



PTB Technical Cooperation in Asia

“Strengthening the Quality infrastructure in Myanmar”

Dr. Tin Win - PTB consultant

Good Standardization practice and ASEAN guide line for harmonisation of standards in ASEAN

World Standards Day in Myanmar
October 16, 2019



Physikalisch
Technische
Bundesanstalt
Braunschweig und Berlin

QI related PTB projects in ASEAN

PTB Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
Nationales Metrologieinstitut

INTERNATIONAL
COOPERATION



Association of Southeast Asian Nations (ASEAN)

Improving Quality Infrastructure in ASEAN



Strengthening Accreditation Networks in Asia Pacific

Planning, preparation, implementation and coordination of international cooperation projects concerning **metrology, standardization, testing, quality assurance, accreditation and certification in the regions of Asia**



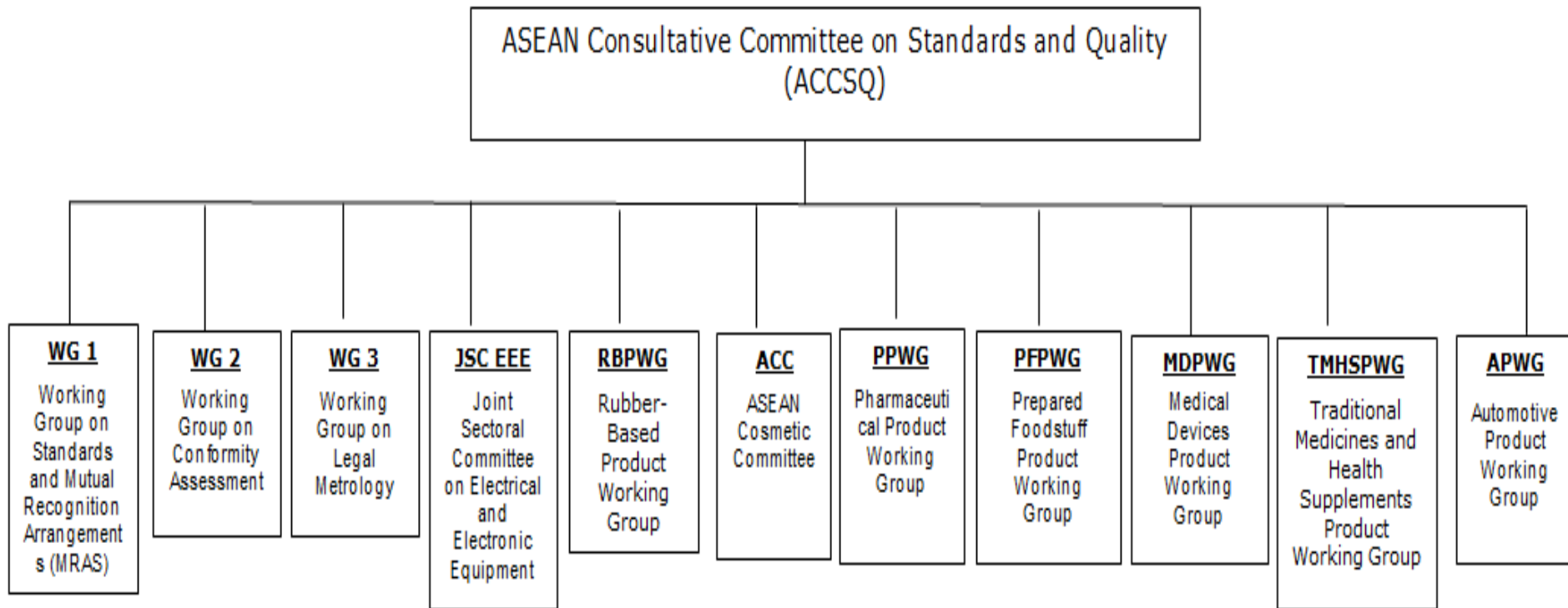
Asia

Promoting regional cooperation in metrology



Partly participating in ARISE Plus “ASEAN Regional Integration Support by EU”

ASEAN Trade Facilitation Work Program



3 Working Groups and 9 Product Working Groups

WG1: Standards and Mutual Recognition Arrangements MRAs

- harmonization of standards and align national standards among AMS;
- harmonize or develop technical regulations for national application;
- strengthen cooperation within ASEAN countries in the area of capacity building, exchange of experts, regulatory infrastructure and HR- development
- AMS modelling their technical standards and regulations after ASEAN harmonized technical standards and regulations

