



# Development of European Ecolabel Criteria for Sanitary Tapware

## TECHNICAL BACKGROUND REPORT

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*DRAFT - WORK IN PROGRESS*

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## Abbreviations

ACS	– Attestation de Conformité Sanitaire
AHWG	– Ad-hoc Working Group
ANQIP	– Portuguese National Association for Quality in Building Installations
ATA	– Attestation of Toxicological aspects
BAT	– Best Available Techniques
BMA	– Bathroom Manufacturers Association in the United Kingdom
BREF	– Reference Document on Best Available Techniques
CEN TC	– European Committee for Standardization-Technical Committee
CO <sub>2</sub>	– Carbon dioxide
DVGW	– German Technical and Scientific Association for Gas and Water
DWD	– Drinking Water Directive
EPA	– United States Environmental Protection Agency
EU	– European Union
GPP	– Green Public Procurement
ISO	– International Standardisation Organisation
kWh	– Kilowatt hour
l/min	– Litres per minute
LDPE	– Low-density polyethylene
MS	– Member State
psi	– Pounds per square inch
s	– Second
UBA	– German Federal Environment Agency
WELL	– Water Efficiency Label

## Introduction

The European Ecolabel<sup>1</sup> is an element of the European Commission's action plan on Sustainable Consumption and Production and Sustainable Industrial Policy<sup>2</sup> adopted on 16 July 2008. This is a voluntary scheme established to encourage manufacturers to produce goods and services that are environmentally friendly. The EU Ecolabel flower logo should also facilitate consumers and organizations (i.e. public and private purchasers) recognizing the best performing in this respect products and making environmentally sound choices more easily. The EU Ecolabel covers already a wide range of products and services, and its scope is constantly being widened. The process of establishing the criteria proceeds at the European level following consultation with experts and all interested parties. A product or a service awarded with this label must meet high environmental and performance standards.

Green Public Procurement (GPP) is defined in the Commission Communication "Public procurement for a better environment"<sup>3</sup> as "a process whereby public authorities seek to procure goods, services and works with a reduced environmental impact throughout their life cycle when compared to goods, services and works with the same primary function that would otherwise be procured." This is also a voluntary instrument, which public authorities can use to provide industry with incentives for developing and marketing more environmentally friendly products<sup>4</sup>.

The EU Ecolabel and GPP criteria have been developed in parallel in the framework of the Ecotapware project<sup>5</sup>.

The primary goal of establishing the criteria for sanitary tapware is the increase of water-efficiency of these products and the related water and energy savings in the use phase, as this phase has been identified to contribute most to the overall environmental impacts caused by this product group. Further, also other aspects related to the improvement of the environmental performance along the product life cycle are considered together with product quality aspects, which are considered relevant for the EU Ecolabel and GPP policy tools.

Establishing the ecological criteria for water-using products and appropriate promotion of the products awarded with the flower symbol (EU Ecolabel mark), if adopted by a wider range of producers and users, will contribute to more environmentally friendly products. This will in

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<sup>1</sup> EU Ecolabel website [http://ec.europa.eu/environment/ecolabel/about\\_ecolabel/what\\_is\\_ecolabel\\_en.htm](http://ec.europa.eu/environment/ecolabel/about_ecolabel/what_is_ecolabel_en.htm).

<sup>2</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – on the Sustainable Consumption and Production and Sustainable Industrial Policy Action Plan, COM (2008) 397, available online: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0397:FIN:en:PDF>.

<sup>3</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Public procurement for a better environment, COM (2008) 400, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0400:FIN:EN:PDF>.

<sup>4</sup> GPP website [http://ec.europa.eu/environment/gpp/what\\_en.htm](http://ec.europa.eu/environment/gpp/what_en.htm).

<sup>5</sup> The complete results of the study are available at the project's website: <http://susproc.jrc.ec.europa.eu/ecotapware/>.

consequence reduce the consumption of water and energy (mainly to heat the water, but also for water pumping and wastewater treatment). Further, this will also result in other environmental benefits, as lower air emissions related to energy production and consumption, higher resource efficiency, etc. Finally, the ecolabelled products should also bring private and public customers direct cost savings (expressed as lower expenses for water and related energy bills).

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# 1. PROJECT BACKGROUND

The European Commission's Directorate General for the Environment has initiated a project directed towards developing a joint evidence base for the EU policy making in the area of water using products. This study has been carried out by the Joint Research Centre's Institute for Prospective Technological Studies (JRC-IPTS) and the AEA consultancy, in cooperation with all interested parties.

The purpose of this project is to develop the EU Ecolabel and Green Public Procurement criteria for sanitary tapware. In addition, the evidence base gathers information and data to assist the potential future development of other environmental policy instruments such as Implementing Measures under the Ecodesign Directive. However, Implementing Measures for taps and showerheads are not developed as part of this project but might be introduced in the future. The results of the study are available at the project's website (<http://susproc.jrc.ec.europa.eu/ecotapware/>).

In the framework of the criteria development process two Ad-hoc Working Group (AHWG) meetings took place:

- 1) 1<sup>st</sup> AHWG meeting was held on 22<sup>nd</sup> of March 2011 in Seville, Spain,
- 2) 2<sup>nd</sup> AHWG meeting was held on 19<sup>th</sup> and 20<sup>th</sup> of October 2011 in Brussels, Belgium.

The purpose of these meetings was the presentation of results of studies conducted in the framework of the Ecotapware project and a following discussion on them with all interested parties.

The discussions and stakeholders' feedback received during the meetings and additionally in a written form along the open consultation phase aid drafting the proposed Ecolabel criteria for the product group of "Sanitary Tapware".

In the framework of the project the following tasks have been concluded (and respective reports prepared):

- 1) Scoping,
- 2) Product definition,
- 3) Economic and market analysis,
- 4) User behaviour,
- 5) Base case assessment,



## 6) Best Available Techniques analysis.

All reports for these tasks constitute the Preliminary Report accompanying the Draft Criteria Proposal. They can be downloaded from the previously mentioned project's website.

One of the main outcomes of the environmental assessment of this product group is that the key environmental impacts along the product's life cycle are related to the consumption of water and related energy to heat the water. Establishing Ecolabel criteria to award the most water efficient products is expected to result particularly in reduction of water and related energy consumption, and consequently in reduction of environmental impacts caused by energy production and consumption, water supply and wastewater treatment.

It should be emphasized that the environmental impacts in the use phase depend strongly on user behaviour, which differs significantly between countries and regions due to a wide variety of factors. With regard to this fact in the framework of the project various assumptions had to be made and this should be kept in mind while analysing the project's results. Further, it should be remembered that sanitary tapware constitutes only a final element of the whole water distribution system and their influence on the overall consumption of water and in particular energy for water heating is limited. Finally, while developing the criteria, not only the environmental aspects shall be considered; ensuring the appropriate drinking water quality and safety issues (e.g. prevention against scalding), as well as ensuring end-user comfort are also of high relevance.

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## 2. PRODUCT DEFINITION AND SCOPE

The definition of the product group of "sanitary tapware" has been made based on the available national and international classifications, standards and legal acts. The preliminary definition and proposed scope of the product group has been discussed further with the stakeholders using the Questionnaire 1 and at the 1<sup>st</sup> and 2<sup>nd</sup> AHWG meetings. The preliminary definitions<sup>6</sup> have been revised in the light of the feedback received<sup>7</sup> and the current version is presented below.

### Proposed group definition and scope

The product group "sanitary tapware" shall comprise: household taps, showerheads and showers which are mainly used to derive water for personal hygiene, cleaning, cooking and drinking, including when they are marketed for non domestic use.

The products covered by the scope of this product group can be defined as follows:

- (1) "tap" means a directly or indirectly, mechanically and/or automatically operated valve from which water is drawn;
- (2) "showerhead" means
  - (a) a fixed overhead or side shower outlet, body jet shower outlet or similar device which may be adjustable, and which directs water from a supply system onto the user; or
  - (b) a moveable hand held shower outlet which is connected to a tap with a shower hose and can be hung directly on the tap or on the wall with the aid of an appropriate support;
- (3) "shower" means a combination of showerhead and interrelated control valves and/or devices packaged and sold as a kit;

Included in the product group is sanitary tapware used typically for domestic functions. Nevertheless, the scope is not restricted to the use of products for domestic use only. It covers also products for similar non-domestic uses e.g. in schools, sport centres etc.

Excluded from the scope of this product group are bathtub taps, double lever/handle showers and non-domestic special purpose sanitary tapware.

Further, for the purpose of this Ecolabel Decision, the following definitions shall apply:

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<sup>6</sup> Presented in the Technical Background Reports for the 2<sup>nd</sup> AHWG meeting and available at the project's website: <http://susproc.jrc.ec.europa.eu/ecotapware/stakeholders.html>.

<sup>7</sup> The main change is related to the inclusion of the definition of the entire shower system in the scope of the study, i.e. "the combination of a showerhead and other interrelated control valves and/or devices packaged and sold as a kit" and the inclusion of electric showers.

- (4) "double lever/handle shower" means a shower equipped with separate levers or handles for the control of the supply of cold and hot water;
- (5) "electric shower" means a shower equipped with a device to locally heat water for the shower using electrical power;
- (6) "non-domestic special purpose sanitary tapware" means sanitary tapware which requires unrestricted water flow in order to fulfil the intended non-domestic function;
- (7) "water flow limiting device" means a technical device limiting water flow to a given volume and allowing a higher water flow only where activated by the user for a chosen period of time within a single use;
- (8) "maximum available water flow rate" means the highest available water flow rate from the system or individual fitting;
- (9) "lowest maximum available water flow rate" means the lowest water flow rate from the system or individual fitting available at full opening of the valve;
- (10) "security technical feature" means a device forming part of a sensor controlled sanitary tapware which is used to prevent continuous water flow by stopping the water supply after pre-set time even if there is a person or an object present within the sensor range.

### 3. ASSESSMENT AND VERIFICATION

The specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant or his supplier or both.

Where possible, the testing shall be performed by laboratories that meet the general requirements of European Standard EN ISO 17025<sup>8</sup> or equivalent.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

As pre-requisite, the product must meet all respective legal requirements of the country (countries) in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

For a more detailed verification procedure please see Appendix I.

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<sup>8</sup> ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories.

## 4. PROPOSED ECOLABEL CRITERIA

The following section presents the criteria proposed for the product group under study. Their selection is based on JRC IPTS work conducted in the frame of Ecotapware project<sup>9</sup>, stakeholders' written feedback and the discussions conducted at the 1<sup>st</sup> and 2<sup>nd</sup> AHWG meetings for the criteria development. Further, taking into account the recommendation of the EU Ecolabel Regulation<sup>10</sup> to seek for harmonisation of the EU Ecolabel scheme and national ecolabelling schemes in Member States (MS), existing national and also industrial criteria schemes were considered.

Criteria are proposed for the following aspects:

- 1) Water consumption and related energy saving
- 2) Materials
- 3) Excluded or limited substances and mixtures
- 4) Product quality and longevity
- 5) Packaging
- 6) User information
- 7) Information appearing on the EU Ecolabel

Single criteria and the rationale for their definition are presented in the following sections.

### 4.1 Criterion 1 - Water consumption and related energy saving

The environmental impact assessment along the product group life cycle, conducted in the frame of the Ecotapware project, showed that the highest environmental benefit which can be achieved in reference to sanitary tapware is related to water saving and consequently also to the reduction of energy consumption for water heating. This reduction results in resource saving, but also in decrease of environmental impacts related to water supply and wastewater treatment (e.g. energy consumption related with abstraction, treatment, pumping, distribution in public water supply systems and later drained and treated in public waste water treatment systems<sup>11</sup>). Further, reducing primary resource depletion due to energy production and the reduction of emissions related to energy generation and consumption is

<sup>9</sup> For details please see the project's website: <http://susproc.jrc.ec.europa.eu/ecotapware/>.

<sup>10</sup> Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, available online at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:027:0001:0019:EN:PDF>.

of importance. More water and energy efficient products will also bring economic benefits for end-users reducing their expenses on water and energy bills.

Calculation of the theoretical saving potential due to application of water-efficient sanitary tapware has been conducted in the frame of the Ecotapware project. It has been estimated that installation of water-saving products would bring a statistical EU 27 household saving of approximately 10 000 litres of water from taps and nearly 3300 litres from showers per year. Additionally, the annual energy saving would amount to approximately 350 kWh and 140 kWh, respectively. The estimated saving potential for the entire EU 27 would amount, depending on the assumptions made, between 73 and 124 TWh for all sanitary tapware used currently in the domestic and non-domestic sectors. It has to be remembered that these values were obtained from calculations, where a high number of assumptions had to be used due to data unavailability. Nevertheless, these estimations arrive at values that clearly indicate the high water and energy saving potential of this product group<sup>12</sup>.

The criteria proposed in the frame of the first criteria area, i.e. water consumption and energy saving, aim at reducing both – water and related energy consumption through application of already known and innovative technologies which are related to regulation of water flow rates, to temperature setting and limiting the time of single water use (with regard to non-domestic applications for multiple users and frequent use).

Nevertheless, it must be kept in mind that though water-saving products shall aim at reducing environmental impacts from water and energy consumption in domestic and non-domestic premises, but at the same time they have to also ensure end-user comfort and fulfilling their needs, prevention of hygienic problems in drinking water supply and distribution, and they have to ensure safety of use (i.e. prevention against scalding).

#### **4.1.1 Criterion 1(a) – Maximum available water flow rate**

##### **Proposed criterion**

The maximum available water flow rates of the sanitary tapware, independent of the water pressure, shall not exceed the values presented in Table 1.

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<sup>11</sup> For example, according to stakeholder's feedback, water supply and treatment in Portugal consumes 1.7 kWh/m<sup>3</sup>.

<sup>12</sup> For details please see the Technical background report for the 1<sup>st</sup> AHWG meeting, available at: <http://susproc.jrc.ec.europa.eu/ecotapware/stakeholders.html>.

**Table 1 Maximum available water flow rates for "sanitary tapware"**

Product sub-group		Water flow rate [l/min]
Kitchen taps	without flow limiting device	6.0
	with flow limiting device <sup>[1]</sup>	8.0
Basin taps	without flow limiting device	6.0
	with flow limiting device <sup>[1]</sup>	8.0
Showers and showerheads <sup>[2]</sup>		8.0

<sup>[1]</sup> The flow limiting device must allow for setting the default water flow rate (water-saving setting) at the value of max of 6/min. The maximum available water flow rate shall not exceed 8 l/min<sup>13</sup>.

<sup>[2]</sup> Showerheads and showers with more than one spray pattern shall fulfil the requirement for the setting with the highest water flow.

### Rationale

The outcomes of this study and the review of existing research confirm that the issue of increasing water efficiency is the most important in the life cycle of this product group. This is related to the long life-time of the products. The proposed criterion is set in order to contribute to reducing water consumption in domestic and non-domestic premises. Further, it is expected to contribute to decreasing consumption of energy to heat the water and cutting related CO<sub>2</sub> emissions due to decreased consumption of hot water, as well as energy required for supply and wastewater treatment.

Due to variability of uses of the products and the related needed flow rates, in the process of stakeholders' consultation it was decided to divide the product group into three sub-groups:

- (a) kitchen taps,
- (b) basin taps,
- (c) showerheads and showers,

and to define the maximum water flow rates separately for each of them.

The "maximum available water flow rate" is defined as the highest available water flow rate from the system or individual fitting. For pillar taps and divided spout outlet kitchen taps, the flow rate shall be the summation of the two flows, i.e. the total flow to basin or sink, even if the sanitary tapware has separate outlets for hot and cold water.

The proposed maximum flow rate values are the outcomes of the technical analysis made, the stakeholders' consultation and the review of existing national and industrial labelling schemes for this product group. The stakeholder emphasized that the limits to the reduction

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<sup>13</sup> Active user intervention shall be required to activate higher water flow for a chosen period of time within a single use.

of the water flow like e.g. the end-user comfort and satisfaction, as well as health and safety aspects (i.e. sanitation, protection against scalding) shall also be taken into account.

