Chapter x – 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 of18 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 2nd 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[1] 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:

Hazard Statement[1]	**Risk Phrase[2]**
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

[1] 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;

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

[1] *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*
[2] *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) No1272/2008 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

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 1 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[2].

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)*
- *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

[2] Direct quote of stakeholders' feedback is given in this section in cursive.

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/cm2/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/cm2/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/cm2/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[3] 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.

[3] Extensive list of references supporting the feedback sent have been submitted to the project team.

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 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[4]) 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.

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*

[4] 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.

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 andare 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[5]. 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 in Member States and its application in the EU Ecolabel scheme for verification purposes should also be considered.

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.

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:

[5] 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.

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).

Nevertheless, migration tests are conducted for organic materials (e.g. German W270[6] and KTW guidelines[7]) 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.

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:

[6] DVGW (The German agency for water and gas) Arbeitsblatt W 270 – Vermehrung von Microorganismen auf Werkstoffen fuer den Trinkwasserbereich (eng. Proliferation of micro-organisms which come into contact with drinking water), 2007.
[7] DVGW KTW Guidelines (Kunststoffe und Trinkwasser; eng. Plastics and Drinking Water) - a series of recommendations for plastic materials used in contact drinking water.

Table 2 Proposal for derogation of the following substances

Hazard Statement[1]	**Risk Phrase**[2]	**Substances**	**Explanation**
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 (behaviour of chips and lubrication).
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	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[8] 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[9] 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 : ≤ 13%*
- *Lead : ≤3.5%*
- *Aluminium : ≤ 1 %*
- *Nickel : ≤ 0.6%*
- *Iron : ≤ 0.5%*
- *Arsenic : ≤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)

[8] Stocks refers to products installed and in use.

[9] EN 16057:2012, Influence of metallic materials on water intended for human consumption. Determination of residual surface lead (Pb). Extraction method.

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

- *According to the 1st 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 ≤ 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 ≤ 0.15%, being far below the acute toxicity CLP cut-off limit for mixtures of 1%. The small percentage of arsenic (≤ 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[10] and SCHER[11] 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 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

[10] EC TCNEC: European Commission Technical Committee on New and Existing Substances.

[11] EC SCHER : European Commission Scientific Committee on Health and Environmental Risk.

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 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[12] 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 negligable 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

[12] EN 15664: Influence of metallic materials on water intended for human consumption. Dynamic rig test for assessment of metal release.

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 : ≤ 13%*
- *Lead : ≤3.5%*
- *Aluminium : ≤ 1 %*
- *Nickel : ≤ 0.6%*
- *Iron : ≤ 0.5%*
- *Arsenic : ≤0.15 %*

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". The respective list in the criteria document will be given as Annex 1.

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/uses of substances are specifically derogated from this requirement:

Ni in stainless steel of all types	All hazard statements and risk phrases
Articles and homogenous parts of sanitary tapware, which fall under Article 23 (d) of Regulation 1272/2008 (includes metals in massive form, alloys) and are listed in Part B of the "Acceptance of metallic materials used for products in contact with drinking water – 4 MS Common Approach (Annex 1A).	All hazard statements and risk phrases

Additionally, the following derogation is proposed for consideration[13]:

Electronic components of sanitary tapware, which fulfil the Directive 2011/65/EU[14]	All hazard statements and risk phrases

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

Many comments[15] 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.:*

[13] For more explanation see section 9.4 Electronic components.
[14] 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.
[15] Direct quote of stakeholders' feedback is given in this section in cursive.

- *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".*

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[16]

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[17]. 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.

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[18]) 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

[16] 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.

[17] 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".

[18] German National Environmental Agency.

rules[19]*. 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[20] 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 information (dated 22nd of June 2012) regarding this list and further work in this area, are given below[21]:

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

[19] 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.
[20] At least when considering the human health hazards.
[21] Annex 2A, also available online at: http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/4ms_combined_positive_list.pdf.

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".

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[22]

- 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)

[22] Annex 2B, also available online at: http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/4ms_positive_list.pdf.

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) [23],
- Guideline for hygienic assessment of elastomers in contact with drinking water (Elastomer Guideline)[24].

Stakeholders' feedback with this regards is welcome.

9.4 Electronic components

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[25] was made by an industrial stakeholder. In accordance with information received, the electronic components of

[23] See: www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/ktw_leitllinie_eng.pdf.
[24] See: http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/elastomerleitlinie_english.pdf.
[25] 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.

sanitary tapware (e.g. sensors) will be covered by the scope of the RoHs Directive from 3rd of January 2013[26]. Nevertheless, as sanitary tapware with electronic components have not been covered in the old RoHs Directive 2002/95/EC[27], 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 21st 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").
- 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.

[26] The change is due to the new definition of "dependent" on electricity.
[27] 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.

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[28]. 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 not to propose to use the above-mentioned standards in this criteria version, but to use the positive lists developed in the framework of the 4 MS group (described before). 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.

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

Criterion 2 Materials – 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.

[28] 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

Metallic and organic materials used in sanitary tapware have to be listed in the positive list of materials, respectively:

- 4 MS Acceptance of Metallic Materials for Products in Contact with Drinking Water, see Annex 1A
- 4 MS Group Combined Positive List of Organic Substances in Contact with Drinking Water, see Annex 2A.

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.*