Harmonization of Standards and Technical Requirements in ASEAN

- Harmonised Standards for 20 Priority Products, Safety and EMC Standards

Prepared foodstuffs

- ASEAN General Standards for the Labelling Prepackaged Food VS product labeling requirements (Myanmar consumer protection law: March 2019)
- ASEAN Principles and Criteria for The Establishment of Maximum Level for Contaminants and Toxins in Food and Feed
- ASEAN Food Safety Policy
- ASEAN Principles and Guidelines for National Food Control System
- ASEAN General Principles of Food Hygiene
- ASEAN Guidelines for Food Import Control Systems
- Guidelines for ASEAN Food Reference Laboratories (AFRL)
- ASEAN Principles for Food Import and Export Inspection and Certification

Pharmaceutical

- ASEAN Variation Guideline for Pharmaceutical Products
- ASEAN Guideline for the Conduct of Bioequivalence Studies
- ASEAN Guideline on Stability Study of Drug Product
- ASEAN Guideline on Analytical Validation
- ASEAN Guideline on Process Validation
- ASEAN Labeling Requirements for Pharmaceuticals

ASEAN does not formulate its own standards; AMS adopt international standards for product of interest as national standards; DIR, IDT, MOD, NEQ

Good standardization practice for development of international standards at DIN, ISO and CEN

- DIN Standards are the results of work at national, European and/or international level. Anyone can submit a proposal for a new standard. Once accepted, the standards project is carried out according to set rules of procedure by the relevant technical committees of DIN, CEN or ISO.
- All stakeholders can participate in this work, including manufacturers, consumers, businesses, research institutes, public authorities and testing bodies
- For work at European and international level, the DIN standards committees send experts to represent German interests within CEN and ISO, respectively
- Standards are developed with full consensus, they are developed by experts with the aim of arriving at a common standpoint, taking the state of the art into consideration
- Standards are reviewed at least every five years. If a standard no longer reflects the current state of technology, it is either revised or withdrawn
- **Process of standard development**

Proposal-->working draft-->committee draft-->final draft-->full standard

Single laboratory validation-->standard validation intercomparison

DIN SPEC(prestandard), DIN SPEC (Technical Report)

EU- WFD- Environmental Quality Standard - 33 Priority hazardous substances as per Directive 2000/60/EC - in µg/l of water

2)Anthracene	0.1
3)Atrazin	0,6
4)Benzene	10
5) Pentabromodiphenylether	0,0005
12) Diethylhexylphthalate	1,3
18) Hexachlorocyclohexane (lindane)	0,02
20) Lead and its compounds	7,2
6) Cadmium and its compounds	0,08
23) Nickel and its compounds	20
21) Mercury and its compounds	0,05
26) Pentachlorobenzene	0,007
28) PAH, Benzo(ghi)perylene	0,002
29) Simazine	1,0
27) Pentachlorophenol	0,4
30) Tributyltin compounds	0,0002
32) Trichloromethane (Chloroform)	2,5

Exiting Standardized Analytical Methods

- The Method Applicability Factor (MAF) has been defined as:

Lower Limit of Application

30 % of EQS

MAF < 1: method is applicable

MAF > 1: method needs attention

MAF > 1 :

- Alachlor (4.8)
- Chlorpyrifos (72)
- Hexachlorbutadiene (11), Pentachlorobenzene (10)
- Hexachlorobenzol (83), Lindane (1.7)
- PAH: BghiPe + IndPyr (21)
- Tributyltin (200)
- Trifluralin (5.6)

**New challenges for analyst
to achieve lower LOD**

Call for the development and enhancement of European Standards to determine the chemical and ecological water quality in support of WFD (September 2008) Mandate 424 to CEN by EU DG Enterprise

WP	Compound	EQS	Required LOQ
WP 1	OCPs		
	Alachlor	300 ng/L	100 ng/L
	Cyclodiene pesticides (Aldrin, Dieldrin, Endrin, Isodrin)	$\Sigma = 10$ ng/L	3 ng/L
	DDT total	$\Sigma = 25$ ng/L	7,5 ng/L
	p,p'-DDT , hexachlorobenzene	10 ng/L	3 ng/L
	Endosulfan	5 ng/L	1,5 ng/L
	Hexachlorobutadiene	100 ng/L	30 ng/L
	HCH	$\Sigma = 20$ ng/L	6 ng/L
	Pentachlorobenzene	7 ng/L	2 ng/L
WP 2	PBDE (BDE28, BDE47, BDE99, BDE100, BDE153, BDE154)	$\Sigma = 0, 5$ ng/L	0,15 ng/L
WP 3	PAH		
	Benzo(b) and (k) fluoranthene	$\Sigma = 30$ ng/L	9 ng/L
	Benzo(ghi)perylene, Indeno(123-cd) pyrene	$\Sigma = 2$ ng/L	0, 6 ng/L
WP 4	TBT	0, 2 ng/L	0,06 ng/L
WP 5	SCCP (C10 to C13)	400 ng/l	130 ng/L