It was indicated that the most appropriate flow rate for basin taps, ensuring end-user comfort and allowing at the same time for rational water consumption, is the value of 6 l/min. In reference to kitchen taps the same water flow value was proposed. Nevertheless, it has also been recognised that in both, kitchens and bathrooms, end-users may also need higher water flow rates for specific uses, i.e. depending on the performed activity (e.g. for washing hands lower flow rates are sufficient, while e.g. in order fill in quickly a pot or a container, a higher water flow rate would be needed). Thus, applying an option of activating a higher flow rate was conceived as a suitable solution. Two maximum available water flow rates are proposed for **basin and kitchen taps** in the current criteria document:

- 6 l/min for products without a possibility of reducing the maximum flow rate to a water-saving mode, i.e. without the flow limiting device,
- 8 l/min for products which allow increasing the flow rate to maximum of 8 l/min, i.e. with the flow limiting device,

The water flow limiting device shall allow for setting the default water-saving mode to a maximum value of 6 l/min. If a higher water flow is required (e.g. to fill a vessel quickly) active user intervention is necessary to overcome this limitation and to activate the higher water flow for a chosen period of time within a single use.

Technical solutions which allow for activating a higher water flow rate include booster buttons (eco-boosters) or mixers with 2-step cartridge (so called taps with water brakes). The tapware flow rate setting returns to the default position when the user shuts off the water or switches off the eco-booster option. More details regarding these technologies can be found in Best Available Techniques (BAT) report of the Ecotapware project<sup>14</sup>.

The most appropriate flow rate for **showers and showerheads**, ensuring on the one hand end-user comfort and allowing on the other hand for rational water consumption, was considered the proposed value of 8 l/min. The large majority of stakeholders agreed with this proposal; though one indicated that “in the EU-Ecolabel criteria for tourism services the requirement currently is 9 l/min”. It was asked for consistency and indicated further that “a mandatory requirement with maximum of 8 l/min flow rate for showers after next revision for tourism enterprises would result in high costs for certified tourism enterprises or new applicants”. Moreover, it was indicated that there are only few showerheads and showers with flow rates lower than 9 l on the market and as there is no criterion on fitness for use, setting too low value can be a risk.



Nevertheless, during the discussions conducted at the EU Ecolabelling Board meeting in June 2012, the majority of MS supported the lower value of 8 l/min.

### Assessment and verification

The following assessment and verification is proposed for this criterion:

The applicant shall declare the product's compliance with the requirement and specify the maximum water flow rate (in l/min) of the product submitted for the labelling procedure together with results of tests conducted in accordance with testing procedure indicated in respective EN standards for the given kind of product (see Table 2). The testing shall be conducted at a pressure of 1.5, 3.0 and 4.5 bar ( $\pm 0.2$  bar) for products claimed to be suitable for high pressure installations (typically 1.0 to 5.0 bar) or at pressure of 0.2, 0.3 and 0.5 bar ( $\pm 0.02$  bar) for products claimed to be suitable for low pressure installations (typically 0.1 to 0.5 bar). A mean value of three measurements shall not exceed the maximum flow rate values indicated in Table 1. For pillar taps and divided spout outlet kitchen taps, the flow rate shall be the summation of the two flows, i.e. the total flow to basin or sink from the hot and cold water tapware. Additionally, for products with an option of economy setting (i.e. flow limiting device), a description of the device applied (i.e. its main technical parameters and installation, setting and use instructions) shall be submitted.

**Table 2 EN standards regarding the product group "sanitary tapware"<sup>15</sup>**

Number	Title
EN 200	Sanitary tapware. Single taps and combination of taps for water supply systems of type 1 and type 2 – General technical specification
EN 816	Sanitary tapware. Automatic shut-off valves (PN10)
EN 817	Sanitary tapware. Mechanical mixing valves (PN10) – General technical specifications
EN 1111	Sanitary tapware. Thermostatic mixing valves (PN10) – General technical specification
EN 1112	Sanitary tapware. Shower outlets for sanitary tapware for water supply systems type 1 and type 2 – General technical specification
EN 1286	Sanitary tapware. Low pressure mechanical mixing valves. General technical specification
EN 1287	Sanitary tapware. Low pressure thermostatic mixing valves. General technical specifications

<sup>14</sup> See chapters 3.1.3 Ecobuttons and Chapter 3.1.4 Taps with water brakes of the report Best Available Technology (BAT), available online at: <http://susproc.jrc.ec.europa.eu/ecotapware/stakeholders.html>.

<sup>15</sup> EN standards related to Electric showers are given in Appendix II.

EN 15091	Sanitary tapware. Electronic opening and closing sanitary tapware
EN 248	Sanitary tapware. General specification for electrodeposited coatings of Ni-Cr
EN 60335-1	Household and Similar Electrical Appliances
EN 60335-2-35	Household and Similar Electrical Appliances, Safety, Particular Requirements for Instantaneous Water heaters

#### 4.1.2 Criterion 1(b) – Lowest maximum available water flow rate

##### Proposed criterion

The lowest maximum available water flow rates of the sanitary tapware, independent of the water pressure, shall not be lower than the values given in Table 3:

**Table 3 Lowest maximum available water flow rates for "sanitary tapware"**

Product sub-group	Water flow rate [l/min]
Kitchen taps	2.0
Basin taps	2.0
Showerheads and showers	4.5
Electric showers and low pressure showers <sup>16</sup>	3.0

##### Rationale

For the need of these EU Ecolabel criteria the following definition is proposed:

“Lowest maximum available water flow rate” is the lowest water flow rate from the system or individual fitting available at full opening of the valve. For pillar taps and divided spout outlet kitchen taps, the flow rate shall be the summation of the two flows, i.e. flow to basin or flow to sink.

Setting the criterion on the lowest maximum available water flow rate (called also the minimum water flow rate) is related to the product safety and performance. The minimum flow rate shall ensure that the performance of an ecolabelled product is adequate under various household conditions and the flow is consistent across different pressure systems.

<sup>16</sup> Products marketed to be suitable for low pressure installations, functioning typically at 0.1 to 0.5 bar.

So far, the development of performance criteria for this product group has been conducted for showerheads, but not for taps. The requirements set in the US WaterSense scheme<sup>17,18</sup> (i.e. spray force and spray coverage) and proposed by a study conducted by the Liverpool John Moores University for United Utilities<sup>19</sup> (i.e. spray pattern (spray distribution), water temperature gradient and skin pressure – velocity of spray) have been presented in the working document for the 1<sup>st</sup> AHWG meeting<sup>20</sup>. Nevertheless, as no standardised EU 27 test methods are available so far, in the current document the requirements on the so called "fitness for use" criteria are not proposed. This area is recommended for consideration in the first criteria revision process, if such test methods are then available.

This current criterion shall ensure that ecolabelled products do not have features which can impede users' satisfaction due to too low water flow and to ensure safety (protection against scalding). After extensive stakeholders' consultation it was agreed to propose for basin and kitchen taps the value of 2 l/min for taps. For showers and showerheads the threshold of 4.5 l/min is chosen as the most appropriate.

Some stakeholders mentioned that higher values could be needed, particularly for the kitchen taps. It was also pointed out that the current EN standards (which are recommended for use, nevertheless; not obligatory in all EU 27 Member States) indicate for taps the value of 4 l/min. Thus, if fulfilling the EN standards is required in a given MS, the minimum water flow rate of the Ecolabelled product put on the market in this country shall not be lower than 4 l/min. This is, nevertheless, not in contradiction with the criterion proposed, which requires the value of 2l/min or higher; which allows the manufacturer for a flexibility of choosing the values of the flow rate up to the level given before in Table 1 (the maximum available water flow rate).

For electric showers (i.e. a shower equipped with open vented instantaneous water heater to locally heat shower water with electrical power) and low pressure showers (i.e. products marketed to be suitable for low pressure installations, functioning typically at 0.1 to 0.5 bar) a lower value of 3 l/min is proposed, as agreed in the process of stakeholders' consultation. The electric showers, depending among other on seasonal temperature changes, can deliver the water flow rate of below 4.5 l/min. Such showers are mainly used in the United Kingdom, where they constitute approximately 50% of the showers sold there. Furthermore, during the EU Ecolabelling Board meeting the UK representatives expressed the need do set the same

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<sup>17</sup> WaterSense – Specification for Showerheads, available online:

[http://www.epa.gov/WaterSense/docs/showerheads\\_finalspec508.pdf](http://www.epa.gov/WaterSense/docs/showerheads_finalspec508.pdf).

<sup>18</sup> WaterSense – Specification for Showerheads – Supporting Statement, available online:

[http://www.epa.gov/WaterSense/docs/showerheads\\_finalsupstat508.pdf](http://www.epa.gov/WaterSense/docs/showerheads_finalsupstat508.pdf).

<sup>19</sup> Critchley R., Phipps D., Water and Energy Efficient Showers: Project Report, United Utilities 2007, available online:

<http://www.unitedutilities.com/Documents/UULJMUwaterenergyefficientshowerFinalreport23rdMay2007.pdf>

<sup>20</sup> For details please see the project's website: <http://susproc.jrc.ec.europa.eu/ecotapware/>.

value for low pressures showers (also used mainly in this MS and in Ireland, but to much lower extent in other countries).

### **Assessment and verification**

The following assessment and verification is proposed for this criterion:

The applicant shall declare the product's compliance with the requirement and specify the lowest maximum available water flow rate of the product submitted for the labelling procedure together with the results of tests conducted in accordance with the testing procedure indicated in respective EN standards for the given kind of product (see Table 2). 1.5, 3.0 and 4.5 bar ( $\pm 0.2$  bar) for products claimed to be suitable for high pressure installations (typically 1.0 to 5.0 bar) or at pressure of 0.2, 0.3 and 0.5 bar ( $\pm 0.02$  bar) for products claimed to be suitable for low pressure installations (typically 0.1 to 0.5 bar). A mean value of three measurements shall not be lower than the flow rate value given in Table 3. For pillar taps and divided spout outlet kitchen taps, the flow rate shall be the summation of the two flows, i.e. the total flow to basin or sink from the hot and cold water tapware.

#### **4.1.3 Criterion 1(c) – Temperature management**

##### **Proposed criterion**

Sanitary tapware shall be equipped with an advanced device or technical solution which allows for the management of temperature and/or hot water by the end-user, for example by limiting the water temperature or the supply of hot water, or by thermostatic adjustment.

The solution shall be specified to provide the user with accurate control over the temperature of the water from the tap or shower, independent of the heating system to which it is connected. Possible solutions may include, for example, a hot water barrier, a cold water supply in middle position and/or a thermostatic mixing valve.

Sanitary tapware designed to be fitted to a water supply that is already temperature controlled and showerheads shall be exempted from this criterion.

##### **Rationale**

This criterion aims at decreasing the consumption of hot water, i.e. reducing energy consumption to heat the water, and at subsequent reduction of the related environmental impacts connected with energy generation and consumption.

According to information of SwissEnergy<sup>21</sup> around 1.5 l of hot water is lost unused for every hand washing activity (i.e. very short time activity) due to the delay in supply of hot water. Also, for some applications, e.g. basin taps in public bathrooms, given temperature for hot water temperature, sufficient for the purpose of the activities, but still not impeding end-user comfort, could be pre-set, allowing to consume only as much energy for water heating as necessary. In accordance with the studies conducted by the Swedish Energy Agency, up to 40% of an average household energy consumption for hot water can be saved thanks to installation of energy-efficient sanitary tapware<sup>22</sup>.

The criterion on temperature management aims at driving technological development of the product group of sanitary tapware and supporting wider use of already existing solutions contributing to reducing the amount of energy which is consumed for heating water, and which in some cases is lost unused.

One of the possibilities to reduce the above mentioned energy loss, pointed by some stakeholders and recommended e.g. in the Austrian Ecolabel<sup>23</sup> and in the Swiss Energy-Label for sanitary tapware (EnergieEtikette)<sup>24</sup>, is the application of middle-position for cold water. It was however mentioned by other stakeholders that such a solution might not be suitable for every climatic conditions.

Energy saving can be also achieved through application of thermostatic mixing valves in showers. As in majority of cases the warm water is derived by users from showers, it is of particular importance that the desired water temperature is achieved quickly. Many stakeholders pointed out that use of double handle/lever products contributes to loss of water and energy, while thermostatic adjustment allows for their saving. Therefore, based on the feedback received double handle/lever showers were excluded from the scope of the current EU Ecolabel criteria for sanitary tapware.

One another solution to reduce the consumption of energy for water heating can be achieved by equipping the sanitary tapware with device which limits the temperature of hot water. If higher temperature is needed, active user intervention is necessary to override this barrier (used e.g. in thermostatic valves).

It is considered of special importance to ensure flexibility to manufacturers and foster development of new technologies; therefore it is suggested that this criterion shall not prescribe any particular technology. The decision how to fulfil this requirement shall be left to the manufacturer even if the User Manual will indicate example of technologies that are

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<sup>21</sup> SwissEnergy, 2011, Energy Label Regulation for Sanitary Fittings, available online: <http://www.bfe.admin.ch/>.

<sup>22</sup> Swedish Energy Agency, 2011, Save energy with efficient tapware, received per e-mail, dated 14.10.2011.

<sup>23</sup> The website of the Austrian Ecolabel is: <http://www.umweltzeichen.at/>.

<sup>24</sup> Meile O., Swiss Federal Office of Energy, Presentation sent by a stakeholder: Die neue EnergieEtikette: Kennzeichnung für Duschbrausen, Armaturen und Wassersparer.

considered as meeting this criteria. In any case, it shall be demonstrated that for the product for which EU Ecolabel shall be awarded the temperature management aspect has been considered.

A voluntary labelling system to indicate the energy efficiency of sanitary tapware based on standardised test methods have been developed in 2010 under the leadership of the Swedish Standards Institute<sup>25, 26</sup>. The standards for measuring energy efficiency have been presented and discussed during the 1<sup>st</sup> AHWG meeting. Due to the fact that these standards refer only to the single-lever tapware mixing valves and thermostatic mixing valves with showers, they could not be currently used for the evaluation of all products covered in the scope of the product group of “sanitary tapware” considered for the EU Ecolabel. Nevertheless, it might be worth observing the application and potential developments of these test methods and considering this issue in the process of revision of EU Ecolabel criteria for this product group in the future.

### **Assessment and verification**

The following assessment and verification is proposed for this criterion:

In the application submitted to the competent body, the applicant shall declare that the product complies with the requirement and provide documentation describing the technology or device applied in the product. Where the water supply is already temperature controlled, the applicant shall explain the specific technical property that makes the sanitary tapware suited for fitting to this form of system.

#### **4.1.4 Criterion 1(d) – Time control**

##### **Proposed criterion**

This criterion applies to sanitary tapware which is sold or marketed together with time control devices (i.e. devices which stop water flow after a certain time if they are not used, for example sensors which stop the water flow when a user leaves the sensor range, or after a set time period of use, for example, time limiters, which stop the water flow when the maximum flow time is reached).

For sanitary tapware equipped with time limiters, the pre-set maximum flow period should not exceed 15 seconds for taps and 35 seconds for showers. Nevertheless, the product shall be

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<sup>25</sup> Svensk Standard SS 82 00 00:Sanitary tapware – Method for determination of energy efficiency of mechanical basin and sink mixing valves.

<sup>26</sup> Svensk Standard SS 82 00 01:Sanitary tapware – Method for determining of energy efficiency of thermostatic mixing valves with showers.

designed to allow the installer to adjust the flow time in accordance with the intended product's application.

For sanitary tapware equipped with a sensor, shut off delay time after usage shall not exceed 1 second for taps and 3 seconds for showers. Furthermore, the sanitary tapware equipped with a sensor shall have an in-built 'security technical feature' with a pre-set shut-off time of maximum 2 minutes to prevent an accident or continuous water flow from taps or showers when not in use.

## Rationale

This criterion is intended only for non-domestic sanitary tapware (basin taps and showers) marketed by the manufacturer as intended for multiple users and high frequency use. End-users' needs in non-domestic premises are easier to be determined (e.g. time needed to wash hands in a public bathroom or for taking a shower in a swimming-pool), as the typical applications/functions the sanitary tapware have to fulfil are more "homogenous" than in the domestic sector.

