行政院所屬各機關因公出國人員出國報告書

出國報告（出國類別：考察）

德國考察水五金驗證制度

服務機關：經濟部標準檢驗局
姓名職稱：孫崇文技正、鄭力賓技士、翁小晴技士
派赴國家：德國
出國期間：中華民國 106 年 10 月 14 日至 10 月 25 日
報告日期：中華民國 106 年 12 月 19 日

摘　要

今日產品規範產生之技術障礙已經超越關稅問題成為自由貿易之主要障礙之一，國內輸歐業者往往因不熟悉歐盟產品規範造成產品研發不斷修正，或因不熟悉產品之當地驗證程序與法規等，而延宕商機，甚至造成我國產業整體競爭力下降。為協助我國水五金產品輸歐，遂提本計畫，以期協助本局飲水用水龍頭指定試驗室未來能取得輸歐水五金相關產品驗證試驗室，期能有效輔導我國水五金業者之產品順利輸歐，提升我國水五金產業之國際競爭力。

本計畫 106 年 10 月 14 日至 10 月 25 日執行期間，由本局第六組與第一組共 3 位同仁，偕同本局飲水用水龍頭指定試驗室－財團法人金屬工業研究發展中心 1 位專責人員共同赴德國，考察水五金產品驗證制度及相關檢測規定，拜訪德波昂市環境與消費者保護局、德國燃氣與供水工業技術和科學協會(DVGW)、德國標準化協會(DIN)、德國聯邦環境局(UBA)及水技術中心(TZW)共 5 個機構。

本計畫「德國考察水五金驗證制度」重要結果臚列如下：

1. 拜訪波昂市環境與消費者保護局，瞭解德國境內飲用水安全規定等相關議題之處理方式。
2. 拜訪 DIN 與 UBA，瞭解德國對水五金產品相關適用標準與驗證規範。
3. 拜訪 DVGW，並瞭解及協助財團法人金屬工業研究發展中心成為 DVGW 認可測試試驗室的可能性，期促使加快驗證程序，縮短業者產品開發時程，降低產業界受技術障礙的影響。
4. 拜訪 TZW，並瞭解及協助財團法人金屬工業研究發展中心與 TZW 建立合作關係的可能性，期降低我國水五金產品輸歐盟之驗證成本，擴大商機及保護消費者權益，提升水五金產業國際競爭力。

關鍵詞：飲用水安全，水五金產品，標準，驗證，認可試驗室

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壹、參訪目的

在全球貿易自由化市場下的經濟競逐，今日產品規範產生之技術障礙已經超越關稅問題成為自由貿易之主要障礙之一。根據世界貿易組織(WTO)統計近年來提報技術障礙的數目已經越來越多。其中又以歐盟最甚，透過中華經濟研究院的「最常引起貿易關切國家」(圖 1)顯示，歐盟最常被提起貿易關切高達 64 案件數。國內輸歐業者往往因不熟悉歐盟產品規範造成產品研發不斷修正，或因不熟悉產品之當地驗證程序與法規等，而延宕商機，甚至造成我國產業整體競爭力下降。

