Japan Business Council in Europe

Certified Reference Materials/Reference Materials under REACH
JBCE contribution to the currently ongoing consultation on SVHCs recommended for REACH Authorization

Dear European Chemical Agency,

28, November 2014

1. Introduction

The Japan Business Council in Europe (JBCE) would like to bring to your attention the subject of Certified Reference Materials/Reference Materials under the REACH Regulation in general and with regard to Authorisation in particular. The issue at hand is traceability, which is a necessary tool to ensure accuracy in the metrology system.

The REACH Regulation provides for a provision on scientific research and development. Article 3(23) states that *"Scientific research and development means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year." Additionally,* Articles 56(3) and 67(1) state that Authorisation and Restrictions shall not apply scientific research and development.

2. Our request and/or inquiry

The JBCE is of the opinion that CRM/RM should be considered as being covered by the provisions on substances subject to scientific research and development and therefore be exempted from the Authorisation and Restrictions processes. We would like to ask for clarification from your side as to whether our understanding is correct.

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EU Transparency Register: 68368571120-55

3. Practical example

Here in the link below of public consultation for authorization substances is an example for pH standard solution that has international and national traceability.

[Disodium tetrabrorate, anhydrous]

http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list

http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf

3.1 Example of traceability

3.11 IUPAC, International Union of Pure and Applied Chemistry

Pure Appl. Chem., Vol. 74, No. 11, pp. 2169–2200, 2002.

INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY

MEASUREMENT OF pH.
DEFINITION, STANDARDS, AND PROCEDURES

(IUPAC Recommendations 2002)

Table 2 Typical values of pH(PS) for primary standards at 0–50 °C (see Section 6.2).

	Temp./°C										
Primary standards (PS)	0	5	10	15	20	25	30	35	37	40	50
0.01 mol kg^{-1} disodium tetraborate	9.464	9.395	9.332	9.276	9.225	9.180	9.139	9.102	9.088	9.068	9.011

Table 2 can be referred from P2179 in the link below.

http://pac.iupac.org/publications/pac/pdf/2002/pdf/7411x2169.pdf

3.12 OIML, International Organization of Legal Metrology

INTERNATIONAL RECOMMENDATION OIML R 54

Edition 1981 (E)

pH SCALE for AQUEOUS SOLUTIONS

Table 1 (cont.) - pH values of buffer solutions

Temperature °C	KH_2PO_4 0.025 mol/kg H_2O + Na_2HPO_4 0.025 mol/kg H_2O [1]	KH_2PO_4 0.008695 mol/kg H_2O + Na_2HPO_4 0.03043 mol/kg H_2O [1]	$Na_2B_4O_7$. 10 H_2O 0.01 mol/kg H_2O [1]	Na H CO_3 0.025 mol/kg H_2O + Na_2CO_3 0.025 mol/kg H_2O [2]	Ca $(OH)_2$ saturated at 25 °C [1]
0	6.984	7.534	9.464	10.317	13.423
5	6.951	7.500	9.395	10.245	13.207
10	6.923	7.472	9.3.32	10.179	13.003
15	6.900	7.448	9.276	10.118	12.810
20	6.881	7.429	9.225	10.062	12.627
25	6.865	7.413	9.180	10.012	12.454
30	6.853	7.400	9.139	9.966	12.289
35	6.844	7.389	9.102	9.925	12.133
38	6.840	7.384	9.081	--------	12.043
40	6.838	7.380	9.068	9.889	11.984
45	6.834	7.373	9.038	9.856	11.841
50	6.833	7.367	9.011	9.828	11.705
55	6.834	--------	8.985	--------	11.574
60	6.836	--------	8.962	--------	11.449
70	6.845	--------	8.921	--------	--------
80	6.859	--------	8.885	--------	--------
90	6.877	--------	8.850	--------	--------
95	6.886	--------	8.833	--------	--------