Annual non-domestic water consumption in the EU 27 through using sanitary tapware is estimated to be approximately 3 615 Mio. m<sup>3</sup> for taps and 362 Mio. m<sup>3</sup> for showers<sup>27</sup>. Regulating the water consumption and eliminating situations where a tap or a shower is left opened though its further use is not intended, as it sometimes happens in public premises, shall contribute to water and related energy savings in the non-domestic sector. Extent of water and related energy lost in this way is very difficult to estimate, even roughly, as it is mainly influenced by user behaviour. Nevertheless, in this way the user behaviour may be influenced.

Further, stakeholders' consultation indicated hygienic reasons for applying sensor solutions, which may be of importance in many public premises.

The question which appeared in this respect in the process of the open consultation is – whether this criterion shall further specify maximum values for time limiters or whether it shall be left the decision of the user/owner, depending on the intended function/application of the sanitary tapware. For example the recently developed WELL water-efficiency labelling scheme<sup>28</sup> sets the following values for self-closing valves: maximum of 10 seconds for basin taps and maximum of 20 seconds for showers. In public procurement criteria document

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<sup>27</sup> More details available in Discussion paper: The application of the Ecodesign Directive 2009/125/E to water-using products (WuP) – Identification of a suitable product group; available at: <http://susproc.jrc.ec.europa.eu/ecotapware/stakeholders.html>

<sup>28</sup> WELL - Water Efficiency Labelling Classification scheme for sanitary valves, 2010, available online at: [http://www.well-online.eu/config/media/files/171\\_WELL%20Klassifizierungsscheme.pdf](http://www.well-online.eu/config/media/files/171_WELL%20Klassifizierungsscheme.pdf).

published by WRAP in 2010<sup>29</sup> the proposed values are 20 seconds for taps and 2 minutes for showers. Thus, it can be seen that these values vary significantly.

The values proposed for the EU Ecolabel are the results of the discussion conducted during the 2<sup>nd</sup> AHWG meeting in Brussels and the further feedback received in this regard and they indicate the maximum pre-set times for the different Ecolabelled sanitary tapware products. Nevertheless, in the user manual further instructions regarding setting the most appropriate time limits will be provided, to adjust the time best to the intended tapware application, depending on the function it will fulfil in given premises.

Furthermore, it was emphasized that the sanitary tapware equipped with a sensor shall have an in-built 'security technical feature' with a pre-set shut-off time of maximum 2 minutes to prevent an accident or continuous water flow from the product when not in use. This "Security technical feature" is defined as a device forming part of a sensor controlled sanitary tapware which is used to prevent continuous water flow by stopping the water supply after a pre-set time even if there is a person or an object present within the sensor range. This device is intended to reduce water consumption but could also, depending on the context, reduce accidents and protect against vandalism. The flow of water can be restarted when there is a movement within the sensor range.

### **Assessment and verification**

The following assessment and verification is proposed for this criterion:

The product or system shall be tested at the pressure range stipulated (3.0 bar ( $\pm$  0.2 bar) for high pressure valves or 0.5 bar ( $\pm$  0.02 bar) for low pressure valves) to verify that the time control shuts off within a 10% tolerance of that specified by the applicant. The applicant shall declare that the product complies with the requirement and specify the type of solution used within its technical parameters (a pre-set water flow time for time limiters, the shut-off delay time after usage for sensors), and provide the results of a test conducted in accordance with the standard EN 15091 for electronic opening and closing sanitary tapware or EN 816 for automatic shut-off valves to the competent body as part of the application.

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<sup>29</sup> In December 2010, WRAP in the UK published 'Procurement requirements for water efficiency' Available from: [http://www.wrap.org.uk/downloads/2011\\_01\\_19\\_WRAP\\_water\\_eff\\_model\\_proc\\_reqs\\_v6\\_FINAL\\_fad042fd.10378.pdf](http://www.wrap.org.uk/downloads/2011_01_19_WRAP_water_eff_model_proc_reqs_v6_FINAL_fad042fd.10378.pdf).



## 4.2 Criterion 2 – Materials

### ***Chemical and hygienic characteristics of materials***

#### **Proposed criterion**

Materials used in products coming into contact with drinking water, or impurities associated with them, shall not release into water intended for human consumption any compounds in the way that either directly or indirectly, reduce the protection of human health. They shall not cause any deterioration in the quality of water intended for human consumption with regard to appearance, odour or taste. Within the recommended limits for correct operation (i.e. conditions of use as laid down in the respective EN standards indicated in Table 2), the materials shall not undergo any change which would impair the performance of the product. Materials without adequate resistance to corrosion shall be adequately protected so that they do not present a health risk.

#### **Rationale**

Quality of drinking water can be affected by a set of different factors. Among them there are: the source of raw water, water treatment processes, materials, stagnation times of the distribution network, pipe materials used, and microbiological activity in water supply and distribution systems. Quality of drinking water can be affected by dissolving of substances from materials due to interaction of the water and the materials. For example some metals used in the networks can dissolve to certain extent in acidic and soft, aggressive carbon dioxide containing water of low alkalinity (solution of substances depends e.g. on the water aggressively). Substances can also dissolve from organic materials present in networks. It concerns in particular additives from polymeric materials. These organic compounds act then as nutrients for microbes, which can result in faulty taste and odour or induce hygienic problems in the drinking water<sup>30</sup>.

The EU Drinking Water Directive (DWD)<sup>31</sup> sets requirements concerning the quality of water intended for human consumption. It sets limits of heavy metal (e.g. lead, copper, nickel) contents in drinking water. Sanitary tapware can constitute a source of low emissions of metal substances to drinking water, though their contribution is considered less relevant than of some other elements of water supply and distribution system, as e.g. of piping system.

DWD obliges Member States to take "all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new

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<sup>30</sup> Rikka M. (Ed.): Drinking Water Quality and Network Materials in Finland. Summary Report. Finnish Institute of Drinking Water, Prizztech Ltd. 2008.

<sup>31</sup> Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, available online: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:330:0032:0054:EN:PDF>

installations remain in water intended for human consumption in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive". Further, these materials shall also not contribute to water quality unacceptable to consumers regarding organoleptic parameters, i.e. taste, smell, appearance.

At present there is a lack of harmonised European standards and methods for testing and authorising use of materials in contact with water intended for human consumption. Further, some stakeholders emphasized that there lacks mutual recognition of laboratory test results between most MS and the national differences are sometimes substantial. Works on harmonising these test methods have been conducted for many years in several frameworks. Efforts are made by the so called MS4 group. Germany, France, the Netherlands and the UK work at establishing a scheme for mutual acceptance of certificates between these four countries. The scope of this work shall cover specification of tests to be applied for materials in contact with water intended for human consumption and preparation of lists of approved substances and materials that can be used with limited further testing. This work is intended to constitute a basis for draft regulatory guidance to CEN and for a discussion in the Expert Working group.

Work on several harmonised standards on testing methods for different materials in contact with drinking water is in advanced state of development in the CEN/TC 164 (or just completed). Among them there are e.g.:

- *prEN 16056 – Influence of metallic materials on water intended for human consumption – Method to evaluate the passive behaviour of stainless steel*
- *EN 16057 – Influence of metallic materials on water intended for human consumption - Determination of residual surface lead (Pb) - Extraction method*
- *EN 16058 – Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of surface coatings with nickel layers - Long-term test method*

Nevertheless, they are still under approval and do not have the formal CEN vote or have just been approved just approved. After this vote National Standardisation Bodies will vote on their conversion to EN standards.

Works are also under development on hygiene standards in drinking water distribution, including hygienic assessment of plastic materials and other non-metallic materials, which shall be in the future harmonised within the EU 27. One of the currently drafted standards regards "Prediction of migration from organic materials using mathematical models". Nevertheless, it should be noted that it will not be available before the beginning of 2014.

So far, most Member States have their own requirements and testing procedures and differences between these various systems exist. Some MS require mandatory certification, while in other countries it is voluntary. Several examples illustrating the variability of systems functioning in the EU 27 are given below<sup>32</sup>.

For example in the UK<sup>33</sup> testing of non-metallic materials and components (e.g. plastics and elastomeric materials) to ensure conformity with the current requirements for odour, flavour, and growth of aquatic microorganisms tests are conducted in accordance with BS 6920:2000<sup>34</sup>. The tests shall be undertaken in a laboratory accredited under ISO 17025. The UK does currently not have an equivalent test standard for metallic products. Previously, BS 7766<sup>35</sup> was used to determine the release of metals into water; nevertheless, it has now been withdrawn due to lacking reproducibility of the results. At present there are no regulatory test requirements for metallic materials of sanitary tapware and the approval in this respect is not required. The new developed in CEN EN 15664<sup>36</sup> series of standards are awaited, however it is not clear how their results will be used then and the requirements set. On the other hand there are requirements set for all stainless steel products used in contact with drinking water. They must be approved under the relevant regulations, unless considered to be a low-risk product/application. Approval for a range of stainless steel materials with specific grades (tested in accordance with BS 7766<sup>35</sup>) is given.

In France, on the other hand product, registration is mandatory and both metallic and non-metallic materials are controlled and must be certified in accordance with ACS standard<sup>37</sup>: organic materials shall be included in a Positive List, while metals are assessed depending on their composition.

In Germany, though formally certification is not required, in praxis it is conducted. Products must comply with requirements given in several guidelines. Plastic products/materials have to conform to the KTW guidelines<sup>38</sup>, recommendations issued by the Federal Environment Agency (UBA)<sup>39</sup>, and all non-metallic materials must be listed in the Positive List. Organoleptic properties, migration, TOC, chlorine demand and microbial growth are tested.

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<sup>32</sup> For details please see: Regulations and standards – Water Treatment Equipment, European Water Treatment Association, available online: <http://www.ewta.eu/assets/Uploads/EU-Directory-of-Regulations-and-Standards.pdf>.

<sup>33</sup> Drinking Water Inspectorate's website: <http://dwi.defra.gov.uk/drinking-water-products/approved-products/index.htm>.

<sup>34</sup> British Standard 6920:2000 - Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of water.

<sup>35</sup> British Standard 7766:1994 – Specification for assessment of the potential for metallic materials to affect adversely the quality of water intended for human consumption.

<sup>36</sup> CEN EN 15664: Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of metal release.

<sup>37</sup> ACS standard – Attestation de Conformité Sanitaire, <http://www.sante.gouv.fr/attestation-de-conformite-sanitaire-acs.html>.

<sup>38</sup> Testing Guideline for Organic Materials (KTW), available online: <http://www.umweltbundesamt.de/wasser-e/themen/trinkwasser/verteilung.htm>.

<sup>39</sup> For details see the Federal Environmental Agency website: <http://www.umweltbundesamt.de/wasser-e/themen/trinkwasser/verteilung.htm>.

Metallic materials appropriate for contact with drinking water shall be listed in special recommendation. At present a draft list of these materials suitable for contact with drinking water exists in Germany. The Federal Environment Agency does not license or certify products. It develops the basis for setting standards for the hygienic assessment of materials. Certification of products in contact with drinking water in Germany is conducted by the German Technical and Scientific Association for Gas and Water (DVGW).

In Austria the materials must be registered in the Austrian Positive List and comply with the KTW recommendation. The procedure of testing is similar as in Germany with the exception of the microbiological test, which is not required. It is also interesting to add that there is a mutual recognition of test results agreed between Austria, Germany, Switzerland and the Netherlands.

In Netherlands products in contact with drinking water must be certified with Attestation of Toxicological aspects (ATA). Organoleptic, microbiological and migration tests are conducted and there exists also a Positive List.

Voluntary certification is set in Belgium, where plastic materials are checked against a Positive List and tested according to the national standard for general hygiene, migration and microbial growth. Positive lists of materials exist also in other countries like the Czech Republic, Denmark or Spain.

Different approaches are applied in this respect in the national Ecolabel schemes. For example in the Catalan Ecolabel<sup>40</sup> the criterion concerning chemical and hygienic behaviour of materials is defined as given in the above proposed criterion formulation. The verification and assessment of this criterion is done in the form of manufacturer's (and/or suppliers') declaration of conformity and approval of respective documentation attached. The same formulation is contained in the Austrian Ecolabel<sup>41</sup> and in the newly developed Blue Angel<sup>42</sup>. Additionally, as already mentioned before, the German Environmental Agency issues guidelines on hygienic assessment of materials in contact with water intended for human consumption<sup>43</sup>. Compliance verification and assessment in the Blue Angel is conducted by evaluating laboratory tests, indicated in these guidelines, submitted by manufacturer and conducted in laboratories that meet the general requirements of EN ISO 17025 or certificates of a respective certified institution.

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<sup>40</sup> Resolució MAH/2407/2009, de 29 de abril, per la que se estableixen els criteris ambientals per a l'otorgament del distintiu de garantia de qualitat ambiental a los productes y a los sistemas que favorecen el ahorro de agua. Diari Oficial de la Generalitat de Catalunya 5460 (2009) 66627-66632. Available at: [http://www.mediambient.gencat.cat/cat/empreses/ecoproductes\\_i\\_ecoserveis/pdf/criteris\\_ambientals/cast/040.pdf](http://www.mediambient.gencat.cat/cat/empreses/ecoproductes_i_ecoserveis/pdf/criteris_ambientals/cast/040.pdf).

<sup>41</sup> The website of the Austrian Ecolabel is: <http://www.umweltzeichen.at/>.

<sup>42</sup> The website of the Blue Angel is: <http://www.blauer-engel.de/>.

With regard to lack of harmonised EU testing methods and unified requirements concerning which substances and materials shall be tested a question appeared: how shall the assessment and verification procedure for a common criterion for hygienic materials quality be formulated. Work under the current criteria development process and the extensive stakeholders consultation resulted in proposing for consideration the following options:

Option 1 – The applicant shall declare the product's compliance with the respective legal requirements in those countries where it is put on the market.

Option 2 – The applicant shall declare the product's compliance with the requirement and provide a copy of certificate stating that the product is suited for contact with drinking water (with regard to hygienic requirements) from one of the laboratories accredited by the Member States.

Option 3 – It could be considered to postpone inclusion of this criterion to the next revision process, when the harmonised testing methods shall already be available.

It was agreed that the current work on the EU Ecolabel criteria development has neither the mandate nor the resources to develop EU wide harmonised standards. Such an approach could be even counterproductive if conflicting with the MS4 activities. Nevertheless, this issue shall be again taken into consideration in the first criteria revision process, if the EU harmonised and applicable standards testing sanitary tapware products in contact with drinking water or the related materials used for their manufacturing are available.

For the current criteria the following criterion and verification are proposed<sup>44</sup>:

Criterion 2. Materials in contact with drinking water

Chemical and hygienic characteristics of materials in contact with drinking water

Materials used in products coming into contact with drinking water, or impurities associated with them, shall not release into water intended for human consumption any compounds in the way that either directly or indirectly, reduce the protection of human health. They shall not cause any deterioration in the quality of water intended for human consumption with regard to appearance, odour or taste. Within the recommended limits for correct operation (i.e. conditions of use as laid down in the respective EN standards indicated in Table 2), the materials shall not undergo any change which would impair the performance of the product. Materials without adequate resistance to corrosion shall be adequately protected so that they do not present a health risk.

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<sup>43</sup> Recommendations of the German Federal Environmental Agency are available online at: <http://www.umweltbundesamt.de/wasser-e/themen/trinkwasser/verteilung.htm>.

<sup>44</sup> Additional information are given in Appendix III

**Assessment and verification:**

The applicant shall declare that the materials used in the product comply with the requirement and submit relevant documentation or test results, as indicated below:

Metallic materials used in sanitary tapware shall be listed in the positive list of “4 Member States Acceptance of Metallic Materials for Products in Contact with Drinking Water” (as given in Appendix 1). The applicant shall submit a declaration of compliance with this requirement. If the metallic materials are not included in this positive list, results of test conducted in accordance with the approach for “Adding Materials to the Composition List within a Category of materials”, described in the above-mentioned document, and using the EN 15664-1 standard, shall be submitted. Alternatively, if obligatory national regulations are in place in the Member State where the product will be placed on the market, a certificate of approval of these metallic materials and/or product issued by responsible national authority or responsible laboratory shall be submitted.