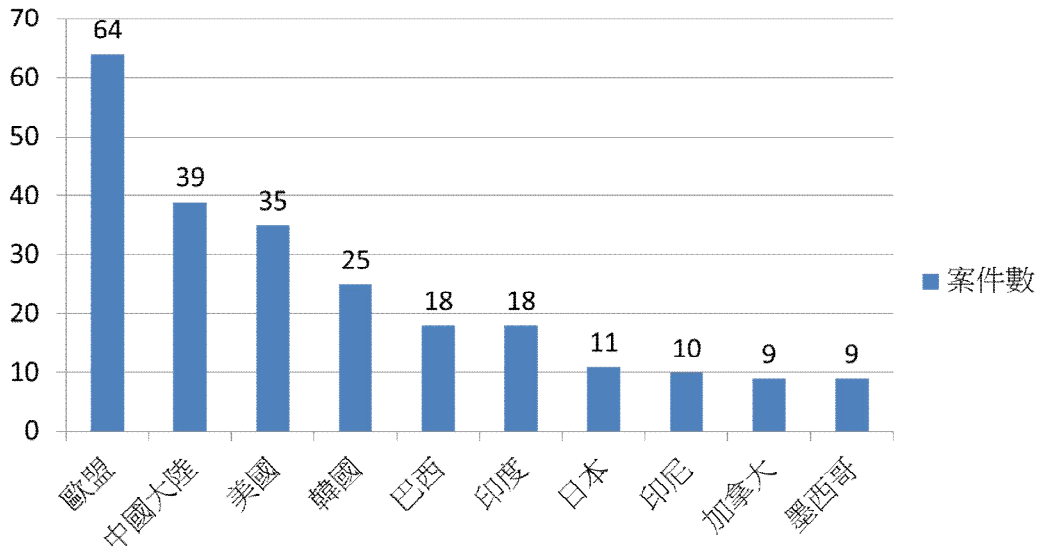


圖 1、最常引起貿易關切國家

本計畫「德國考察水五金驗證制度」之執行由本局第六組(生化科孫技正崇文、化學科鄭技士力賓)、第一組翁技士小晴共 3 位同仁，並協同本局飲水用水龍頭指定實驗室：財團法人金屬工業研究發展中心區域研發服務處智慧技術組「臺灣衛材開發與測試研究所」林副工程師世杰一同前往，除為協助業者熟悉與瞭解水五金產品輸歐所需符合之「產品規範(4MS)」，以確保產品基本性能無虞，並協助財團法人金屬工業研究發展中心「臺灣衛材開發與測試研究所」，有否辦理輸歐水五金產品驗證事項之可能，尋求德國相關驗證機構之認可或與認可實驗室間相互認可，其檢測報告可為驗證機構(如 DVGW)所採用，則可更有效輔導業

者，縮短產品送測時因驗證制度的不熟悉，影響產品上市之時程，有效降低水五金業者對新產品開發的投資成本，擴大水五金產品輸歐的經濟規模。

本局持續提升檢驗技術與能量及標準的調和，並持續檢討消費性商品的品項、檢驗標準與檢驗項目，藉由此次考察行程更加瞭解德國對水五金產品相關適用標準與驗證規範、標準作業程序及與本局目前作業規定、法規、作業程序及檢驗設備等各面向之差異，以對本局開發及建置實驗室設備及商品安全制度能與國際接軌，輔導廠商提升產品品質與技術層次並保障消費者權益。

以「產品驗證」環境而言，廠商測試的「成本高」與「時間長」，不利於產業競爭。就「水五金產品」而言，國外驗證程序困難繁雜，國內衛浴五金廠商大部分皆屬於中小型企業，多數欠缺檢測設備且無專業人員來處理國外測試業務，致無法自行建立產品測試技術與相關資訊，使得廠商要進入國際市場遇到瓶頸與困難。且當廠商將產品送至國外檢測時，發生產品不合格，廠商無法立即了解產品不合格之原因，往往需等產品寄回後，才可分析不合格原因，也因此造成產品驗證時程冗長，而影響商品銷售。

以「產業型態」分析，「法規標準測試」及「產品驗證」為衛浴產品要進入市場銷售的最大障礙，提升國內檢測能量除可協助廠商了解產品測試、驗證服務程序並協助業者快速進入衛浴產品銷售市場，也是本次考察預期解決之產業問題。為突破國外衛浴產品法規障礙，協助業界縮短開發時程及成本，本計畫至德國「燃氣與供水工業技術和科學協會(Deutscher Verein des Gas - und Wasserfaches, DVGW)」、「水技術中心(Technologiezentrum Wasser, TZW)」與「德國聯邦環境局(Umweltbundesamt, UBA)」，促進技術交流，並尋求財團法人金屬工業研究發展中心測試室被認可的可能性，期促使加快驗證程序，縮短業者產品開發時程，降低產業界受技術障礙的影響。

本局自從公告「飲水用水龍頭商品」之相關檢驗規定，並自 106 年 1 月 1 日生效以來，舉辦了多次的說明會，會中均有廠商提及台灣自來水還不能生飲的問題，有鑑於此，本次行程也特別透過德國在臺協會經濟組安排參訪波昂市環境與

消費者保護局(Amt für Umwelt,Verbraucherschutz und Lokale Agenda der Bundesstadt Bonn)－「波昂市淨水廠」與德國聯邦環境局(UBA)－「柏林自來水試驗場」，瞭解德國致力於全國生飲水上的努力及飲用水的衛生條件，探究飲用水與用水產品之間的連結。除此之外也安排「德國標準化協會(Deutsches Institut für Normung e.V., DIN)」，瞭解目前德國標準化的制定流程。

