



## TECHNICAL BOARD

### CEN/BT by correspondence

<b>For vote</b>	<b>Issue date:</b>	2018-12-05
<b>According to IR2 Clause 6.1.4</b>	<b>Deadline:</b>	2019-03-05

### SUBJECT

#### Creation of a new CEN Technical Committee on 'Regulated chemicals in products'

### BACKGROUND

On 22 November 2018, AFNOR submitted a proposal to CCMC for the creation of a new Technical Committee to work on European Standards and other deliverables for regulated chemicals in products (see Annex to BT N 11389).

The proposed Technical Committee would be responsible for the development of the deliverables in the area of processes and methods for the verification of compliance with regulatory requirements on regulated chemical products. A starting point for the new proposed Technical Committee would be the work programme developed by CEN-CLC/BTWG 13 'PAH' in reply to the Standardisation Request M/556 on compliance with maximum content criteria of Polycyclic Aromatic Hydrocarbons in rubber and plastic components of articles placed on the market for supply to the general public in support of Regulation (EC) No. 1907/2006 (see separate document BT N 11387 Annex 1).

Where relevant, the new Technical Committee will liaise with existing CEN Technical Committees, e.g. CEN/TC 52 'Safety of toys', CEN/TC 136 'Sports, playground and other recreational facilities and equipment', CEN/TC 158 'Head protection' amongst others mentioned in Annex to BT N 11389.

By BT 65/2017, BT decided that the following criteria are to be met for acceptance of such a proposal for new work (in a new area):

- Vote according to Internal Regulations Part 2 clause 6.1.4;  
*Note: Possible votes are 'Agrees', 'Disagrees with comments' and 'Abstains'. Any vote indicating 'Deferred decision' will be counted as 'Disagrees with comments'.*
- At least 5 members express commitment to participate.

As a consequence, BT Members are requested to state explicitly, by means of the commenting field provided in the BT-balloting tool, whether or not they are committed to participate in the work.

## PROPOSAL(S)

BT,

- having considered the proposal for a new field of technical activity submitted by AFNOR as included in BT N 11389;
- considering that the following members have expressed commitment to participate:
  - <members>
- decides to create a new CEN/TC xxx with the following preliminary title and scope:  
Title: CEN/TC xxx 'Regulated Chemicals in Products'  
Scope: Standardisation of processes and methods for the verification of compliance with regulatory requirements on the metrology of regulated chemicals in products. In particular, it focuses on:
  - sample preparation,
  - quantification of regulated substances in matrix or product,  
Excluded: waste and specific products already addressed by a dedicated Technical Committee;
- allocates the secretariat of CEN/TC xxx to AFNOR;
- asks the new CEN/TC xxx to submit its final title and scope for BT approval by August 2019.

2018-11-30 – PK



PROPOSAL for a NEW FIELD OF TECHNICAL ACTIVITY	
Date of circulation .....	<b>CEN/TC / SC N .....</b> (where appropriate)
Secretariat .....	<b>CENELEC/TC / SC (Sec) .....</b> (where appropriate)
Type of technical body proposed (TC / SC / BTTF)	<b>Technical Committee</b> .....

**IMPORTANT NOTE: Incomplete proposals risk rejection or referral to originator.**

The proposer has considered the guidance given in Annexes 1 and 2 during the preparation

**Proposal** (to be completed by the proposer)

<p><b>Title of the proposed new subject</b> (The title shall indicate clearly and unambiguously, yet concisely, the new field of technical activity which the proposal is intended to cover.)</p> <p>Regulated chemicals in products</p>
<p><b>Scope statement of the proposed new subject</b> (The scope shall precisely define the limits of the new field of technical activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned.)</p> <p>Standardisation of processes and methods for the verification of compliance with regulatory requirements on the metrology of regulated chemicals in products. In particular, it focuses on:</p> <ul style="list-style-type: none"><li>• sample preparation,</li><li>• quantification of regulated substances in matrix or product,</li></ul> <p>Excluded: waste and specific products already addressed by a dedicated technical committee</p>

## Purpose and justification for the proposal.

Chemicals in products are increasingly controlled and regulated. The identification and traceability of substances in products is made mandatory by European regulations, in particular by REACH (Regulation 1907/2006/EC). Private contracts may also establish further requirements. Thus, in manufacturing a product, industrials must make sure that they have a robust traceability process covering their entire supply chain.