Organic materials shall be tested in accordance with the respective national requirements of the Member State where the product will be placed on the market. A certificate or, if appropriate, test results issued by responsible national authority or responsible laboratory shall be submitted.

Additionally, if required by the national regulations or the Member State where the product is placed on the market, test results for enhancement of microbial growth and assessment of odour and flavour assessment of water shall be submitted.

### **4.3 Criterion 3 – Excluded or limited substances and mixtures**

In the framework of the development of the criteria it has been agreed that additional criterion on excluded substances and mixtures (as introduced in all new EU Ecolabel criteria decisions developed or revised after the implementation of the new EU Ecolabel Regulation 66/2010) will be included in the criteria set. Consequently, stakeholders' consultation was conducted to identify substances, which might need to be derogated for this product group.

Below, first the new criterion text (i.e. two sub-criteria) is presented. The information received regarding the potential derogation and its analysis are given in Appendix III.

**(a) Hazardous substances and mixtures**

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any article<sup>45</sup> of it shall not contain substances meeting criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EC nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006. The risk phrases below generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

**List of hazard statements:**

<b>Hazard Statement<sup>1</sup></b>	<b>Risk Phrase<sup>2</sup></b>
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62

<sup>45</sup> In Regulation (EC) No 1907/2006 (REACH) Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28
H371 May cause damage to organs	R68/20/21/22
H372 Causes damage to organs through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting harmful effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41

<sup>1</sup> Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

<sup>2</sup> Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC and Directive 1999/45/EC as amended

Substances or mixtures which change their properties through processing (e.g., become no longer bioavailable, or undergo chemical modification in a way that removes the previously identified hazard) are exempted from the above requirement.

Concentration limits for substances or mixtures which may be or have been assigned the hazard statements or risk phrase listed above, meeting the criteria for classification in the hazard classes or categories, and for substances meeting the criteria of Article 57 (a), (b) or (c) of Regulation (EC) No 1907/2006, shall not exceed the generic or specific concentration



limits determined in accordance with the Article 10 of Regulation (EC) No 1272/2008. Where specific concentration limits are determined they shall prevail over the generic ones.

Concentration limits for substances meeting criteria of Article 57 (d), (e) or (f) of Regulation (EC) No 1907/2006 shall not exceed 0,1% weight by weight.

The final product must not be labelled according to the hazard statements above.

The following substances/components are specifically derogated from this requirement:

Nickel in stainless steel of all types	All hazard statements and risk phrases	
Articles and homogenous parts of sanitary tapware made of alloys, which fall under Article 23 (d) of Regulation 1272/2008 and are listed in Part B of the "Acceptance of metallic materials used for products in contact with drinking water – 4 MS Common Approach" or fulfil the requirements to be added to this list ( see Appendix 1)	All hazard statements and risk phrases	
Nickel in protective coating layer, if the release of nickel from nickel layers or a coating containing nickel on inner surfaces of products which are intended to come into contact with drinking water tested in accordance with EN 16058 <sup>46</sup> standard does not exceed 10 µg.*	All hazard statements and risk phrases	
Polycyclic Aromatic Hydrocarbons in black rubber	H350 May cause cancer	R45
Electronic components of sanitary tapware, which fulfil the requirements of Directive 2011/65/EU <sup>47</sup>	All hazard statements and risk phrases	

\*Where national requirements of the Member State where the product will be placed on the market or respective testing procedure for the release of nickel from coating are in place, a proof that these national requirements are met can be submitted instead to prove the compliance with this requirement.

#### Assessment and verification:

For each article or any homogenous part of it the applicant shall provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by their suppliers, on the non-classification of the substances or materials with any of the hazard classes associated to the hazard statements referred to in the above list in accordance with Regulation (EC) 1272/2008, as far as this can be determined, as a

<sup>46</sup> EN 16058 Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of surface coatings with nickel layers - Long-term test method.

minimum, from the information meeting the requirements listed in Annex VII of Regulation (EC) 1907/2006. This declaration shall be supported by summarized information on the relevant characteristics associated to the hazard statements referred to in the above list, to the level of detail specified in section 10, 11 and 12 of Annex II of Regulation (EC) 1907/2006 (Requirements for the Compilation of Safety Data Sheets).

Information on intrinsic properties of substances may be generated by means other than tests, for instance through the use of alternative methods such as in vitro methods, by quantitative structure activity models or by the use of grouping or read-across in accordance with Annex XI of Regulation (EC) 1907/2006. The sharing of relevant data is strongly encouraged.

The information provided shall relate to the forms or physical states of the substance or mixtures as used in the final product.

For substances listed in Annexes IV and V of REACH, exempted from registration obligations under Article 2(7)(a) and (b) of Regulation 1907/2006 REACH, a declaration to this effect will suffice to comply with the requirements set out above.

***(b) Substances listed in accordance with article 59(1) of Regulation (EC) No 1907/2006***

No derogation from the exclusion in Article 6(6) of the Regulation (EC) No 66/2010 shall be given concerning substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations > 0.1%. Specific concentration limits determined in accordance with Article 10 of Regulation (EC)

No 1272/2008 shall apply in cases where the concentration is lower than 0.1%.

***Assessment and verification:*** *The list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:*

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

*Reference to the list shall be made on the date of application. The applicant shall provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures in accordance with Annex II to Regulation (EC) No 1907/2006 for substances or mixtures. Concentration limits shall be specified in the Safety Data Sheets in accordance with Article 31 of Regulation (EC) No 1907/2006 for substances and mixtures.*

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<sup>47</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

## **4.4 Criterion 4 – Product quality and longevity**

### **4.4.1 Criterion 4(a) General requirements**

#### **Proposed criterion**

The product shall comply with the general requirements of the respective EN standards listed in Table 2 or with the corresponding mandatory national legal regulations. The requirement regarding water flow rates is excluded from this criterion.

Where applicable, cleaning of the product elements, which may be necessary under normal use conditions, shall be possible with use of simple tools or agents.

### **4.4.2 Criterion 4(b) – Exposed surface condition and quality of Ni-Cr coating**

#### **Proposed criterion**

A sanitary product which has a metallic Ni-Cr coating (regardless of the nature of the substrate material) shall comply with the standard EN 248<sup>48</sup>.

### **4.4.3 Criterion 4(c) – Reparability and availability of spare parts**

#### **Proposed criterion**

The product shall be designed in such a way that its exchangeable components can be replaced easily by the end-user or a professional service engineer, as appropriate. Information about which elements can be replaced shall be clearly indicated in the information sheet attached to the product. The applicant shall also provide clear instructions to enable the end-user or trained experts, as appropriate, to undertake basic repairs.

The applicant shall further ensure that spare parts are available for at least seven years from the end of production.

### **4.4.4 Criterion 4(d) – Warranty**

#### **Proposed criterion**

The applicant shall give a warranty for repair or replacement of minimum four years.

#### **Rationale**

Product shall fulfil the general quality requirements which contribute to its proper functioning over its lifetime. The EN standards mentioned in Table 2 include (where appropriate, i.e.

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<sup>48</sup> EN 248:2003 Sanitary tapware. General specification for electrodeposited coatings of Ni-Cr.

depending on the product type) requirements and test methods for evaluating the following aspects: leaktightness, mechanical characteristics, hydraulic characteristics, acoustic characteristics and maintenance<sup>49</sup>. With regard to showerheads with spray device for jet, the last mentioned aspect refers e.g. to the possibility of removing the device by use of simple tools in order to enable cleaning of the product (when necessary) and its long-term appropriate functioning.

Further, as most surfaces of sanitary tapware are covered with Ni-Cr coatings in order to ensure adequate condition and quality of the exposed surfaces of sanitary tapware the criterion 6(b) is proposed. Two characteristics are tested in accordance with the EU harmonised standard EN 248:2003 "Sanitary tapware – General specification for electrodeposited coatings of Ni-Cr": resistance to corrosion and adherence. These tests aim to evaluate and ensure the appropriate quality of the coating.

Moreover, from the point of view of saving raw materials needed for manufacturing sanitary tapware and to reduce emissions and other environmental impacts related to the production phase, the issue of lifetime extension is of importance. In order to ensure longevity of the products, they shall be designed in a way which allows end-user/installer to replace the elements which may have a shorter lifetime (e.g. seals) and repair them easily with use of simple tools. This aspect shall be taken into account in the design phase.

With this regard, it is further required that spare parts are available to purchase for end-users, even several years after production of a given product model is stopped. Based on the stakeholders' feedback the period of seven years was chosen.

Additionally, it was indicated that producers shall ensure warranty conditions valid at least four years, as all products of this product group have relatively long lifetime.

### **Assessment and verification**

The following assessment and verification is proposed for this criterion:

The applicant shall declare that the product complies with these requirements and provide samples of the product information sheet and warranty terms to the competent body as part of the application.

With regard to points (a) and (b) the applicant shall additionally provide the competent body with the results of tests conducted in accordance with the standards listed in Table 2 as regards point (a) and the standard EN 248 as regards point (b) as part of the application.

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<sup>49</sup> A table indicating which tests should be conducted for various kinds of products with indication of the respective EN standards will be available in user manual.

## 4.5 Criterion 5 – Packaging

### Proposed criterion

Packaging shall meet the following requirements:

- (a) all packaging components shall be easily separable by hand into individual materials in order to facilitate recycling,
- (b) where used, cardboard packaging shall consist of at least 80 % recycled material.

### Rationale

Based on the information received from the retail stores and suppliers in the framework of the project, sanitary tapware is predominately supplied in cardboard packaging. Additionally some smaller amounts of plastic, e.g. LDPE bags, are used<sup>50</sup>. Due to the long lifetime of this product group (approximately 16 years for taps and 10 years for showerheads and showers in the domestic sector, 10 and 7 years, respectively, in the non-domestic sector<sup>51</sup>), packaging does not play very important role in these products' life cycle, as it was demonstrated in the conducted technical analysis.

General regulations concerning the management of packaging and packaging waste to are covered by the Directive 94/62/EC<sup>52</sup>. Nevertheless, as also mentioned during the AHWG meetings, packaging is a horizontal issue, and even if not very relevant for a certain product group, the total mass of packaging used in EU 27 is very significant and the EU Ecolabel criteria shall also cover requirements on packaging and packaging waste and signal to consumers importance of this issue. Further, it was emphasized that packaging is the first element which a consumer sees, and ecolabelled products, as environmentally preferable products, shall also be distributed in appropriate environmentally friendly packaging, which facilitates also its sound waste management (e.g. easy collection, separation and recycling).

It was agreed that the generally applicable criteria set in EU Ecolabel decisions for other product groups, in particular for long-life products, shall be proposed for the Ecolabel criteria for sanitary tapware.

### Assessment and verification

The applicant shall declare that the product complies with the requirement and provide the competent body with a sample(s) of the packaging as part of the application.

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<sup>50</sup> Please see the Base-case assessment report, available at: <http://susproc.jrc.ec.europa.eu/ecotapware/stakeholders.html>

<sup>51</sup> Please see the Market and economic analysis & Consumer behavior report, available at: <http://susproc.jrc.ec.europa.eu/ecotapware/>

<sup>52</sup> European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, available online at: [http://europa.eu/legislation\\_summaries/environment/waste\\_management/l21207\\_en.htm](http://europa.eu/legislation_summaries/environment/waste_management/l21207_en.htm)

## 4.6 Criterion 6 – User information

### Proposed criterion

The product shall be accompanied by relevant user information which provides advice on the product's proper and environmentally friendly use as well as its maintenance. It shall bear the following information in print (on the packaging and/or on documentation accompanying the product) and/or in electronic format:

- (a) information that the main environmental impact is related to the use phase of the product, i.e. to consumption of water and related energy for water heating and advice on how rational use can minimise the environmental impact,
- (b) information that the product has been awarded the EU Ecolabel, together with a brief, specific explanation as to what this means in addition to the general information provided alongside the EU Ecolabel logo,
- (c) the maximum flow rate in l/min (tested as indicated in Criterion 1(a)),
- (d) installation instructions, including information on the specific operating pressures that the product is suitable for,
- (e) advice concerning the issue of water stagnation and a related warning against drinking tap water after a longer stagnation time (applicable for taps). Moreover, the following information can be added: "If a new tap is mounted it is recommended that especially babies and children do not use this tap water for drinking for about three months". Additionally, suggestions for alternative uses of the stagnation water could be indicated, like: "To avoid the wastage of drinking water, use stagnation water e.g. for flushing toilet, taking a shower or watering flowers e. g. in the morning or after holidays".
- (f) recommendations on the proper use and maintenance (including cleaning and decalcification) of the product, mentioning all relevant instructions, particularly:
  - (i) advice on maintenance and use of products,
  - (ii) information about which spare parts can be replaced,
  - (iii) instructions concerning the replacement of washers if taps drip water,
  - (iv) advice on cleaning sanitary tapware with appropriate materials in order to prevent damage to their internal and external surfaces,
  - (v) advice on regular and proper service of aerators (cleaning at least once annually to avoid contaminates or legionella).

For sanitary tapware (except showerheads) which is not equipped with time control devices, the following text shall be visibly reproduced on the packaging of the product:

"This EU Ecolabel product is intended for domestic use. It is not intended for use in a non-domestic environment for multiple and frequent use (e.g. public facilities in schools, offices, hospitals, swimming-pools)".

For sanitary tapware which is equipped with time control devices, the following text shall be visibly reproduced on the packaging of the product:

"This EU Ecolabel product is particularly intended for use in non-domestic environment for multiple and frequent use (e.g. public facilities in schools, offices, hospitals, swimming-pools)".

For 'restricted flow showerheads' information should be placed on the product sheet regarding the need of checking the compatibility when used with electric shower, e.g. "please check that this restricted flow showerhead is compatible with your existing shower system in case you plan to use it with an electric shower".

### **Rationale**

Due to the fact that the key factor in the area of sustainable water consumption with regard to use of sanitary tapware is the end-user behaviour, appropriate consumer information is of high importance. Thus, beside installation and maintenance instructions (as described above), information concerning rational water consumption and recommendations concerning potential saving in general and with regard to the given product use shall be attached to the product. This information shall also contain reference to the potential of saving energy to heat the water and the explanation about other environmental impacts which can be reduced due to rational water and in particular hot water consumption.

Further, importance of exchanging used parts and preventing dripping water from sanitary tapware shall be emphasized as these can contribute to high losses of completely unused water, which can however easily be avoided.

Information concerning the suitability of product for a given pressure system shall also be highlighted (if appropriate) and consequences of installing improper appliances to the existing system shall be pointed out.

Finally, it has been also proposed to add on the products' packaging or accompanying information additional notice regarding product's suitability for domestic use or non-domestic applications (for multiple users and frequent use) in order to promote using in the non-domestic premises products, which are equipped with time limitation devices and in this manner to contribute to reduction of single water use in this sector.

### **Assessment and verification**

The following assessment and verification is proposed for this criterion:

The applicant shall declare that the product complies with the requirement and provide the competent body with a sample or samples of the user information and/or a link to a manufacturer's website containing this information as part of the application.

## **4.7 Criterion 7 – Information appearing on the EU Ecolabel**

### **Proposed criterion**

The optional label with text box shall contain the following text:

- Improved water efficiency
- Increased energy saving potential
- “With this certified product you may save water, energy and money.”

The guidelines for the use of the optional label with the text box can be found in the "Guidelines for the use of the EU Ecolabel logo" on the website:

<http://ec.europa.eu/environment/ecolabel/promo/pdf/logo%20guidelines.pdf>.

### **Rationale**

The Ecolabel placed on the packaging shall contain clear message indicating the advantages related to the purchase and use of ecolabelled products. It shall constitute an incentive to choose the product due to its preferable environmental performance in comparison with other products. The information which appears on the Ecolabel shall refer to improved water efficiency and lower energy consumption due to considering in the product design the issue of temperature management.

### **Assessment and verification**

The following assessment and verification is proposed for this criterion:

The applicant shall provide a sample of the printed paper product showing the label, together with a declaration of compliance with this criterion.



