_en/standard/napkin/img/the_standards_for_marketing_approval_of_sanitary_napkins.pdf https://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/seiri_zairyou.pdf</p>		
US-004					<p>1. Do you have any additional comments?</p> <p>YES:</p> <ul style="list-style-type: none"> • madesafe.org is a source, as is FDA and OSHA of work in this area mostly as a result of the toxic shock issue and for the disposal as regulated waste. <p>New Zealand and other countries have recently addressed providing free products to students and education campaigns.</p>		

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Template for comments and secretariat observations

Date:2021-06-17

Document:

Project:

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Observations of the secretariat
US- 005					<p>2. Are you aware of any national standards covering any aspects of menstrual health or products?</p> <p>YES:</p> <ul style="list-style-type: none"> • There are national standards to help prevent toxic shock syndrome • Both FDA and OSHA have regulations <p>Also, it appears that there are already existing voluntary international standards</p>		
ANEC -006				ge	ANEC supports the proposal for standardization of menstrual products.		
SE- 007			Do you have any additional comments?		YES. We are excited for this new area of standardization finally being proposed and very happy to be part in the coming developments.		
SE- 008			Have you had resistance to this project from national stakeholders ?		YES. 1 stakeholder has expressed concerns about the necessity of international standards. However, the other stakeholders are on the contrary convinced international standards in this area really can benefit users all over the world.		
SE- 009			Is there any legislation in your country covering this area?		YES. These products fall under the Product Safety Act in Sweden.		
ID- 010		Part A. 3		ge	Indonesia encourage the proposal of Safety and performance of menstrual products, since there is no international standard to be a reference for countries to make their national standard. Some countries		

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Template for comments and secretariat observations

Date:2021-06-17

Document:

Project:

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Observations of the secretariat
					<p>already have their national standard, but it varies widely from country to country. To have the same platform of consumers safety, health, security and environment protection as well, particularly on the product safety caused by the use of hazardous chemicals, Indonesia strongly recommends ISO COPOLCO to make an international standard of menstrual products.</p>		

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² **Type of comment:** **ge** = general **te** = technical **ed** = editorial

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Propo
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File: COPOLCO N605_INSO.docx

We do not support the proposal for standardization of menstrual products.

File: COPOLCO N605_SAC.docx

China’s national standard related to this area:

GB/T 8939-2018 Sanitary absorbent pads (panty liner)

Legislation :

Currently, Consumer Protection Law, Product Quality Law and Criminal Law of China have some principle regulation.

File: COPOLCO N605_SSMO.docx

<u>No.</u>	<u>Questions</u>	<u>Possible Answers</u>
1	Do you support the proposal for standardization of menstrual products?	Yes No * Abstain
2	Do you have national standards covering any aspects of menstrual health or products?	Yes No Abstain
3	Is there any legislation in your country covering this area?	Yes No Abstain
4	Have you had resistance to	Yes *

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2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

MB/ NC ¹	Line number	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Propo
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			this project from national stakeholders?	No Abstain		
5			Do you have any additional comments?	Yes *		
				Abstain		

(*) A Comment is required for this answer value.

*The most popular types of product are the most detrimental to the natural environment, particularly due to the hidden plastic in disposable items.

*Awareness is very important especially for women who felt that menstruation was is something to be ashamed of, a feeling that is still prevalent in society and popular culture

*Menstrual products have an environmental cost at the end use.

*Menstrual product in toilets, latrines affects the sewerage system.

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2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

COPOLCO N605_ANEC.doc: Collation successful

COPOLCO N605_ANSI.docx: Collation successful

COPOLCO N605_BSN.doc: Collation successful

COPOLCO N605_JISC.docx: Collation successful

COPOLCO N605_SA.doc: Collation successful

COPOLCO N605_SIS.doc: Collation successful

COPOLCO N605_TISI.doc: Collation successful

Collation of files was successful. Number of collated files: 10

SELECTED (number of files): 10

PASSED TEST (number of files conformed to CCT table model): 7

FAILED TEST (number of files conformed to CCT table model): 0

COPOLCO N605_INSO.docx: Collation successful

COPOLCO N605_SAC.docx: Collation successful

COPOLCO N605_SSMO.docx: Collation successful

PASSED OTHER FILES (number of files to be collated at the end of the result file not conformed to CCT table model): 3

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