Some discussions have already taken place within CEN-CENELEC/BT/WG 13 "Polycyclic Aromatic Hydrocarbons (PAH)", following Standardisation request M/556<sup>1</sup>. After conducting a study to identify existing methods to determine, measure, sample and extract PAH in articles, the group concluded that there was indeed a need for an European standard on this topic and that it should be developed by a new CEN Technical Committee. Additionally, the group recommended that this future Technical Committee should not limit itself to PAH but should cover other kinds of regulated chemicals in products, since those chemicals are subject to similar regulatory requirements. Indeed, while no other Standardisation Request has been introduced so far, it is reasonable to expect that, in the near future, the European Commission will express the need for European Standards covering other substances.

Waste are excluded from this proposal as they are not akin to a product. Another reason to exclude waste is that this topic is covered by CEN-CENELEC/BT/WG 11 on Sustainable chemicals.

The purpose of this proposed Technical Committee is to develop those standards

- that are not covered by an existing technical committees (for example TCs in the construction sector develop many standards on chemicals and will of course continue to do so if the proposed TC is established)
- or that cannot be developed by existing technical committees dedicated to specific materials, due to the complexity of the cross sector or cross matrix implications of relevant regulations (for instance, M/556 requests one standard covering both plastic and rubber materials, while no single existing TC would be legitimate to handle the work).

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<sup>1</sup> See standardisation request M/556 of 1.12.2017 as regards compliance with maximum content criteria of Polycyclic Aromatic Hydrocarbons in rubber and plastic components of articles placed on the market for supply to the general public, in support to Regulation (EC) No. 1907/2006.

Is the proposed new subject actively, or probably, in support of European legislation or established public policy?

Yes     No

If Yes, indicate if the proposal is

- in relation to EC mandate(s): M/556
- in relation to EC Directive(s)/Regulation(s): Regulation 1907/2006/EU
- in relation to other legislation or established public policy: .....(give details)

#### Proposed initial programme of work

The first part of the proposed work programme would be to answer the Standardisation request M/556 (Compliance with maximum content criteria of Polycyclic Aromatic Hydrocarbons in rubber and plastic components of articles placed on the market for supply to the general public in support of Regulation (EC) No. 1907/2006).

Based on the recommendations arising from the evaluation of existing standardised and non-standardised methods, a European standard will be developed for the determination of content and selected polycyclic aromatic hydrocarbons (PAH) in plastic and rubber components of articles placed on the market for supply to the general public. This standard will be published in 2022.

The detailed work programme of the proposed new TC would be the following:

- Selection of samples (1st semester 2019)
- Development and optimisation of the PAH content method based on the recommendations made by CEN-CENELEC/BT/WG 13 and in house validation of the method (2019 until March 2020)
- Interlaboratory validation of the method (2020)
- Standardisation of the method (CEN enquiry and formal vote) for a publication in 2022.

More detail is available in the revised CEN-CENELEC/BT/WG 13 work programme.

The work programme will likewise consider emerging standardisation needs regarding new regulated substances and/or new matrices.

#### A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing CEN, CENELEC, 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.)

The purpose of this work is to avoid duplication of standardisation work that is handled in different CEN or CENELEC TCs dealing with regulated chemicals. The work already undertaken in the relevant technical committees (at European or international levels) will be taken into account from the outset, before starting the development of new deliverables.

The aim of this Technical Committee is to develop standards with a scope that could be developed neither by a specific technical committee nor by several technical committees, due to the cross sectorial or to cross matrix implications of relevant regulations. For instance, M/556 covers both plastic and rubber materials, which are dealt with by distinct TCs, while no single existing TC is legitimate to handle the work.

#### A listing of relevant existing documents at the international, regional and national levels.

Any known relevant documents (such as standards and regulations) shall be listed, regardless of their source, and should be accompanied by an indication of their significance.