## 4.8 Further considerations

### 4.8.1 Issues to be considered in the criteria revision process

As already mentioned before, there are some aspects which are recommended for consideration in the future process of revision of the EU Ecolabel criteria for this product group. They are briefly mentioned below:

#### 1) Establishing "fitness for use" criteria"

Currently, there lack EU harmonised testing methods to evaluate the fitness for use of the sanitary tapware. As mentioned in the section 4.1.2 such testing methods are only available for showers and showerheads, nevertheless, they are neither standardised in the EU Member States, nor widely used so far. There lack completely testing methods for taps. Due to this fact it has been decided to propose in the current criteria set establishing the requirement of the minimum water flow rate, which shall ensure end users comfort and meeting their needs. Nevertheless, the values proposed allow also on water saving.

#### 2) Assessment and verification procedure for the criterion 2 – Material requirements – Chemical and hygienic characteristics of materials

As explained in section 1.1 with regard to lack of harmonised EU testing methods and unified requirements concerning which substances and materials shall be tested it has been proposed to set the current assessment and verification of the above criterion as follows: *"The applicant shall declare that the materials used in the product comply with the requirement and submit relevant documentation or test results, as indicated below:*

*Metallic materials used in sanitary tapware shall be listed in the positive list of "4 Member States Acceptance of Metallic Materials for Products in Contact with Drinking Water" (as given in Appendix 1). The applicant shall submit a declaration of compliance with this requirement. If the metallic materials are not included in this positive list, results of test conducted in accordance with the approach for "Adding Materials to the Composition List within a Category of materials", described in the above-mentioned document, and using the EN 15664-1 standard, shall be submitted. Alternatively, if obligatory national regulations are in place in the Member State where the product will be placed on the market, a certificate of approval of these metallic materials and/or product issued by responsible national authority or responsible laboratory shall be submitted.*

*Organic materials shall be tested in accordance with the respective national requirements of the Member State where the product will be placed on the market. A certificate or, if appropriate, test results issued by responsible national authority or responsible laboratory shall be submitted.*

*Additionally, if required by the national regulations or the Member State where the product is placed on the market, test results for enhancement of microbial growth and assessment of odour and flavour assessment of water shall be submitted".*

This option shall ensure that all the ecolabelled products are tested or the materials used for their manufacturing are allowed for contact with drinking water, either in accordance with the Common Approach of the 4 MS scheme or the national requirements of the MS where the product will be sold.

In order to ensure in the future the complete harmonisation of the requirements in the EU27, this issue shall be again taken into consideration in the first criteria revision process, when the EU harmonised and applicable standards for testing sanitary tapware products or materials used for their manufacturing are expected to be available.

- 3) Exploring whether an energy efficiency/consumption measurement and criteria in addition to water flow measurement and criteria might be 1) feasible and 2) meaningful/helpful in terms of driving further future savings.

#### **4.8.2 Manufacturing processes**

In the preliminary discussions on the criteria development the potential proposal of a criterion regarding "Manufacturing processes – surface treatment" was considered. It should aim at promoting manufacturers who choose along their production chain best (from the environmental viewpoint) available technologies (BAT). Some stakeholders indicated that the surface treatment processes are of highest importance in the manufacturing phase and could be considered in this respect. The manufacturers would have to demonstrate that they do comply with general environmental legislation. Further, taking into account the environmental impacts of surface treatment, the manufacturers (and/or their suppliers, in applicable) would have to demonstrate that they conduct their processes in accordance with the most environmentally friendly technologies. Among the processes of special concern mentioned were: reuse of the Chromium VI or use of Chromium III, zinc processing without cyanide, water recirculation systems, preventing/not using chlorinated solvents, and other. The latest available version of the Reference Document on Best Available Techniques for the Surface Treatment of Metals and Plastics (BREF) was proposed to be used as a reference document indicating best practices.

Nevertheless, in the process of criteria development and based on the results of the technical analysis conducted it was decided not to set a criterion in this area. The LCA conducted showed that the contribution of the manufacturing phase to the overall environmental impacts of this product group is very low in comparison with the use phase, for

most impact categories below 1%. The detailed results can be found in the report of Base Case Assessment<sup>53</sup>. It has been discussed that the EU Ecolabel is not an appropriate policy tool to stimulate development in this area for this particular product group. The manufacturer stakeholders emphasized further that the production processes are already subject to numerous items of EU and national legislation that set limits for emissions to air, soil and water. Furthermore, technical difficulties in using BREF (which is a very extensive and complex document, updated once in several years) as a reference document were also indicated. It was emphasized that different parts of production and manufacturing processes take place in several places, also outside the EU, which makes very difficult to establish feasible and reliable verification of compliance, going beyond a plain self-declaration.

Due to the negligible impact from the manufacturing phase and having in consideration the additional difficulty of having a feasible and credible verification procedure, it was decided not to establish a criterion on surface treatment and manufacturing processes in the current criteria set.

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<sup>53</sup> Available online at the project's website: <http://susproc.jrc.ec.europa.eu/ecotapware/stakeholders.html>.

## 5. SUMMARY

This document has been prepared as the background report accompanying the development of Ecolabel criteria for sanitary tapware. The proposed criteria aim, in particular, at promoting water-efficient products, which in consequence have also reduced impact on consumption of energy needed to heat the water. The criteria furthermore aim at supporting products of high quality ensuring long-term appropriate functioning and proved to be safe for consumers. Further, the information which should accompany the ecolabelled products shall educate and constitute support for the end users how to responsibly and environmentally conscious use these products, contributing to lower environmental impacts related to water consumption.

The criteria are proposed for each of the following aspects:

- 1) Water consumption and related energy saving
- 2) Materials
- 3) Excluded substances and mixtures
- 4) Product quality and longevity
- 5) Packaging
- 6) User information
- 7) Information appearing on the EU Ecolabel

Based on the study conducted, increase of water-efficiency of taps and showerheads has been identified as the main reason for establishing the ecological criteria for sanitary tapware, since the use phase contributes most to the environmental impacts caused by this product group along its life cycle. Nevertheless, also other aspects related to the life cycle of this product, which improvement can bring environmental benefits, are considered and rationale to establishing the criteria are presented.

## APPENDIX I

### ***Guidelines for a procedure for checking the criteria in respect of applications: use of test laboratories***

The national competent body or eco-labelling board will consider the applications individually taking into account the following approach and making a decision according to the specific situation without prejudice to the credibility of the European eco-labelling scheme.

- 1) Laboratory tests shall be performed by laboratories that are accredited for the specified test method according to ISO 17025 or GLP, where possible. The Competent Bodies accept accredited laboratories in all Member States in the EU/EEA and in countries that have signed the mutual recognition agreement according to ILAC, the international accreditation organisation.

If in the Member State where the applicant submits its dossier or where the company or the concerned production plant or service is based, one or more laboratories are accredited according to ISO 17025 or GLP, applicants shall use such a laboratory, either in that Member State or another.

- 2) Laboratories with an accreditation for tests other than those required by the criteria can be accepted if they submit a declaration that the tests are carried out following the same quality management procedures as the tests for which they obtained an accreditation. In case of doubt, the competent body or national board shall inspect the lab that carries out the tests or shall select an accredited auditor who will be charged to do so.
- 3) If neither point 1 or 2 is possible, applicants should call on a non-accredited independent laboratory certified or approved by a Government Department or other public body in a Member State.

In case of doubt, the competent body or national board shall inspect the lab that carries out the tests or shall select an accredited auditor who will be charged to do so.

- 4) If none of points 1 - 3 are possible, applicants may have the tests performed by an independent laboratory that is neither accredited nor approved by authorities according to point 3.

Laboratories with a quality management system shall be preferred. A laboratory situated in an organisation holding an ISO 9001- certificate, may be accepted if the scope of the certification includes the laboratory.

The competent body or national board shall verify the competence of the laboratory that carries out the tests or shall select an accredited auditor who will be charged to do so.

- 5) If none of the above mentioned points can be fulfilled, the applicant may have the tests carried out in a company laboratory (that is not accredited ISO 17025 or GLP, as this would be covered by point 1). The competent body or national board shall ensure that the tests are properly carried out or shall select an accredited auditor who will be charged to do so.

In this case, the laboratory shall have a quality management system. A laboratory within an organisation holding an ISO 9001 certificate is accepted as being under appropriate quality management, if the scope of the certification includes the laboratory.

This option may also be used for continuous monitoring of the production, including discharges and emissions, and for testing fitness for use when no standard test method exists.

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## APPENDIX II

### STANDARDS RELATED TO ELECTRIC SHOWERS<sup>54</sup>

#### Safety

EN 60335-1: 1994 Safety of household and similar electrical appliances - Part 1: General requirements

EN 60335-2-35: 2002 Household and similar electrical appliances - Safety - Part 2-35: Particular requirements for instantaneous water heaters

EN 60335-2-41 (if including a pump): 2003 Household and similar electrical appliances - Safety - Part 2-41: Particular requirements for pumps

EN 62233: 2008 Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure

#### Electro Magnetic Compatibility Directive (EMC)

EN 55014-1: 2006 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission

EN 55014-2: 1997 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 2: Immunity - Product family standard

EN 61000-3-11: 2000 Electromagnetic compatibility (EMC) - Part 3-11: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems - Equipment with rated current  $\leq 75$  A and subject to conditional connection

EN 61000-3-12 Electromagnetic compatibility (EMC) - Part 3-12: Limits - Limits for harmonic currents produced by equipment connected to public low-voltage systems with input current  $> 16$  A and  $\leq 75$  A per phase

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<sup>54</sup> The specifics of which standard to use will depend on the specific configuration of the electric shower. These standards are used to establish compliance with the Low Voltage Directive (LVD) and the Electro Magnetic Compatibility Directive (EMC).

## APPENDIX III

### DEROGATION REQUESTS

In the framework of the development of the criteria it has been agreed that additional criterion on excluded substances and mixtures (as introduced in all new EU Ecolabel criteria decisions developed or revised after the implementation of the new EU Ecolabel Regulation 66/2010) will be included in the criteria set. Consequently, stakeholders' consultation was conducted to identify substances, which might need to be derogated for this product group.

Below, first the new criterion text is presented, and in the following sections the feedback received and its analysis are given.

#### 1. Criterion on excluded or limited substances and mixtures

The new EU Ecolabel Regulation 66/2010 requires that certain types of substances are not allowed in ecolabelled products:

*"The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency".*

Nevertheless, it recognizes also that in certain circumstances restriction of some substances may not be technically or economically viable. Therefore, in the Article 6(7) the Regulation states that:

*"For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from paragraph 6".*

On the other hand, some specific substances are strictly (and without exception) excluded from the ecolabelled products: *"No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 and that are identified*



according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(2)".

With this regard after additional consultation phase conducted after the 2<sup>nd</sup> AHWG meeting, to ensure the compliance with the requirements of the Articles 6(6) and 6(7) an additional criterion on **Excluded or limited substances and mixtures** is incorporated in this criteria draft proposal. Such a requirement may not be found in many previously developed EU Ecolabel criteria. Nevertheless, the new regulation made its inclusion obligatory.

With this regards, the industry was invited to submit derogations (motivated and accompanied by information on the function of the respective substance, content in the product and the additional rationale substantiating the request – reasons) for substances, which are classified but cannot be substituted or eliminated, and do fulfil the conditions set in Article 6(7).

The formulation of the criterion is given below:

### **Criterion - Excluded or limited substances and mixtures**

#### **(a) Hazardous substances and mixtures**

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any article<sup>55</sup> of it shall not contain substances meeting criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EC nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006. The risk phrases below generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

#### **List of hazard statements:**

<b>Hazard Statement<sup>1</sup></b>	<b>Risk Phrase<sup>2</sup></b>
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24

<sup>55</sup> In Regulation (EC) No 1907/2006 (REACH) Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28
H371 May cause damage to organs	R68/20/21/22
H372 Causes damage to organs through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting harmful effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41

<sup>1</sup> Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

<sup>2</sup> Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC and Directive 1999/45/EC as amended

Substances or mixtures which change their properties through processing (e.g., become no longer bioavailable, or undergo chemical modification in a way that removes the previously identified hazard) are exempted from the above requirement.

Concentration limits for substances or mixtures which may be or have been assigned the hazard statements or risk phrase listed above, meeting the criteria for classification in the hazard classes or categories, and for substances meeting the criteria of Article 57 (a), (b) or (c) of Regulation (EC) No 1907/2006, shall not exceed the generic or specific concentration limits determined in accordance with the Article 10 of Regulation (EC) No 1272/2008. Where specific concentration limits are determined they shall prevail over the generic ones.

Concentration limits for substances meeting criteria of Article 57 (d), (e) or (f) of Regulation (EC) No 1907/2006 shall not exceed 0,1% weight by weight.

The final product must not be labelled according to the hazard statements above.

The following substances or product components are specifically derogated from this requirement:

Substance	Hazard statements and risk phrases

**Assessment and verification:** *For each article or any homogenous part of it the applicant shall provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by their suppliers, on the non-classification of the substances or materials with any of the hazard classes associated to the hazard statements referred to in the above list in accordance with Regulation (EC) 1272/2008, as far as this can be determined, as a minimum, from the information meeting the requirements listed in Annex VII of Regulation (EC) 1907/2006. This declaration shall be supported by summarized information on the relevant characteristics associated to the hazard statements referred to in the above list, to the level of detail specified in section 10, 11 and 12 of Annex II of Regulation (EC) 1907/2006 (Requirements for the Compilation of Safety Data Sheets).*

*Information on intrinsic properties of substances may be generated by means other than tests, for instance through the use of alternative methods such as in vitro methods, by quantitative structure activity models or by the use of grouping or read-across in accordance with Annex XI of Regulation (EC) 1907/2006. The sharing of relevant data is strongly encouraged.*

*The information provided shall relate to the forms or physical states of the substance or mixtures as used in the final product.*

*For substances listed in Annexes IV and V of REACH, exempted from registration obligations under Article 2(7)(a) and (b) of Regulation 1907/2006 REACH, a declaration to this effect will suffice to comply with the requirements set out above.*

**(b) Substances listed in accordance with article 59(1) of Regulation (EC) No 1907/2006**

No derogation from the exclusion in Article 6(6) of the Regulation (EC) No 66/2010 shall be given concerning substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations > 0.1%. Specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008 shall apply in cases where the concentration is lower than 0.1%.

**Assessment and verification:** *The list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:*

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

*Reference to the list shall be made on the date of application. The applicant shall provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures in accordance with Annex II to Regulation (EC) No 1907/2006 for substances or mixtures. Concentration limits shall be specified in the Safety Data Sheets in accordance with Article 31 of Regulation (EC) No 1907/2006 for substances and mixtures.*

## **2. Derogation requests – Overview**

In the framework of stakeholders' consultation several derogation requests have been submitted. The input sent to JRC/IPTS was evaluated and it is presented together with the conclusions from this analysis. First, the general overview of all substances asked to be derogated is presented and general stakeholders' points of view are given. In later sections the rationale are presented substance by substance.

Several industrial stakeholders (manufacturers and associations) responded and submitted to the project team their requests for derogations. The following compounds were addressed:

- nickel in stainless steel,

- nickel used in corrosion protection on the surface of taps and showerheads,
- chrome used to protect the nickel layer on the surface of taps and showerheads,
- lead contained in brass alloy,
- arsenic contained in the brass alloy,
- polycyclic aromatic hydrocarbons (PAHs) in black rubber.

Furthermore, the stakeholders emphasized that apart from the materials containing the above-mentioned substances, some of the components of sanitary tapware (e.g. aerators, check valves, cartridge bodies, etc.) include many different **plastic**. With this regard, they highlighted that in most cases the manufacturers of the plastic compounds will not share their recipe with manufacturers or other actors, except of the certification bodies responsible for approvals of products in contact with drinking water. Thus, receiving from the manufacturers of these plastic materials a certificate of compliance with the excluded and limited substances and mixtures criterion does not seem feasible for the industry. In their opinion, the only way to ensure the safety of the materials and components used in sanitary tapware would be through requesting a certificate of compliance with applicable drinking water regulations. Only then it is ensured that the respective competent bodies responsible for approvals of products in contact with drinking water have analysed the recipe and have tested migration of substances into the drinking water. These plastic materials could contain substances classified as hazardous in accordance with the above mentioned 25 R-phrases/H –statements list. Nevertheless, such information cannot be obtained by the sanitary tapware manufacturer. But the materials approved are safe for use in products in contact with drinking water.