貳、參訪機構、參訪行程及洽談對象

一、參訪機構

(一)、「波昂市環境與消費者保護局」（Amt für Umwelt,Verbraucherschutz und Lokale Agenda der Bundesstadt Bonn / Stadthaus, Berliner Platz 2 , 53103 Bonn）簡介：

波昂市環境與消費者保護局之地址為 Stadthaus, Berliner Platz 2, 53103 Bonn，屬於波昂市政府組織，其所在城市為波昂市(Bonn)，波昂市為前西德的首都，德國重要的政治中心，有 6 個聯邦部門駐在波昂市，目前波昂市人口約 36 萬人。

目前波昂市市長為 Ashok Sridharan 先生，市政府員工約 5000 人，波昂市政府的組織架構於市長辦公室室底下有 5 個部門，分別為第 1 部門為總務部，第 2 部門為財務部，第 3 部門為規劃、環境和運輸部，第 4 部門為文化、體育和科學部，第 5 部門為社會事務、教育和衛生部。

(二)、「德國燃氣與供水工業技術和科學協會」(Deutscher Verein des Gas - und Wasserfaches, DVGW / Josef-Wirmer Straße 1-3, 53123 Bonn)簡介：

德國燃氣與供水工業技術和科學協會（以下簡稱 DVGW）為「驗證機構（Certification Body）」，是一個致力於燃氣和水工業技術發展的非政府機構。現任總裁是 Michael Riechel 先生，DVGW 組織架構為第 1 部門：監管政策、新聞和公共關係部、第 2 部門：會員、產品和營銷部、第 3 部

門：技術和創新管理部、第 4 部門：職業教育部、第 5 部門：天然氣技術和能源系統部、第 6 部門：為財政部、第 7 部門：供水部、第 8 部門：內部服務和 IT 部及第 9 部門：工作人員和法律部，共 9 個部門，另外 DVGW 的研究中心有 4 家天然氣領域的研究所（檢測實驗室）及 5 家水領域的研究所（檢測實驗室），本次考察計畫的「水技術中心」即為 DVGW 水領域研究所之一。DVGW 成立於西元 1859 年，一開始由燃氣公會的成員所組成，直到 1870 年加入水道相關產業，才正式跨足「燃氣」與「水」兩種產業。DVGW 建立之初即參與了歐洲、德國的相關標準的發展與制定，對於歐洲市場一體化標準的發展做出極大的貢獻，並持續關注於「技術安全」、「衛生」及「環境保護」等領域，始終保持其在天然氣及水工業安全技術方面的領導地位。

(三)、「德國標準化協會」(Deutsches Institut für Normung e.V., DIN / Am DIN-Platz Burggrafenstraße 6,10787 Berlin)簡介：

DIN 於西元 1917 年創立(迄今是逢其成立 100 週年)，為國際性標準化組織，屬非政府組成機構，經註冊成為協會。目前有超過 3 萬 2 千名技術委員，分別來自業界、研究單位、消費者及大眾。研究的標準主題包括聲學、運動設備、水資源管理及太空旅行，甚至包括工業 4.0[註 1] 及小型城市等主題，其標準之制定以市場為導向，並期望促進全球貿易、鼓勵合理化、注重品質保證、環境保護，同時著重改善安全性及具良好溝通性。

註 1：德國政府提出的高科技計畫，以智慧製造(Smart Manufacturing)為導向的的第 4 次工業革命，2013 年德國聯邦教育、研究、經濟、科技等單位將其納入《高技術戰略 2020(High-tech Strategy 2020)》的十大發展專案計畫，投資預計超過 2 億歐元之研究發展經費，用來提升製造業的電腦化、數位化及智能化。