See CEN-CENELEC/BT/WG 13 Scoping study

**Known patented items**

Yes       No    If "Yes", see CEN-CENELEC Guide 8 and provide full information in an annex

**A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) in particular those who are immediately affected from the proposal (see Annexes 1 and 2) and how they will each benefit from or be impacted by the proposed deliverable(s)**

Main categories of stakeholders:

- Trade and industry: all organisations within the product value chain or trade that are required to declare or to identify regulated substances, such as
  - o Professional organisations in the area of materials, food, paper, plastics, chemicals, recycling, mechanical engineering...
  - o Professional organisations representing small- and medium-sized enterprises
  - o Businesses that are to comply with regulated substances: automotive, chemicals, aerospace and defence industry, distribution, recycling, metals, paper, ceramics, copper, plastics, textiles...
- National public authorities responsible for the implementation of European regulations or directives on substances: ministries and public organizations related with regulated substances, environment, health, competition, market surveillance...
- Academic and research bodies, such as research bodies and laboratories dedicated to analytical/chemical methods
- Testing laboratories

**Liaisons:**

**A listing of relevant external European or international organizations or internal parties (other CEN, CENELEC, ETSI, ISO and/or IEC committees) to which a liaison should be established (in the case of ISO and IEC committees via the Vienna or Dresden Agreements).**

As the scope of the proposed TC involves different sectors, the following TCs could be interested for liaison (non-exhaustive list):

- CEN/TC 52 Safety of toys
- CEN/TC 136 Sports, playground and other recreational facilities and equipment
- CEN/TC 158 Head protection
- CEN/TC 162 Protective clothing including hand and arm protection and lifejackets
- CEN/TC 164 Water supply
- CEN/TC 193 Adhesives
- CEN/TC 194 Utensils in contact with food
- CEN/TC 248 Textiles and textile products
- CEN/TC 252 Child care articles
- CEN/TC 289 Leather
- CEN/TC 309 Footwear
- CEN/TC 351 Construction Products - Assessment of release of dangerous substances
- CEN/TC 352 Nanotechnologies
- CEN/TC 444 Test methods for environmental characterization of solid matrices
- CENELEC/TC 111X Environment
- CEN-CENELEC/BT/WG 11 Sustainable chemicals

Efficient liaisons between the technical committees will be one of the success factors for this standardisation work.

Liaisons will allow sharing existing documents (at European or International levels) and developing common test methods if necessary.

**Joint/parallel work:**

**Possible joint/parallel work with:**

- CEN (please specify committee ID)
- CENELEC (please specify committee ID)
- ISO (please specify committee ID)
- IEC (please specify committee ID)
- Other (please specify)

**Name of the Proposer**  
(include contact details)

AFNOR

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In case of questions, do not hesitate to contact Ms Laurie JARDEL (laurie.jardel@afnor.org) or Ms Corinne DEL CERRO (corinne.delcerro@afnor.org).

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

In case of acceptance of the proposal, AFNOR is willing to undertake the secretariat of the Technical Committee.

Alain COSTES

AFNOR Standardisation Director

**Signature of the proposer**

**Annex(es) are included with this proposal** (give details)

## **Informative Annex 1 "Principal categories of market needs"**

- Consumer protection and welfare
- Environment
- Innovation
- Support to:
  - public policy
  - European legislation/regulation
- Market access/barriers to trade, i.e. enhancing the free movement of:
  - services
  - goods
  - people
- Interoperability
- Health/Safety
- Terminology

## **Informative Annex 2 "Principal categories of stakeholders"**

- Industry and commerce,
  - where particularly appropriate, to be identified separately as
    - Large enterprises (those employing 250 staff or more)
    - Small and medium sized enterprises (SME), (those employing 250 staff or fewer)
- Government
- Consumers
  - including those organizations representing interests of specific societal groups, e.g. people with disabilities or those needing other particular consideration)
- Labour
- Academic and research bodies
- Non-governmental organisations (NGO),
  - including organizations representing broad or specific environmental interests
- Standards application business (e.g. testing laboratories, certification bodies)

Sometimes it is valuable also identify the immediate affected stakeholders from industry and commerce in terms of their position in a product value chain, as follows:

- Supplier
- Manufacturer
- Intermediary (e.g. warehousing, transport, sales)
- Service provider
- User of the product or service
- Maintenance / disposal

NOTE: 'Immediately affected stakeholders' are considered to be those who, within the context of the proposal, would be in a position to implement the provisions of the intended standard(s) into their products, services or management practices.