Manufacturers association in their feedback raised concerns that the proposed criteria would not be workable and would probably impair the ability of manufacturers to apply to the Ecolabel.

### **Overview of the substances for which derogations were requested**

In the following table the overview of substances submitted for derogation evaluation is given:

Table 4 Substances submitted for consideration for derogation

H411 Toxic to aquatic life with long-lasting effects	R51-53	antimony
H301 Toxic if swallowed	R25	arsenic
H331 Toxic if inhaled	R23	
H400 Very toxic to aquatic life	R50	
H410 Very toxic to aquatic life with long-lasting effects	R50-53	
H400 Very toxic to aquatic life	R50	phosphorus
H300 Fatal if swallowed	R28	
H330 Fatal if inhaled	R23/26	
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62	lead
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22	
H410 Very toxic to aquatic life with long-lasting effects	R 50	
H410 Very toxic to aquatic life with long-lasting effects	R50-53	zinc
H351 Suspected of causing cancer	R40	nickel
H350 May cause cancer	R45	PAH

In the below sections the requests for derogation are presented<sup>56</sup>.

### 3. Nickel in stainless steel

#### Derogation requested

A derogation request for nickel in stainless steel has been sent to the JRC/IPTS. The attached supporting information and rationale are presented in the section below.

*Nickel improves general corrosion resistance and prompts the formation of austenite (i.e. it is an austenite stabiliser). Stainless steels with 8-9% nickel have a fully austenitic structure and exhibit superior welding and working characteristics to ferritic stainless steels. Increasing nickel content beyond 9% further improves both corrosion resistance (especially in acids) and workability.*

*From a regulatory perspective, nickel in stainless steel is the main substance of concern. Nickel (metal) has the following CLP harmonized classifications:*

- *Carc. 2 H351 (R45)*
- *Skin Sens. 1 H317 (R43)*

<sup>56</sup> Direct quote of stakeholders' feedback is given in this section in cursive.

- STOT RE 1 H372

*In accordance with the CLP, mixtures containing 1% or more of nickel are classified with the same hazards as nickel metal. While stainless steels containing 10% or more nickel must be classified STOT RE 1 (H372) and stainless steels containing 1-10% nickel must be classified STOT RE2.*

*Many stainless steels contain nickel as a deliberate alloying addition. The most commonly used stainless steels contain ~10% nickel. However, the range covers 0 – 38% nickel and even many of the so-called nickel-free stainless steels contain up to 1% nickel as an impurity.*

*REACH recognizes that, amongst other materials, alloys are special preparations and Annex 1, 0.11 states that “When assessing the risk of the use of one or more substances incorporated into a special preparation (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account.”*

*Stainless steels are a well-known example of special preparations and that the hazard properties of nickel are not expressed by stainless steels. This recognized in the following EU legislation:*

- *CLP Regulation (1272/2008) Annex I, 1.1.3.2, Note 7: Alloys containing nickel are classified for skin sensitization when the release rate of 0,5 µg Ni/cm<sup>2</sup>/week, as measured by the European Standard reference test method EN 1811, is exceeded.*
- *Directive 2004/96/EC amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of nickel for piercing post assemblies specifies a maximum release rate of 0.2 µg Ni/cm<sup>2</sup>/week (i.e. replacing a concentration limit of 0.5% Ni max).*
- *Directive 94/27/EC amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of nickel-containing articles in close and prolonged contact with the skin, which specifies a maximum release rate of 0.5 µg Ni/cm<sup>2</sup>/week.*
- *Directive 2009/48/EC on the safety of toys. Recital 21 indicates the need to ensure a high level of protection of children against risks caused by chemical substances in toys, especially CMR substances and allergenic substances and certain metals. In this regard, it states “Nickel in stainless steel has proven to be safe, and consequently it is appropriate that it can be used in toys”. A further reference to nickel in stainless steel is made in Annex II (Particular Safety Requirements), III Chemical Properties, 6. Points 3, 4 and 5 shall not apply to nickel in stainless steel.*

*These legislative outcomes are supported by an extensive body of evidence<sup>57</sup> which demonstrates that, for stainless steels, the release of metals in biological fluids is not proportional to the chemical composition. In particular, the release of metals from stainless steel has been studied in artificial body fluids to mimic dermal, inhalation or gastrointestinal exposure scenarios. When the releases of different metal constituents of stainless steel are compared, iron is usually released at higher amounts than chromium and nickel. However, in all cases the release of metal ions is very low. In general, the less alloyed ferritic stainless steel grades release more metals. However, the increase is attributed to the release of iron. The differences in release rates between different stainless steel grades or surface finishes are usually small (e.g. 2-fold).*

*Significant differences were seen when metal released from stainless steel was compared with that released from pure metals. Thousand-fold differences in iron and nickel release were seen in a study in which the release from stainless steel grade 316 sheets was compared to the release from nickel metal and iron in artificial lysosomal fluid. The releases of chromium were on the same level both from stainless steel and from pure chromium metal. These in vitro studies suggest that while chromium bioaccessibility from stainless steel is similar to that from metallic chromium, the iron and nickel bioaccessibility from stainless steel is significantly lower than from metallic iron and nickel. These results strongly support the conclusion that the health effects of stainless steel cannot be estimated solely on the basis of its bulk contents of iron and nickel. This can be explained by the chromium oxide passivation layer enveloping the stainless steel surface. It has been shown that chromium oxide enrichment in the surface occurs during in vitro incubation in artificial biological fluids, and decreases release rates to a very low level that is sustained over time. Although few in number, in vivo studies indicate metal release in animals is similarly low.*

*Furthermore, an independent assessment of this body of evidence by the Finnish Institute of Occupational Health (FIOH) entitled “Review on toxicity of stainless steel” concludes that “in vitro release tests show that nickel release from stainless steel in artificial lung fluids is substantially (hundred or even 1000-fold) lower than from nickel particles, due to the chromium-(III) oxide enrichment at the surface of stainless steel. The existence of low inhalation toxicity, compared to nickel powder, is supported by a recent 28 days stainless steel inhalation toxicity study. Therefore, no classification for target organ toxicity in repeated exposure to stainless steel is proposed. Also no classification for mutagenicity or carcinogenicity is proposed. Although some grades of stainless steel show somewhat higher release of nickel than grade AISI 316L (which is the grade mostly used in toxicity tests), the differences between grades are low when compared to the differences seen in the release of*

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<sup>57</sup> Extensive list of references supporting the feedback sent have been submitted to the project team.



*nickel from pure nickel and stainless steel. Thus, these conclusions can be regarded to apply for all common grades of stainless steel including grade 303 with the highest nickel release.” FIOH’s conclusions concerning stainless steel and carcinogenicity are supported by IARC’s conclusion that stainless steel implants are not classifiable as to their carcinogenicity to humans (Group 3).*

### **Conclusions on derogation request for nickel in stainless steel**

Based on the analysis of the feedback submitted, it is proposed to derogate the use of nickel in stainless steel for the product group of sanitary tapware. The reason for the derogation is that nickel when incorporated into stainless steel does not behave like nor have the same hazard profile as the substance nickel. Stainless steel is an alloy (special mixture) and should be evaluated based on the properties of the alloy. This is in line with Article 8 (6) of CLP (EC 1272/2008) that states “*Tests that are carried out for the purposes of this Regulation shall be carried out on the substance or on the mixture in the form(s) or physical state(s) in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.*”

Tests on stainless steel containing nickel show that stainless steel does not exhibit the same hazard properties as nickel and should not be classified accordingly (as concluded e.g. in the report “Review on Toxicity on Stainless Steel” by the Finnish Institute of Occupational Health in 2010).

A derogation of Nickel in stainless steel was also investigated in other product groups (e.g. imaging equipment<sup>58</sup>) in which it was concluded that it need only be considered when nickel is used in stainless steel of high-sulphur grades (S > 0.1%) and this in case of direct skin contact. Nevertheless, so far as there is no prolonged contact with the product in the normal use of tapware (the relevant steel grades are commonly used for screws, mechanical or electrical parts which would be concealed), the risk of skin sensitisation would be negligible and additional restrictions are not proposed in this respect.

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<sup>58</sup> For details please see the report regarding the derogation for hazardous substances criterion, available online at: <http://susproc.jrc.ec.europa.eu/imaging-equipment/docs/Ecolabel%20Criterion%20Derogations%20Hazardous%20Substances.pdf>.

#### 4. Nickel in protective layer

##### **Derogation requested**

A further derogation request for nickel contained in the protective layer at the surface of sanitary tapware was submitted to the JRC/IPTS. The rationale for this derogation is given below.

*Nickel is needed as a compound for corrosion protection on the surface of taps and showerheads. According to information obtained from industrial stakeholders, 98% of all taps available on the market are protected with thin nickel layer and chromium-plating layer. In accordance with the information received, currently there is no other process available on the market which could replace this plating process without vast influence on the product price. In REACH nickel is addressed in reference to touchable surfaces. Nevertheless, nickel on the touchable surface of sanitary tapware is covered by a layer of metallic chrome.*

Several industrial stakeholders asked for derogation of nickel contained in the protective layer on the tapware. Beside the supportive statements regarding the derogation of nickel, the project team received one comment from stakeholder who expressed concern in relation to the derogation for nickel, indicating that nickel failures (i.e. nickel leaching from taps) occur sometimes. In a study cited by the stakeholder 23 out of 12,036 of the products tested (i.e. 0.2%) did not comply with the threshold value set (20 µg/l).

Recently, EN standard 16058:2012 (Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of surface coatings with nickel layers - Long-term test method) have been announced and will be published before the end of this year. This standard specifies a procedure to determine the release of nickel from nickel layers or a coating containing nickel on inner surfaces of products which are intended to come into contact with drinking water. Using this standard has been considered in the process of the criteria development; nevertheless, there was agreement that it is still too early and this issue could be considered again in the future, ahead the first revision of the criteria, when its applicability and suitability will be better known. This issue is described in more detail later in the section relating to Criterion 2.

##### **Conclusions on derogation request for nickel in protective layer**

After analysis of the information collected it is proposed to derogate nickel used in the protective surface layer.

The share of products in which nickel is found in the protective layer is very high (approximately 98%) whereas and furthermore there is currently no economically viable

alternative solution which could avoid the presence of nickel. The only possible alternative could be to use polymer based materials or stainless steel but these are not widely applied and are not seen as direct alternatives and therefore they are not considered relevant at this stage.

The evidence on the level of the risk to human health associated with nickel when it is leached to the water phase is not clear. The only available information provided states that 0.2 % of the products investigated released in the tests a higher concentration than the threshold value of 20 µg/l. Nevertheless, the analysis of the actual risk that the presence of nickel in tap water could have (e.g. contribution to sensitisation of the skin) did not give conclusive results<sup>59</sup>. Based on this evidence we cannot form a robust conclusion. Further analysis of available information on the risk that nickel leaching may pose is proposed for the next criteria revision in which a re-evaluation of this derogation shall be conducted. By then the new EN standard 16058:2012 will be available and used in EU Member States and its application in the EU Ecolabel scheme for verification purposes should also be considered. In the current criteria set it is proposed to derogate Ni in this protective layer under condition that its release is tested using the above-mentioned or equivalent national standards.

## **5. Chromium in protective layer**

### **Derogation requested**

Derogation request was also sent by the stakeholders for chromium contained in protective layer on the surface of sanitary tapware.

As already mentioned chrome protects the nickel layer on the surface and additionally gives the necessary hardness of the surface that the product can withstand all the influences during use and cleaning of the product. Regarding the presence of chrome, concerns could be raised especially in cases where chrome forms part of acidic compounds. However, on the finished products after a high quality plating process chrome should only be present in metallic form.

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<sup>59</sup> Ewence A., Rumsby P., Rockett L., Davey A., Williams H., Danby S., Cork M., School A Review of Skin Irritation and Tap Water Quality, WRc Ref: DWI8375.01, 2011; available online at: <http://dwi.defra.gov.uk/research/completed-research/reports/dwi70-2-257.pdf>.

## **Conclusions on derogation request for chromium**

Chromium is found in the final product in metallic form. Chromium in this form is not classified as hazardous in accordance with the CLP Regulation 1272/2008; and therefore any investigation of derogation for this substance is not considered to be required.

## **6. Polycyclic aromatic hydrocarbons (PAHs)**

### **Derogation requested**

A derogation request for polycyclic aromatic hydrocarbons (PAHs) contained in black rubber was sent to JRC/IPTS.

*Black rubber is used for some components of sanitary tapware. This material contains PAHs, and there is none black rubber without PAHs available. PAHs are classified with H350 statement (may cause cancer), as indicated in below:*

H350 May cause cancer	R45	PAH	Polycyclic Aromatic Hydrocarbons (PAH) are contained in every black rubber elastomer in the sense of small concentrations being detectable. However concentrations are proven below any limit causing health risks if the black rubber materials have got drinking water approvals. The approval of black rubber requires a long-term migration test being passed (compare KTW-A regulation).
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Nevertheless, migration tests are conducted for organic materials (e.g. German W270<sup>60</sup> and KTW guidelines<sup>61</sup>) to control and prove that black rubber materials used in tapware do not release to the drinking water PAHs in doses which can be health-affecting. This issue is addressed also in the section regarding Criterion 2.

<sup>60</sup> DVGW (The German agency for water and gas) Arbeitsblatt W 270 – Vermehrung von Mikroorganismen auf Werkstoffen fuer den Trinkwasserbereich (eng. Proliferation of micro-organisms which come into contact with drinking water), 2007.

<sup>61</sup> DVGW KTW Guidelines (Kunststoffe und Trinkwasser; eng. Plastics and Drinking Water) - a series of recommendations for plastic materials used in contact drinking water.

## **Conclusions on derogation request for PAHs**

The presence of PAHs in black rubber seems to be unavoidable with current technology. However, it should be taken into account that black rubbers must undergo a long-term migration test before they can be given drinking water approval. The approved rubbers can then demonstrate that no or low risk is posed due to PAHs presence in this material. On this basis it is proposed that PAHs found in black rubber which is approved for drinking water can be derogated.

## **7. Copper alloys**

### **Derogation requested**

Finally, the industry stakeholders submitted the following list of substances contained in copper alloys for derogation consideration:

Table 2 Proposal for derogation of the following substances

<b>Hazard Statement<sup>1</sup></b>	<b>Risk Phrase<sup>2</sup></b>	<b>Substances</b>	<b>Explanation</b>
H411 Toxic to aquatic life with long-lasting effects	R51-53	antimony	Antimony is used in some brass alloys in order to reduce dezincification (max. concentration is 0.1%).
H301 Toxic if swallowed	R25	arsenic	Arsenic may be used up to 0,2% in brass alloy composition to reduce dezincification.
H331 Toxic if inhaled	R23		
H400 Very toxic to aquatic life	R50		
H410 Very toxic to aquatic life with long-lasting effects	R50-53		
H400 Very toxic to aquatic life	R50	phosphorus	Phosphorus used in some specific grades of brass (up to 0,3%) to reduce dezincification (for example: lead-free ECOBRFASS contains Phosphorous).
H300 Fatal if swallowed	R28		
H330 Fatal if inhaled	R23/26		
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62	lead	Lead is one of the main constituents of brass (up to 4%). It is used to improve machinability of the alloy

H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22		(behaviour of chips and lubrication).
H410 Very toxic to aquatic life with long-lasting effects	R 50		
H410 Very toxic to aquatic life with long-lasting effects	R50-53	zinc	Zinc is by definition a constituent of brass alloy. The ratio between copper and zinc induces machinability and mechanical characteristics. Zinc is also the main constituent of zamak alloy, which is often used for components such as handles, buttons... Zinc is a metallic alloy that can be injected and therefore can contribute to create complex and thin shapes in metal, with upper durability.

### **Derogation request**

The industry association stakeholder submitted to JRC/IPTS very comprehensive information and analysis regarding the copper alloys in the context of the criterion on excluded substances and mixtures (given below).