EMRP SRT-ENV-12

The objectives include:

- 1) Development of a metrology infrastructure for pollutants in aquatic environments, including aqueous soils, sediments and biota media, under the WFD.
- 2) Development and validation of traceable measurement methods for samples which contain priority substances in concentration as low as required by the WFD. These methods must be applicable in routine laboratories conditions.
- 3) Development and validation of sample preparation techniques for the quantitative extraction and preconcentration of key measurands from the aquatic compartments.
- 4) Development of reference materials in respect with the concept of “whole water” defined in the WFD, thus including suspended particulate matter (SPM), sediments and biota.
- 5) Development of methods for the preparation of sufficiently homogeneous and stable aqueous proficiency testing samples which contain the target analytes in concentration as low as required by the WFD.

Project Proposal – General

- focus: WFD priority analytes for which applicable methods at EQS limits in whole water are missing (e.g. TBT, PBDE, OCP, PAH, SCCP)

traceable methods at high metrological level, which could serve as a reference for monitoring
- main consortium: BAM, IRMM, LGC, LNE, PTB...
- unfunded partners: CENAM, Mexico
NMIA, Australia
GKSS Forschungszentrum, Institute for Coastal Research/
Operational Systems, Geesthacht, Germany
PT-WFD
- stakeholder: Water & Marine Unit of EC
standardization bodies (CEN TCs Water Analysis and
Characterization of Sludges, ISO TC Water Quality,
DIN committee Water Investigation)
- **total eligible budget: 4500 k€, i.e. large project**

Project Proposal – Workpackages

- **WP1:** Project management and coordination (**leader: BAM/PTB**)
- **WP2:** Development and validation of a traceable analytical method for TBT in natural water with an LOQ smaller than 30% of the EQS (EQS: 0.2 ng/L), i.e. 0.06 ng/L (**leader: BAM**) objectives 2, 3 →
- **WP3:** Development and validation of a traceable analytical method for technical PBDE in natural water with an LOQ smaller than 30% of the EQS (EQS: \sum PBDE 0.5 ng/L), i.e. 0.15 ng/L (**leader: PTB**) objectives 2, 3 →
- **WP4:** Development and validation of a traceable analytical method for selected PAHs? in natural water with an LOQ smaller than 30% of the EQS (**leader: LNE**) objectives 2, 3 →
- **WP5:** Advanced analytical platforms for monitoring the interaction and partitioning of selected pollutants in environmental aquatic compartments (**leader: LGC**) objectives 2, 3 →
- **WP6:** Feasibility study for the preparation of reference materials and PT samples (**leader: IRMM**) objectives 4, 5 →
- **WP7:** Impact, dissemination and knowledge transfer at the European level (**leader: PTB/BAM**) objectives 1, 3 →

Standard deliverables for CEN TC 230

- FprEN 16693:2013-Water quality — Determination of organochlorine pesticides (OCP) in whole water samples using solid phase extraction (SPE) with SPE-disks combined with gas chromatography mass spectrometry (GC-MS)
- FprEN 16691:2014-Water quality — Determination of selected poly aromatic hydrocarbons(PAH) in whole water samples — Method using disk based solid phase extraction and gas chromatography and mass spectrometry (GC/MS)
- FprEN 16694:2013- Water quality – Determination of selected polybrominated diphenyl ether (PBDE) congeners in whole water samples with disk-based solid phase extraction followed by gas chromatography-mass spectrometry (GC-MS)
- FprEN/TS 16692:2013- Water quality — Determination of tributyltin (TBT) in whole water samples using solid phase extraction (SPE) and gas chromatography with triple



Horizontal standardisation for the implementation of

Sewage Sludge Directive 86/278/EEC
Soil Monitoring Directive (Proposal 2004)
Biowaste Directive (Proposal 2004)
Landfill Directive 1999/31/EC
Water Framework Directive

DG ENV HAS ISSUED A MANDATE TO CEN FOR THE
DEVELOPMENT OF HORIZONTAL STANDARDS
IN THE FIELDS OF SLUDGE, BIOWASTE AND SOIL

Determination of PAH by GC-MS and HPLC-FLD/DAD (prEN 16181)

Determination of PCB by GC-MS and GC-ECD (prEN 16167)

Determination of Phthalates by GC-MS (FprCEN/TS 16183)

Determination of Nonylphenols by GC-MS after derivatization (FprCEN/TS 16182)