(四)、「德國聯邦環境局」(Umweltbundesamt, UBA / Wörlitzer Platz 1, 06844 Dessau-Roßlau)簡介：

德國聯邦環境局（以下簡稱 UBA）為德國的中央環保部門，UBA 辦公室分布在德國 13 個地方，其中有 7 個地方是空中監測網絡的測量站，大約有 1,500 名員工，包含生物學、化學、經濟學、法學和工程學等領域專家，UBA 執行環境法律，包括排放交易、化學品、藥品和殺蟲劑的批准，政策立法的建議，在實驗室、模擬設備和測量站，收集和分析自己的環境數據和第三方的環境數據，同時，與國家環保部門和衛生部門緊密合作，是德國與世界衛生組織、聯合國歐洲經濟委員會和環境署以及歐洲環境局等眾多國際機構的合作夥伴和聯絡點。

UBA 分 5 個部門，第 1 部門：環境規劃、可持續性戰略部、第 2 部門：環保、保護生態系統部、第 3 部門：可持續生產、產品、循環經濟部、第 4 部門：化學品安全部及第 5 部門：德國排放權交易部。

德國聯邦環境局（UBA）主要是承接歐盟所發出來的各項指令，再將指令轉換成為德國境內法規，除此之外也自行開發各項方法與各項研究，許多時候德國的規範都會高於歐盟所發出的指令。一般而言，指令會由 UBA 來解釋，再建議德國聯邦衛生及社會安全部（Bundesministerium für Gesundheit und Soziale Sicherung），最終在 16 個邦實行。如前述所提及的波昂環保局就是遵循德國聯邦環境局所發布的指令來執行管制。

(五)、「水技術中心」(Technologiezentrum Wasser, TZW / Karlsruher Straße 4 76139 Karlsruhe)簡介：

德國燃氣與供水工業技術和科學協會(DVGW)有 9 個研究所部門，其中 4 家天然氣領域的研究所及 5 家水領域的研究所;「水技術中心（簡稱 TZW）」則屬於 DVGW 之水領域研究所，專職水資源相關議題的研究與發展，也參與相關法規制定，員工約 150 人，涵蓋「環境生技」、「地下水」、「土壤」、「化學分析」及「水資源品質」等領域專長人員。測試實驗室也專職執行相關的水資源測試，特別是在飲用水試驗。目前依循 UBA 所佈達的指示進行水資源的研究與方法開發及產品檢測。

二、參訪行程

自 106 年 10 月 14 出發至 10 月 25 日返臺，參訪行程及工作內容，如表 1：

表1、參訪行程及工作內容說明

日期及時間	地點	機構	目的及工作內容
106 年 10 月 14 日至 15 日（六）、（日）	臺北（Taipei）->德國法蘭克福（Frankfurt） 列車 德國法蘭克福（Frankfurt）->德國波昂（Bonn）	去程 宿：德國波昂（Bonn）	106.10.13（五）臺北出發（配合航班）Flight NO：CI061 臺北，Time：23：30 抵達德國法蘭克福，Time 06：50 （航程 13hr20min） 列車德國法蘭克福->德國波昂（車程 2 hr19 min）
106 年 10 月 16 日至 17 日（一）、（二）	德國波昂（Bonn）	105.10.16（一） 德國環境暨消費者保護局（Amt für Umwelt,Verbraucherschutz und Lokale Agenda der Bundesstadt Bonn / Berliner Platz 2 , 53103 Bonn） 宿：德國波昂(Bonn) 105.10.17（二） 德國 DVGW 總部（DVGW / Josef-Wirmer Straße 1-3, 53123 Bonn） 宿：德國波昂（Bonn）	105.10.16（一） 搭車前往德國環境暨消費者保護局： 1.環境管理系統與制度規劃及蒐集相關資訊。 2.消費者保護管理系統與制度規劃及安全管理通報系統。 3.高風險商品品項判定。 105.10.17（二） 搭車前往德國 DVGW 總部： 1.驗認證過程及品質有效確保。 2.產品相關規範、技術標準、法規及政府特別要求。 3.產品判定基準及最新動向及蒐集相關資訊。 4.歐盟對毒性分類、產品及安全性要求。 5.評估 DVGW 與金工中心開發與測試研究所（TPL）雙方檢測報告相互認可之可行性。
106 年 10 月	德國波昂（Bonn）->德	106.10.18（三）	106.10.18（三）