#### Summary

*In view of Article 6(6), an evaluation of the hazards, potentially arising from the copper-containing materials, in accordance with the information on harmonised classification of the alloying metals and the CLP mixtures rules, has been made (see below sub-section regarding assessment). From this assessment, it can be concluded that the copper-containing materials, accepted in the 4 Member States common composition list for contact with drinking water, do not merit classification entries (as explained below). Therefore, the copper alloys retained in this list, which is explained in the following paragraph, do fulfil Article 6(6) and for that reason the tapware industry has no need for derogation according Article 6(7).*

*It has been recognised, in both REACH and EU Classification guidelines, that alloys are “special mixtures” whose properties cannot reliably be predicted from the properties of each of the alloying elements. Therefore, to assess the hazards of alloys, information on composition and metal-ion release potentials need to be considered.*

Assessment of copper alloys against the recently proposed Ecolabel criteria for sanitary tapware: hazardous substances and mixtures

Background information

Chromium-nickel electroplated and copper alloy-based products dominate the global sanitary tapware market. The JRC/IPTS/AEA Task 2 & 3 report (dated September 2011) estimates that the 2008 annual production of taps and showerheads, respectively, in the EU is approx 164.6 million taps and approx 54.9 million showerheads. These figures represent values of €2.7 billion and €2.4 billion respectively. However, taking into account imports and exports, the authors estimate the apparent annual EU consumption of taps and showerheads to be 185.4 million units and 61.8 million units respectively. According to data provided by the International Copper Association (ICA) and the International Wrought Copper Council (IWCC), approximately 300,000 tonnes of copper alloys are used in the production of drinking water system products such as taps, shower heads, fittings and valves. This value closely matches the 350,000 tonnes, provided by the JRC/IPTS Task 2 & 3 report, and highlights the market leadership of copper-based sanitary tapware.

The same report estimates that, by 2012, the EU stocks<sup>62</sup> of sanitary tapware will have reached the following levels: non-domestic taps, 80 million units; non-domestic showerheads, 30.2 million units; domestic taps, 1.1 billion units and domestic showerheads, 262 million units.

The two main components of copper alloy-based sanitary tapware are copper and zinc. These alloys additionally contain small amounts of other metals such as lead (Pb), arsenic (As), tin (Sn), aluminium (Al), iron (Fe) and nickel (Ni).

To ensure that metal releases to drinking water are aligned with the drinking water directive, a harmonised CEN standard EN 16057<sup>63</sup> was developed under a European Commission mandate for CPDW subject to the requirements of the Construction Products Regulation. Following an extensive testing programs, several copper alloys have been accepted as products for contact with drinking water (see Annex 1A: 4MS acceptance of metallic materials for products in contact with drinking water), with other alloys still under evaluation. The maximum levels of the minor metals in the alloys, accepted in the 4 MS composition list, can be summarised as follows:

- Tin :  $\leq 13\%$
- Lead :  $\leq 3.5\%$

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<sup>62</sup> Stocks refers to products installed and in use.

<sup>63</sup> EN 16057:2012, Influence of metallic materials on water intended for human consumption. Determination of residual surface lead (Pb). Extraction method.

- Aluminium :  $\leq 1\%$
- Nickel :  $\leq 0.6\%$
- Iron :  $\leq 0.5\%$
- Arsenic :  $\leq 0.15\%$

*In view of the recently (June 2012) proposed additional criterion (Excluded or limited substances and mixtures) for awarding ecolabels to sanitary tapware, an initial evaluation of the hazards potentially arising from the alloys, in accordance to the information on harmonised classification of the metals and the CLP mixtures rules, has been made below.*

*First of all, no metals are on the list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 (see*

*[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp))*

*The need for hazard classification in accordance with the classification rules for mixtures has therefore been assessed.*

- *According to the 1<sup>st</sup> ATP of the CLP regulation, **nickel**, in its massive form (> 1 mm diameter), **has the following harmonised classification entry:***
  - *Carc. 2 H351 (R45)*
  - *Skin Sens. 1 H317 (R43)*
  - *STOT RE 1 H372*

*In accordance with the CLP guidance, **mixtures containing  $\leq 1\%$  nickel in massive form do not need to be classified.** The copper alloys accepted by the 4 MS Group for inclusion in the **Composition List contain 0.1 – 0.6% Ni and therefore hazard classification due to nickel is not necessary.***

- *According to the DSD (annex VI entries) and the ECHA CLP inventory on harmonised classification, **arsenic and arsenic compounds are classified as:***
  - *Acute Tox 3 H301 and H 331*
  - *Aquatic Acute 1 H400*
  - *Aquatic Chronic 1 H410*

*The alloys, accepted by the 4 MS Group for inclusion in the Composition List, have arsenic at levels  $\leq 0.15\%$ , being far below the acute toxicity CLP cut-off limit for mixtures of 1%. The small percentage of arsenic ( $\leq 0.15\%$ ), present in massive form, is furthermore not expected to raise a concern for environmental classification.*



- According to the DSD, zinc powders were classified with an acute and environmental classification entry (annex VI). **Zinc** in massive form was assessed by the zinc consortium for the REACH registration and it was concluded that **there is no need for classification of massive zinc**. Initial information on the releases of zinc from various Cu-Zn alloys, during transformation/dissolution tests in environmental media according to the CLP 2012 guidance, demonstrated low environmental releases supporting the view that there is no need for the environmental classification of Cu-Zn alloys.
- **Copper, aluminium, iron, tin and lead are not listed in the ECHA harmonised CLP inventory list**. Their massive forms were assessed by the consortia for the REACH registration and, from the REACH information, it was concluded that none of these massive forms merit classification. For **copper**, the Voluntary Risk Assessment on copper and copper compounds also concluded that, in accordance with the CLP guidelines, **copper massive forms do not merit hazard classification**. The full copper risk assessment report and reviews by the EC TCNEC<sup>64</sup> and SCHER<sup>65</sup> are available from:

<http://echa.europa.eu/web/guest/information-on-chemicals/transitional-measures/voluntary-risk-assessment-reports>.

From this assessment, it can be concluded that the **copper alloy materials, listed in the 4MS composition list, do not merit classification entries**. The 4 MS common composition list is a well-justified tool to assess hazards from metallic materials used in sanitary tapware.

#### **Additional information on copper alloys**

##### **Metallic materials in contact with drinking waters – Copper and Copper Alloys as part of the 4 MS metals positive list**

According to data provided by the International Copper Association (ICA) and the International Wrought Copper Council (IWCC), approximately 300,000 tonnes of copper alloys are used in the production of drinking water products such as taps, shower heads, fittings and valves. As producers of metallic materials, the European copper industry, represented by its leading associations (European Copper Association (ECI) and International Wrought Copper Council (IWCC)), was involved from the outset in the development of the EAS/4 MS Group metals approval scheme. Under the guidance of CEN and the regulator responsible for metals, ECI and IWCC have developed and prepared

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<sup>64</sup> EC TCNEC: European Commission Technical Committee on New and Existing Substances.

*methods and rules for testing and acceptance copper alloys for drinking water applications (see Annex 1B).*

*In order to meet the future requirements of the DWD, ECI and IWCC started, 15 years ago, an industry-wide initiative to:-*

- a) Test existing copper alloys for their compatibility with the DWD/EN 15664*
- b) Modify/adapt the chemical composition of existing alloys where high metal release rates were observed by:
  - (i) Reducing the content of critical elements*
  - (ii) Enhancing performance by the use of additional elements**
- c) Search for alternative (non-health-relevant) elements to replace substances of concern. Any alternative would need to have the same mechanical/functional characteristics (indispensable technical properties) as those that were to be replaced.*

*A particular focus of the copper industry has been the evaluation of the technical feasibility of, and limits to, the reduction and/or replacement of the **lead** content in copper alloys.*

*Lead is needed in alloys for corrosion resistance. Several hazard statements apply for lead compounds. The hazard of a substance depends, nevertheless, on the field of application of the product that contains this substance. For example, for lead in welding alloys, contained in them in high concentrations, it has been proven dangerous because of lead vapours emitted during the welding process. On the contrary, lead in copper alloys like CW617N being used for sanitary tapware has proven not to migrate to drinking water. The maximum content of lead in this brass alloy is 2.50 %. The lead does not migrate out of the brass also due to the fact that the touchable surface is protected with nickel and chrome layer. Long-term migration tests have shown that the maximum lead concentration in the drinking water is below any health hazard (and below the maximum allowed concentrations of any European drinking water regulation). Thus, from a health perspective, the alloy is considered safe for the consumer although it contains lead.*

*Additionally, the following properties of lead (Pb) need to be taken into account when searching for alternatives:*

*Lead, embedded as tiny globules (e.g. in brass alloys), acts as lubricant and, most importantly, as a chip breaker, allowing machining of semi-products without continuously damaging the product itself or the tools used for machining. In addition, Pb exhibits*

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<sup>65</sup> EC SCHER : European Commission Scientific Committee on Health and Environmental Risk.

*corrosion inhibition characteristics, minimizing the corrosion/metal release of other constituent substances.*

*The combination of these three properties presents a significant challenge in the search for a suitable substitute for Pb. Nevertheless, over the last 10-15 years, the industry has managed to reduce to a minimum the amount of Pb needed for a series of copper alloys and yet continue to fulfil the technical requirements of the materials. This was successfully achieved by either reducing as far as technically feasible the Pb content in the alloy itself and/or by adding other elements.*

*Another significant challenge in the research and development to replace substances of concern has been to maintain and further enhance the very good recyclability of copper materials. Especially, as amongst other benefits, recyclability is one of the most valuable characteristics of copper alloys. As elsewhere in the world, the use of bismuth (Bi) in copper alloys has been explored as a complete replacement for lead. However, the European copper industry has learned that Bi exhibits a series of technically and environmentally relevant disadvantages. Amongst other adverse outcomes, bismuth destroys copper alloy recycling loops and thereby undermines the industry's efforts to further enhance the percentage of re-used copper-based materials.*

### **Results gained so far**

*A broad range of copper alloys are proven to be suitable for use in contact with drinking water due to their high value chemical composition and corrosion resistance, while a few other copper alloys failed to pass the EN 15664<sup>66</sup> test.*

*Of those that failed the test, some will potentially completely disappear from the market. However, others are essential to downstream industry (e.g. taps and pumps) to provide the technical characteristics required of their products. These essential alloys have undergone iterative modification by the European copper industry towards significantly lower levels of metal release.*

*This enormous effort has generated a list of copper alloys that represents both positively approved materials and candidates still subject to the approval/evaluation process. It is anticipated that Germany's UBA will publish a first non-provisional version of its positive list of metals for the use in Drinking Water by the end of 2012.*

*The stakeholders proposed to refer to the first non-provisional UBA-list (later versions will cover further alloys when finally and positively approved) when applying the European ECO-label for taps.*

## **Conclusions on derogation request for alloys**

Alloy' is defined as "a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means". Classification rules for alloys fall under Article 23 (d) of Regulation 1272/2008. Complete avoidance of the presence of the given hazardous substances in Table 2 is not technically possible. Furthermore, the associated risk is different or may even be negligible when a compound is bounded in the form of alloys. Therefore an investigation on restricting the maximum concentration level seems to be the most appropriate approach.

Furthermore, given the specifications contained within Drinking Water Directive, these metals have been investigated in detail by member states. A European wide regulation of them is not, however, available yet. Currently, restrictions based on the extensive work of the 4 MS group form the basis for our investigation. A stricter limitation regarding these metals cannot be substantiated unless the "precautionary principle" is applied. This is not proposed here as there are no widely used alternatives available and the results of the work of the 4 MS group build a firm basis for allowance of safe materials in the framework of the EU Ecolabel scheme.

In conclusion, for alloys it is proposed that the derogation is granted under the condition that their upper allowable concentration limits do not exceed the ones defined by the 4MSs scheme. In the situation that during the criteria validity stricter requirements either from the common work of these 4 MS or on the European level are proposed then a re-evaluation of this issue is proposed. An amendment of the criteria decision in which the stricter thresholds are applied would then be considered necessary.

*The maximum levels of the minor metals in the alloys, accepted in the 4 MS composition list, can be summarised as follows:*

- *Tin :  $\leq 13\%$*
- *Lead :  $\leq 3.5\%$*
- *Aluminium :  $\leq 1\%$*
- *Nickel :  $\leq 0.6\%$*
- *Iron :  $\leq 0.5\%$*
- *Arsenic :  $\leq 0.15\%$*

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<sup>66</sup> EN 15664: Influence of metallic materials on water intended for human consumption. Dynamic rig test for assessment of metal release.

It is thus proposed to allow in sanitary tapware copper alloys under the condition that they are listed in Part B of the "Acceptance of metallic materials used for products in contact with drinking water – 4 MS Common Approach" or fulfil the requirements to be added to the Composition List within a category of materials. The respective list and the requirements for adding a material to the positive list in the criteria document will be given as Annex 1. Furthermore, equivalent approval in accordance with Member States obligatory regulations (where the product is placed on the market) shall also be accepted.

## 8. Summary

Summarising, the following derogations to the hazardous substance substitution set in the criterion on excluded substances and mixtures are proposed:

### Derogations

The following substances/components are specifically derogated from this requirement:

Nickel in stainless steel of all types	All hazard statements and risk phrases	
Articles and homogenous parts of sanitary tapware made of alloys, which fall under Article 23 (d) of Regulation 1272/2008 and are listed in Part B of the "Acceptance of metallic materials used for products in contact with drinking water" – Common Approach" or fulfil the requirements to be added to this list as indicated in Appendix 1.	All hazard statements and risk phrases	
Nickel in protective coating layer, if the release of nickel from nickel layers or a coating containing nickel on inner surfaces of products which are intended to come into contact with drinking water tested in accordance with EN 16058 <sup>67</sup> standard does not exceed 10 µg.*	All hazard statements and risk phrases	
Polycyclic Aromatic Hydrocarbons in black rubber	H350 May cause cancer	R45
Electronic components of sanitary tapware, which fulfil the requirements of Directive 2011/65/EU <sup>68</sup>	All hazard statements and risk phrases	

\* Where national requirements of the Member State where the product will be placed on the market or respective testing procedure for the release of nickel from coating are in place, a proof that these national requirements are met can be submitted instead to prove the compliance with this requirement.

<sup>67</sup> EN 16058 Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of surface coatings with nickel layers - Long-term test method.

<sup>68</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

## 9. Link to Criterion 2 Materials – Chemical and hygienic characteristics of materials

Many comments<sup>69</sup> received from the industrial stakeholders but also several Competent Bodies (CBs) were related to the link between the substances criterion and the release of harmful substances to drinking water. It was emphasized that the criterion on excluded substances and mixtures cannot solve the problem of safety of drinking water and, consequently, do not prevent the potential health impacts. Additionally, it was indicated that the REACH Regulation EC 1907/2006 refers directly to chemicals but not to finished products, thus for this product group additional provisions are needed to ensure high quality and safety of the products.

Below this issue, addressed by one CB, is presented on the example of lead. *"In accordance with the CLP Regulation lead contained in alloy is not classified as hazardous. The process of leaching of lead into the drinking water depends on numerous factors, e.g.:*

- *the alloy (the same content of lead has different impact depending on the composition of the alloy),*
- *stagnation of water (time drinking water stands in the tap without movement, e.g. overnight, holidays, ...),*
- *water quality (especially water with a low pH leaches heavy metals from the taps and fittings),*
- *build-up of lead layers (corrosion, metal-cutting during manufacturing) with positive as well as negative influence on the concentration of lead in drinking water the concentration of lead itself in the alloy has only a minor impact".*

In summary, it has been concluded that *"for the product group of sanitary tapware the criterion on exclusion or limitation of substances (including potential derogations for substances, which in accordance with the article 6(7) cannot be substituted and can be derogated from the restriction) does not solve the problem of substances leaching to the drinking water. The health risks are not related directly to the content of the undesired substance in the product but are associated with leaching processes, which are influenced among others by the length of period of water stagnation and the pH of the water (as well as the manufacturing and cleaning process). It was emphasized that requirement of testing for release of the harmful substances as well as user information about the handling of the taps in a precautionary manner for some situation seem to be more goal-oriented".*

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<sup>69</sup> Direct quote of stakeholders' feedback is given in this section in cursive.