https://www.oiml.org/en/files/pdf_r/r054-e81.pdf/view

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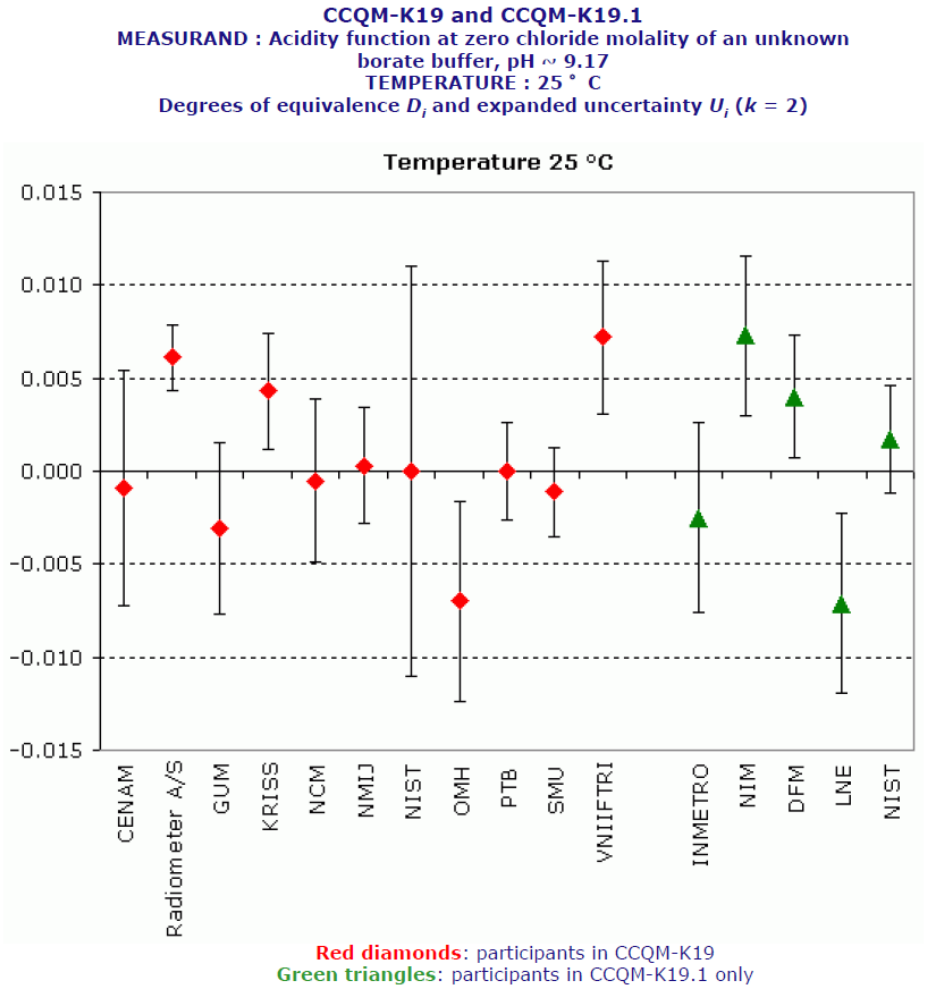
3.13 ISO 10523:2008 Water quality – Determination of pH

http://www.iso.org/iso/catalogue_detail.htm?csnumber=51994

3.14 CCQM, Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology

CCQM-K19: pH measurement of borate buffer solutions (coordinator)



http://kcdb.bipm.org/AppendixB/

3.15 NIST, National Institute of Standards and Technology in US

https://www-s.nist.gov/srmors/view_detail.cfm?srm=187e

3.16 PTB (Germany), LNE (France), DFM (Denmark), SMU (Slovakia), OMH (Hungary) in EU

3.17 JCSS in Japan

[About JBCE]

Created in 1999, **the Japan Business Council in Europe (JBCE)** is a leading European organisation representing the interests of almost 70 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, railway, textiles and glass products. Together, our member companies represented in 2013 global sales of 1.4 trillion euros. Building a new era of cooperation between the European Union (EU) and Japan is the core of our activities. www.jbce.org

The following associations and institutes are in the position to support JBCE response.

Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA) has been an active forum for measuring instruments manufacturers since its establishment in 1948. It has 85 companies as regular members and 29 companies & 7 organizations as supporting members. JEMIMA members contribute to a wide variety of industries by supplying products as "Mother Tools of the industry" for R&D design, and manufacturing.

JEMIMA activities are becoming more and more global, since most of the issues our industry is facing are also global. By actively working on these issues, we help our members to meet the challenge and promote the development of the industry worldwide. To achieve these goals, JEMIMA take "Globalization & promotion of International activities" to be one of the focal activities.

This nationwide organization was founded with the purpose of contributing to the advancement of science and technology by improving technologies related to analytical instruments and promoting the progress of the analytical-instruments industry, thereby contributing to the Japanese economy and the livelihood of its citizens.

Japan Business Council in Europe

The Japan Reagent Association was established in 1948 as the organization of Japanese companies associated with manufactures of reagents. Our membership consists of more than 110 companies of multinational corporations, those are active mainly in USA, Europe and Asia, including import and sales business of reagents and apparatus. The chief aim of JRA is to contribute the stable lives of the citizens and to the sound development of the technology.

NMIJ

"The Metrology Institute of Japan (MIJ) and the Metrology Management Center both of which are part of the National Institute of Advanced Industrial Science and Technology (AIST), together make up the National Metrology Institute of Japan (NMIJ). Those two equally important NMIJ organizations cooperate with each other for NMIJ to function as a single institution in charge of measurement standards. NMIJ devotes to various tasks in order to facilitate development of Japanese economic activities in the international market. NMIJ forms consistent policies concerning measurement standards and legal metrology. NMIJ also conducts research and development activities of measurement standards. Moreover, NMIJ provides metrological services such as testing and inspections of measuring instruments as well as metrological training. In doing so, NMIJ does the best to fulfill the responsibility of representing Japan in international activities regarding measurement standards and legal metrology, under the Meter Convention and the International Organization of Legal Metrology (OIML) Convention."

The Japan Chemical Industry Association (JCIA) was established in 1948, and now has nearly 170 member companies, with 80 organizations engaged in the manufacturing and handling of chemical products and related services. With the basic idea of "coexistence and co-prosperity with society," for almost 60 years, JCIA has actively undertaken activities to fulfill its mission of promoting the stable development of the chemical industry. These activities have both contributed to the economic prosperity of Japan and have elevated the standards of the chemical industry.

In addition to serving as Japan's representative member of the International Council of Chemical Associations (ICCA), consisting of the world's chemical associations, JCIA has engaged in voluntary global initiatives to resolve issues faced by chemical companies and associations throughout the world, including matters related to the environment, chemical safety and measures to prevent global warming.