18 日 （三）	國柏林（Berlin）	搭列車前往德國柏林（DVGW 因籌備 11 月 28-30 日在科隆市(Köln)的年度展示會，只給予 10.17 的參訪行程） 宿：德國柏林（Berlin）	搭列車：德國波昂（Bonn）->德國柏林（Berlin）（車程 5 hr12 min）
106 年 10 月 19 日至 21 日 （四）～（六）	德國柏林（Berlin）	106.10.19（四） 1.駐德國臺北代表處(Markgrafenstrasse 35，10117 Berlin) 2.DIN- the German Institute for Standardization Am DIN(Platz Burggrafenstraße 6,10787 Berlin) 宿：德國柏林（Berlin） 106.10.20（五） 3.德國聯邦環境部環境局總部（Umweltbundesamt /Wörlitzer Platz 1, 06844 Dessau-Roßlau） 宿：德國柏林（Berlin） 106.10.21（六） 宿：德國柏林（Berlin）	106.10.19（四） 搭車前往德國臺北代表處： 1.拜會駐德國臺北代表處。 搭車前往德國標準組織(DIN)： 2.DIN- the German Institute for Standardization Am DIN 2.1 驗認證過程及品質有效確保。 2.2 赴 DIN 標準組織產品相關規範與技術標準及政府特別要求。 2.3 產品判定基準及最新動向及蒐集相關資訊。 106.10.20（五） 搭車前往德國聯邦環境部環境局總部： 3.德國聯邦環境部環境局總部 3.1 歐盟對毒性分類、產品及安全性要求。 3.2 水五金產品對環境影響之評估及最新動向。 3.3 環境管理系統與制度規劃及蒐集相關資訊。 106.10.21（六） 1.資料綜整 2.準備後續行程
106 年 10 月 22 日 （日）	德國柏林（Berlin）->德國法蘭克福（Frankfurt）	宿：德國法蘭克福（Frankfurt）	列車德國柏林（Berlin）->德國法蘭克福（Frankfurt）（車程 5 hr03 min）
106 年 10 月 23 日	德國法蘭克福（Frankfurt）	106.10.23（一） Technologiezentrum	106.10.23（一） 搭車前往 TZW：

（一）		Wasser(TZW)/ KarlsruherStraße84 76139 Karlsruhe 宿：德國法蘭克福（Frankfurt） (TÜV Rheinland LGA 因場地因素無法參訪，需至 11 月，故臨時安排 TZW)	1.實驗室對水五金產品分類及要求。 2.水五金產品測試及判定基準。 3.水五金產品相關規範與技術標準。 4.水龍頭之殘響試驗技術及要求。
106 年 10 月 24 日至 25 日 （二）、（三）	德國法蘭克福（Frankfurt）-> 臺北（Taipei）	返程	106.10.24（二）法蘭克福出發 Flight NO：CI062 Time：11：20 抵達臺北 Time 06：10 （航程 12 hr50 min）

三、洽談對象

表 2、參訪機構及洽談對象

編號	機構名稱	參訪地址	主要洽談對象	部門／職稱
1	波昂市環境與消費者保護局（Amt für Umwelt,Verbraucherschutz und Lokale Agenda der Bundesstadt Bonn）	Berliner Platz 2 , 53103 Bonn	Mr. Hans-Arno Wietschel-Ulrich	基礎水域保護(Untere mweltbehörde) ／科長(Abteilungsleiter)
2	德國燃氣與供水工業技術和科學協會（DVGW）	Josef-Wirmer Straße 1-3, 53123 Bonn	Ms. Renata Schmitt & Mr. Marko Greuel	技術和創新管理部(Techn. Betriebswirt) ／品質管理代表(Qualitätsmanagementbeauftragte)

3	德國標準化協會 (Deutsches Institut für Normung e.V., DIN)	Platz Burggrafenstraße 6,10787 Berlin	Mr. Andreas Paetz	水資源標準委員會 (Normenausschuss Wasserwesen) ／主席 (Teamkoordinator)
			Mr. Erik Heldt	水資源標準委員會 (Normenausschuss Wasserwesen) ／計畫經理 (Projektmanager)
			Mr. Norbert Müller	德國萊茵 TÜV (TÜV Rheinland) ／產品經理 (Produktmanager)
4	德國聯邦環境局（Umweltbundesamt, UBA）	Platz 1,06844 Dessau-Roßlau	Ms. Bettina Rickert	第 2 部門環保，保護生態系統-提高飲用水衛生 (Fortentwicklung der Trinkwasserhygiene)
			Mr. Daniel Mahringer	第 2 部門環保，保護生態系統-飲用水資源和水處理 (Trinkwasserressourcen und Wasseraufbereitung)