Extensive consultation with the industrial, NGOs and MS stakeholders along the criteria development process resulted in the proposal of the Criterion 2 Materials – Chemical and hygienic characteristics of materials. Nevertheless, due to lack of European wide harmonisation of testing methods for materials in drinking water, it occurred difficult to propose harmonised requirements, equally strict throughout all EU MS. Additional consultation conducted in recent months resulted in a new proposal, which is linked with the criterion on excluded substances and mixtures and is described below.

In the below section, first a description of the 4 MS approach worked by some MS with the goal to aid harmonisation of the requirements in the European Union (sent to JRC/IPTS by the stakeholders) is presented, and subsequently a proposal of the amended Criterion 2 is given.

## **9.1 Four Member States common composition list**

### ***Regulatory Background***

*“The European Drinking Water Directive 98/83/EC (DWD) came into force in 1998 and set standards for drinking water quality at the point of use (i.e. the tap in domestic water distribution systems). This Directive harmonized the quality of drinking water across the European Union, with a transition period of 15 years (i.e. ending in 2013) during which the limit values for metals are to be implemented.*

*At that time, a European wide collaboration was initiated towards developing a unified “European Acceptance Scheme (EAS) for materials and products in contact with drinking water” (EAS). The EAS activities, guided by European Commission (DG Enterprise), were aimed at:*

- a) avoiding barriers to trade,*
- b) implementing water safety plans to ensure a very high level of water quality from the source to the tap.*

*Unfortunately, in the absence of a suitable legal basis, in 2006 the EAS activities ceased. In its place, a smaller “harmonisation project” limited to the requirements of the (former) Construction Products Directive (CPD) formed the basis of further work (i.e. this further work is unable to completely fulfil the original aims of the EAS).*

### **4 MS Group activities**

*When the EC-EAS activities ceased in 2006, four Member States (Germany, France, Netherlands and the United Kingdom), took up the challenge to address the health-related issues identified by the EAS. As these countries had strongly supported the EAS, they undertook further development of major parts of the EAS and established the so-called '4 MS Group Acceptance Scheme'. This 4 MS Group mutual acceptance scheme is now at an advanced stage and it is under discussion with the other European Member States. In contrast to the EAS (a top-down-approach by the EC), the 4 MS Group Acceptance Scheme may be described as a "bottom-up-approach". Both schemes aim to provide European-wide high quality drinking water at the tap.*

### ***The 4 MS System in short***<sup>70</sup>

*There are four broad groups of materials in contact with drinking water. Each material group has its own properties and a need for a specific system of testing and approval. In addition, the development and control of those systems requires regulatory guidance. The 4 MS Group has shared responsibility for these materials as follows, but in order to avoid national dominance all decisions need the approval of the 4 MS Group:*

- *Metals: Germany,*
- *Elastomers: United Kingdom,*
- *Plastics: The Netherlands,*
- *Cementitious Materials: France.*

## **9.2 Metallic materials**

### **Metal approval according to the EAS/4 MS System**

*With regard to metals, one great success of the EC-driven EAS activities was the development of EN 15664 (parts 1 and 2) by CEN<sup>71</sup>. EN15664 (parts 1 and 2) defines a test method for metallic materials for their conformity (metal release) with the DWD. This test is the only long-term test (min 26 weeks) in Europe that realistically simulates flow periods, stagnation times and water consumption in a four-person household plumbing installation. Among other advantages, EN 15664's long-term test period refers to the "weekly average life-long consumption" – an approach upon which most of the DWD-metals guideline values are based.*

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<sup>70</sup> Additional information regarding the 4 MS Group collaboration as well as the 4 MS Group approaches towards positive lists for metallic, organic and cementitious materials can be found using the following link:

<http://www.umweltbundesamt.de/wasser/themen/trinkwasser/4ms-initiative.htm>.



*In a joint effort between EU Member States and the metal alloys industry, the metal releases from various metallic materials have been assessed in order to secure high quality drinking water. The initiative has resulted in a 4 Member States common composition list of metallic materials accepted for contact with drinking water. Within the 4 MS Group, Germany has taken responsibility for metals approval. In Germany, the drinking water department of UBA (Umweltbundesamt<sup>72</sup>) is active in this regard on behalf of, and mandated by, the German Health Ministry. Thus, UBA take preliminary (pass/fail) decisions on whether or not a metallic material is to be placed on the UBA metals positive list in accordance with the acceptance rules<sup>73</sup>. Before a candidate material is placed on the 4 MS metals positive list, the other Member States of the 4 MS Group review UBA's recommendation.*

*The 4 MS list, now agreed by several other MS, represents the most thoroughly investigated instrument, fully accounting for potential human health hazards of the metallic materials used for products in contact with drinking water. It therefore supports the objective, of the Ecolabel regulation, to promote products with less environmental impact during their entire life cycle.*

Several stakeholders who submitted their feedback regarding the criterion on substances, mentioned and supported using the 4 MS common composition list as instrument to verify the compliance with the Criterion 2 (Chemical and hygienic behaviour of materials) and linking it to the Criterion on excluded or limited substances and mixtures<sup>74</sup> in the Ecolabel. For more details on this scheme for metallic materials, please see also Annex 1A and 1B.

It is proposed to require in the EU Ecolabel for sanitary tapware that metallic materials used are listed in the current Positive List of Metallic Materials developed by the 4 MS group. This list will be attached to the criteria document in Annex I.

### **9.3 Plastic materials and elastomers**

Regarding organic materials there are a lot of national regulations in force in different Member States in Europe. In the current situation manufacturers have to fulfil the requirements of the country where they place their product on the market.

Simultaneously, like for the metallic materials, a positive list for organic materials allowed for products in contact with drinking water has been developed by the 4 MS group. Available

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<sup>71</sup> There is also a test DIN 50930-6 "Corrosion of metals - Corrosion of metallic materials under corrosion load by water inside of tubes, tanks and apparatus – Part 6: Influence of the composition of drinking water".

<sup>72</sup> German National Environmental Agency.

<sup>73</sup> As mentioned above, positive list of metallic materials can be found on the UBA webpage using the following link: <http://www.umweltbundesamt.de/wasser/themen/trinkwasser/4ms-initiative.htm>.

<sup>74</sup> At least when considering the human health hazards.

information (dated 22<sup>nd</sup> of June 2012) regarding this list and further work in this area, are given below<sup>75</sup>:

## **4MS Group Combined Positive List of Organic Substances in Contact with Drinking Water**

### **Introduction**

*“An essential element of the regulatory arrangements for control of the hygienic performance of products in contact with drinking water is the examination and approval of the inputs and constituents that go to make up products. The 4MS Group has agreed procedures for the evaluation of organic substances in use in products in its report “Positive Lists for Organic Materials” published in December 2011. This Report sets out the process to be followed for the assessment and acceptance of substances.*

*This approach will be used for all new substances being brought forward for approval, but provision needs to be made to rationalise and agree for common use substances that appear on the existing Positive Lists in use in France, Germany and the Netherlands. This document indicates how this is to be achieved.*

### Creation of “Core Lists”

*The plan for the future is to identify in the Combined List substances which are assessed by Member States according to the criteria for approval set out in the 4MS Common Approach for “Positive lists for organic materials”. The result of this assessment is stipulated in an Opinion. Following agreement on the Opinion by the other Member States the approved substance will be scheduled in the relevant 4MS Core List (plastics, rubber products, coatings or lubricants Core List). New items assessed and approved from today will appear directly in the relevant Core List.*

### Transitional Period

*A transitional period of five years has been fixed by the 4MS for this review exercise to give time to the manufacturers to deliver an application dossier according to the 4MS Common Approach “Positive Lists for Organic Materials” which will allow the insertion of a substance in one of the 4MS Core Lists.*

*Thus the Core Lists used in common by the 4MS will grow during this period and the number of substances approved for use in only one country will diminish. At the end of the five year period all individual national lists are in accordance with the 4 MS Core Lists and the Combined List will be withdrawn”.*

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<sup>75</sup> Annex 2A, also available online at: <http://www.umweltbundesamt.de/wasser->

The list of materials already put on the list can be also found in Annex 2A to this document. While more information regarding the procedure of acceptance and the entire scheme are attached as Annex 2B, i.e.:

Positive Lists for Organic Materials - 4MS Common Approach<sup>76</sup>

- Part A – Compilation and management of a suite of Positive Lists (PLs) for organic materials
- Part B – Assessment of products for compliance with Positive List requirements (Conversion Factors - CFs)

In order to unify the requirements regarding organic materials used in the EU ecolabelled sanitary tapware it is proposed to use the current version of the Positive List of Organic Materials developed by the 4 MS group. This list will be attached to the criteria document in Annex II.

### **Additional requirements for organic materials**

Apart from referring to the above-mentioned positive list in the requirements of the Criterion 2, the stakeholders proposed to take into consideration testing of hygienic characteristics (which are related the use of problematic materials and/or from the manufacturing process) like e.g. odour or microbial growth.

In order to test these aspects the following test methods and two guidelines of the German National Environmental Agency were proposed for consideration:

- EN 12873: Influence of materials on water intended for human consumption - Influence due to migration,
- EN 1420-1: Influence of organic materials on water intended for human consumption - Determination of odour and flavour assessment of water in piping systems
- EN 16421 Influence of materials on water for human consumption - Enhancement of microbial growth (EMG)
- Guideline for Hygienic Assessment of Organic Materials in Contact with Drinking Water (KTW Guideline)<sup>77</sup>,
- Guideline for hygienic assessment of elastomers in contact with drinking water (Elastomer Guideline)<sup>78</sup>.

## **9.4 Electronic components**

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[e/themen/downloads/trinkwasser/4ms\\_combined\\_positive\\_list.pdf](#).

<sup>76</sup> Annex 2B, also available online at: [http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/4ms\\_positive\\_list.pdf](http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/4ms_positive_list.pdf).

<sup>77</sup> See: [www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/ktw\\_leitlinie\\_eng.pdf](http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/ktw_leitlinie_eng.pdf).

<sup>78</sup> See: [http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/elastomerleitlinie\\_english.pdf](http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/elastomerleitlinie_english.pdf).

Finally, for electronic components it was highlighted that it is very difficult to obtain information regarding the content of various substances in the electronic parts, which are not purchased by the tapware manufacturers but from other producers. The stakeholders highlighted that information on the composition of the electronic components will not be made available to them. In this situation, a proposal to set the minimum requirements for electronics in tapware according to the new RoHS 2 Directive 2011/65/EU<sup>79</sup> was made by an industrial stakeholder. In accordance with information received, the electronic components of sanitary tapware (e.g. sensors) will be covered by the scope of the RoHS Directive from 3<sup>rd</sup> of January 2013<sup>80</sup>. Nevertheless, as sanitary tapware with electronic components have not been covered in the old RoHS Directive 2002/95/EC<sup>81</sup>, in accordance with Article 2(2) of the RoHS 2, a transition period applies to them, and no compliance with the requirements of the directive is requested till 21<sup>st</sup> of July 2019.

For the purpose of the EU Ecolabel in order to address the hazardous substances in the electronic parts the requirement of compliance with the RoHS 2 Directive for electronic parts is proposed.

## **9.5 Additional considerations regarding the Criterion 2 Materials – Chemical and hygienic characteristics of materials**

After the discussions conducted at the EU Ecolabelling Board meeting in June 2012, additional consideration of the Criterion 2 formulation and verification, and assessment procedure was conducted. Supplementary information was asked from various national competent bodies for approval of product in contact with drinking water regarding their schemes for testing or acceptance of materials and/or products.

Additionally, the state-of-art of development of the EN standards for testing release of nickel and lead from products in contact with drinking water was analysed. The following standards have been published recently (in May 2012):

- EN 16057:2012 Influence of metallic materials on water intended for human consumption
  - Determination of residual surface lead (Pb) - Extraction method (which describes the "test method to determine the amount of lead on the surface of test specimens made from lead containing copper alloys").

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<sup>79</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

<sup>80</sup> The change is due to the new definition of "dependent" on electricity.

<sup>81</sup> Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

- EN 16058:2012 Influence of metallic materials on water intended for human consumption
  - Dynamic rig test for assessment of surface coatings with nickel layers - Long-term test method (which "specifies a procedure to determine the release of nickel from nickel layers or a coating containing nickel on inner surfaces of products which are intended to come into contact with drinking water").

Industry and experts from the respective competent bodies for testing the products in contact with drinking water were consulted regarding the applicability of these standards in the framework of the currently proposed criteria for the product group of sanitary tapware. Furthermore, consultation regarding proposals for the limit values for both metals was conducted.

Only one stakeholder (competent body for testing of products in contact with drinking water) supported using the EN 16058:2012 test method for nickel release and submitted the proposal for limit value of 20 µg<sup>82</sup>. Another Competent Body of the MS, where this test is now being implemented, proposed a stricter threshold of 10 µg. Other, particularly industrial, stakeholders submitted negative opinion on the practicability of the standards' application for the purpose of the Ecolabel, at least in this criteria version. They claimed that the testing is lengthy and conducted in very limited number of laboratories, as introduced only recently; therefore not used on broader scale by the sanitary tapware industry so far. Furthermore, the stakeholders pointed out that there is very little evidence that these standards are suitable to be used (e.g. the EN 16057 does not measure the direct release of lead to drinking water but evaluates the amount of lead that is at the surface of the alloy; i.e. there lacks a link between this test method and the water quality; regarding the EN 16058 standard, the test takes 26 weeks, which is perceived very long).

Base on the analysis of the above-given feedback it has been decided to propose to use the the positive lists developed in the framework of the 4 MS group (described before). After additional discussions with the experts of the 4MS scheme, a reference to the standard EN 16068 is also proposed. Nevertheless, also equivalent national testing shall also be accepted.

Ahead the future revision of the criteria for the product group of sanitary tapware, these issues should be taken into particular consideration, as both, more experience will be available with using the newly developed EN standards and the application of the positive list in the EU 27.

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<sup>82</sup> For more details please see: Statutory order concerning approval of construction products in contact with drinking water – Draft, available online at:  
[http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa\\_notif\\_overview&iYear=2012&inum=344&sNLang=FR&lang=en](http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&iYear=2012&inum=344&sNLang=FR&lang=en)

The amended formulation of the Criterion 2 is proposed as follows:

Criterion 2 Materials in contact with drinking water – Chemical and hygienic characteristics of materials

Substances and materials used in products coming into contact with drinking water, or impurities associated with them, shall not release into water intended for human consumption any compounds in the way that either directly or indirectly, reduce the protection of human health. They shall not cause any deterioration in the quality of water intended for human consumption with regard to appearance, odour or taste. Within the recommended limits for correct operation (i.e. conditions of use as laid down in the respective EN standards indicated in Table 2), the materials shall not undergo any change which would impair the performance of the product. Materials without adequate resistance to corrosion shall be adequately protected so that they do not present a health risk.

**Assessment and verification:** *the applicant shall declare that the product complies with the requirement and submit relevant documentation or test results, as indicated below:*

*Metallic materials used in sanitary tapware shall be listed in the positive list "Acceptance of Metallic Materials for Products in Contact with Drinking Water" as given in Appendix 1. The applicant shall submit a declaration of compliance with this requirement. If the metallic materials are not included in this positive list, results of test conducted in accordance with the approach for "Adding Materials to the Composition List within a Category of Materials", as described in Appendix 1, and using the EN 15664-1 standard, shall be submitted. Alternatively, if obligatory national regulations are in place in the Member State where the product will be placed on the market, a certificate of approval of these metallic materials and/or product issued by national authorities or responsible laboratories shall be submitted.*

*Organic materials shall be tested in accordance with the respective national requirements of the Member State where the product will be placed on the market. A certificate or, if appropriate, test results issued by national authorities or responsible laboratories shall be submitted.*

*Additionally, if required by the national regulations or the Member State where the product is placed on the market, test results for enhancement of microbial growth and assessment of odour and flavour assessment of water shall be submitted.*