Determination of Linear alkylbenzene sulfonates (LAS) by HPLC-MS/FLD (FprCEN/TS16189)

Determination of PCDD and PCDF and coplaner PCB by GC-MS (ISO FDIS 13914-Soil quality: 2012)

Toxicologically derived limit value for pathway soil-human,
Germany 2002

Use	Benzene mg/kg	Toluene mg/kg	Xylene mg/kg	Ethylbenzene mg/kg
Play ground	0,1	10	10	3
Living area	0,2	10	10	3
Industrial and trading area	0,4	100	100	30

LOD should be at about 25% of the limit values

Performance characteristics (09.2005)**BTEX in soil , low trace level A: ISO 22155:2006**

Parameter	L	n _a	X _{ref} mg/kg	x mg/kg	R %	Vr mg/kg	Vr %	VR mg/kg	VR %
Benzene	20	1	0,043	0,043	100,00	0,004	9,47	0,009	20,85
Toluene	20	1	0,063	0,066	104,76	0,005	7,96	0,014	20,51
Ethylbenzene	21	0	0,072	0,067	93,06	0,005	7,57	0,012	18,35
m/p-Xylene	20	1	0,057	0,055	96,49	0,005	9,72	0,011	19,64
o-Xylene	21	0	0,068	0,062	91,18	0,005	7,73	0,012	19,00
L	Number of laboratories				R	Recovery			
n _a	Number of outliers Type B; Type C					Vr	Repeatability STD.		
X _{ref}	Reference value = gravimetric concentration					Vr %	Relative Repeatability STD		
x	Mean value					VR	Compareability STD.		
						VR%	Relative Compareability STD		

Mandate 445 – Call for tender



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

New Approach Industries, Tourism and CSR
International regulatory agreements, toys safety, CSR

Brussels, 9th July 2009

M/445 EN

**STANDARDISATION MANDATE ADDRESSED TO CEN AND CENELEC
WITHIN THE FRAMEWORK OF DIRECTIVE 2009/48/EC REVISING
DIRECTIVE 88/378/EEC CONCERNING THE SAFETY OF TOYS**

2nd Call for Tender

for

1 Lead Laboratories for the development and validation of test methods for a standard on phenol,

2 Peer Review Laboratories to support the development and validation of test methods for certain standards,

and for

5 Reference Material Suppliers to provide the reference materials for the test method development and validation

Launch: 2019-09-03
Offer period/Deadline for tenders: 2019-10-17

Call for tender for development and validation of standardized test for methods for EN 71- „Safety of Toys“

The following subprojects require the development and validation of standardized test methods and are subject to this call for tender:

1. Elaboration of a new standard EN 71-aa “Safety of toys – Part aa: Formamide in foamed toy materials”
2. Elaboration of a new standard EN 71-bb “Safety of toys – Part bb: TCEP and alternative flame retardants”
3. Elaboration of a new standard EN 71-cc “Safety of toys – Part cc: Isothiazolinones in aqueous (toy) materials”
4. Elaboration of a new standard EN 71-dd “Safety of toys – Part dd: Phenol”
5. Elaboration of a new standard EN 71-ee “Safety of toys – Part ee: Bisphenol A”

For each of those subprojects, a Lead Laboratory and a Peer Review Laboratory will be contracted which will cooperate in the development and validation of the required test method(s). In addition, for each subproject a Reference Material Supplier will be selected who will provide the reference materials required for the test method development and validation. **Please note that the Lead**

RASFF-Rapid Alert System for Food and Feed of EU

Notifications on Myanmar

Year	Findings	Action
2002	prohibited substance chloramphenicol (0,1 mg/kg - ppm) in shrimps	alert
2003	Nitrofurantoin + nitrofurazone in king prawns Chloramphenicol in shrimps	alert
2005	Chloramphenicol + infested with insects and mould in dried fish and prawns	alert
2006	Chloramphenicol in tilapia	alert
2007 2008	Histamine in fish and fish products	Border rejection
2009	Chloramphenicol in crustaceans	border rejection
2013	Chloramphenicol in other food products	Border rejection
2014	Fraudulent health certificate for chloramphenicol in dried shrimps	Border rejection
2015	Unauthorised GMO long grain rice	alert
2017	Parboiled rice infested with insects and mites	Border rejection
2018	Abnormal smell of mould of parboiled rice, dead insects in white rice	Border rejection

Thank you for your attention!

Dr. Tin Win

drtinwin07@gmail.com

Technical Cooperation in Asia
Physikalisch-Technische Bundesanstalt (PTB)

Bundesallee 100
38116 Braunschweig, Germany