5	水技術中心 (Technologiezentrum Wasser, TZW)	Karlsruher Straße 84 76139 Karlsruhe	Dr. Josef Klinger	常務董事 (Geschäftsführer) ／ 執行長(CEO)
			Dr. Frank Sacher	技術和經濟部門主管(Abteilungsleiter Technologie und Wirtschaftlichkeit)

叁、考察過程

一、波昂市環境與消費者保護局(Amt für Umwelt,Verbraucherschutz und Lokale Agenda der Bundesstadt Bonn)

(一) 波昂市環境與消費者保護局會議討論要點節錄如下：

本次波昂市環境與消費者保護局之基礎水域保護科科長 Mr. Hans，為我們歸納了三大點（附錄 1），並介紹其工作內容，包括環境保護政策、水域保護方法、地表保護與舊有廢棄物處理，並解說德國境內飲用水規定等相關議題，議程中提及早期波昂市的供水管線為鉛管，目前波昂市的供水管線已全數更換完畢，大部分為銅管，小部分為高分子材料管。該市水源保護區的淨水廠負責自來水淨化的處理過程，因其水源保護區之水質，富含礦物質屬於硬水，尤其該區因土壤中磷含量特別高，其自來水淨化處理過程需有降低水中磷含量之製程，再搭配應用次氯酸鈉除菌技術等，經該水廠淨化處理後的自來水即可供應生飲。德國水五金產品之 26 週至 52 週材料溶出性能測試依規定需使用自來水進行測試。

圖 2、拜會波昂市環境與消費者保護局

(二)考察波昂市淨水廠要點節錄如下：

接著我們前往距離波昂市區大約 35 分鐘的水源保護區中的淨水廠，波昂水源保護區的水，因含礦物質比較多，都屬於硬水，同時並特別針對水中「磷」含量的處理，也介紹「除菌」的技術(附錄 2)。

圖 3、考察參觀波昂市淨水廠

二、德國燃氣與供水工業技術和科學協會(Deutscher Verein des Gas - und Wasserfaches, DVGW)

DVGW 會議討論要點節錄如下：

德國燃氣與供水工業技術和科學協會(Deutscher Verein des Gas - und Wasserfaches, DVGW)總部技術和創新管理部品質管理代表 Ms. Renata 說明 DVGW 為德國認證機構(DAkkS)認可之驗證機構，DAkkS 已獲認證之實驗室使用國際試驗室認證聯盟(International Laboratory Accreditation Cooperation，ILAC)[註2]組合標記(圖 4)，Ms. Renata 同時熱心為我們講解取得水五金驗證之 DVGW 測試試驗室認可應具備之資格條件及申請流程(圖 5)。

圖 4、獲認證符合性評鑑機構 ILAC MRA 組合標記

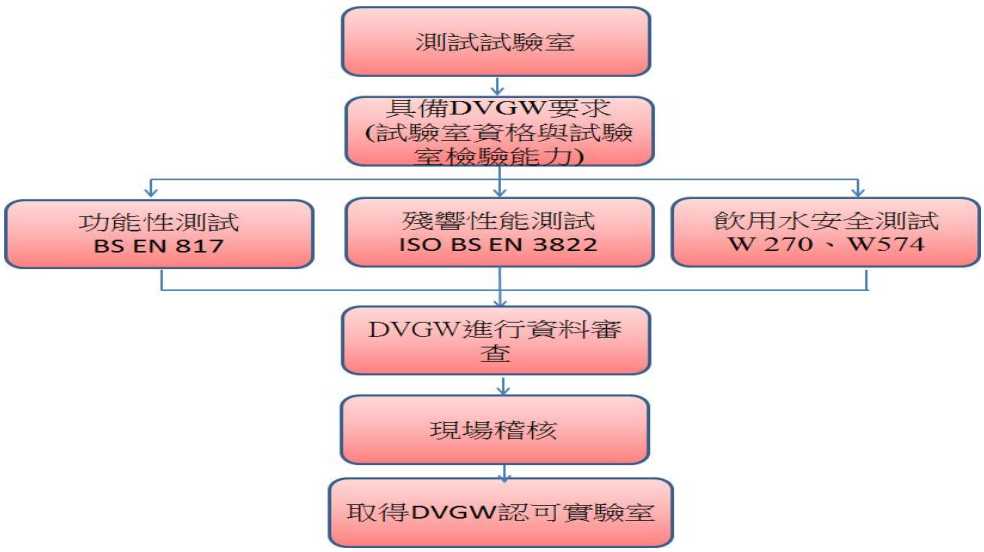


圖 5、德國 DVGW 產品測試試驗室之認可流程

申請試驗室應具備國際試驗室認證聯盟(ILAC)所認證之 ISO 17025[註3]測試試驗室資格，以及建置水龍頭機械功能性測試規範 EN 817[註4]、殘響性能(噪音)測試標準 ISO 3822-1[註5]，及飲用水安全測試等檢測能力，其中飲用水安全測試部分包括飲用水接觸材料微生物檢測評估規範 DVGW W 270[註6]與飲用水設備之材料試驗規範 DVGW W 574[註7]。

註 2：國際試驗室認證聯盟(International Laboratory Accreditation Cooperation，ILAC)，我國之財團法人全國認證基金會(TAF)及德國認證機構(Deutsche Akkreditierungsstelle, DAkkS)皆為 ILAC 相互承認協議(MRA)簽署會員，DVGW 為 DAkkS 認可之驗證機構。

註 3：ISO 17025「General requirements for the competence of testing and calibration laboratories」相當於 CNS 17025「測試與校正試驗室能力一般要求」。

註 4：EN 817「Sanitary tapware - Mechanical mixing valves (PN 10) - General technical specifications」。(水龍頭機械混合閥(PN 10) -一般技術規範)。

註 5：ISO 3822-1 「Acoustics - Laboratory tests on noise emission from appliances and equipment used in water supply installations - Part 1: Method of measurement」 (聲學-用於供水裝置設備的噪音試驗室測試-第 1 部分：測量方法)。

註 6：DVGW W 270「 Microbial Enhancement on Materials to Come into Contact with Drinking Water – Testing and Assessment」 (飲用水材料的微生物增長-檢測和評估) 。

註 7 ： DVGW W 574 「 Sanitärarmaturen als Entnahmearmaturen für Trinkwasser-Installationen – Anforderungen und Prüfungen」(飲用水設備的安裝配件-要求和測試) 。

試驗室向 DVGW 遞交申請文件，經 DVGW 文件審查通過後，派遣專家至申請試驗室進行現場稽核，符合 DVGW 認可規範者成為其認可試驗室，其所出具的測試報告可被 DVGW 水五金驗證時所採認。目前 DVGW 有認可亞洲區測試試驗室之相關規劃，而除了需符合 ISO 17025 、EN 817、ISO 3822-1、DVGW W 270、DVGW W 574 等規範之硬實力以外，軟實力例如：申請試驗室之測試品質水準及市場需求量等，也是 DVGW 決定試驗室認可時之重要考量因素。

DVGW 如果採認財團法人金屬工業研究發展中心的測試報告，水五金產品測試這個工作就可以在臺灣執行，如此可降低業者因語言所帶來的隔閡，測試實驗室也可以直接針對產品不合格的地方對業者提出建議改正方案，這樣不只可以減少往來的時間，更可讓業者了解產品如何設計，相信對於產品的研發與性能的提升是頗具成效。其次，我們最關心的是 DVGW 的驗證在歐盟的效力，依照 DVGW 的說法，他是可以通行在整個歐盟的，並且 DVGW 在 2016 年才獲得最

佳驗證單位的獎項，所以公信力是沒有問題的。

業者送交水五金產品至 DVGW 認可之測試試驗室，進行產品之功能性、殘響性能及飲用水安全測試，此外，零組件經佐證符合英、法、德及荷蘭四國 4MS (Four Member States) [註8] 規範正面表列材質(附錄 3、附錄 4)之水五金產品可以免除飲用水安全測試之 DVGW W 574 材料試驗部分。業者取得合格產品測試報告後，備齊申請文件向 DVGW 申請水五金產品驗證，經 DVGW 書面審查通過後核發驗證證書，則該業者即可於驗證產品上使用 DVGW 之產品驗證標誌，業者取得 DVGW 水五金產品驗證流程如圖 6 所示，圖 7 則為 DVGW 所核發證書之範例。

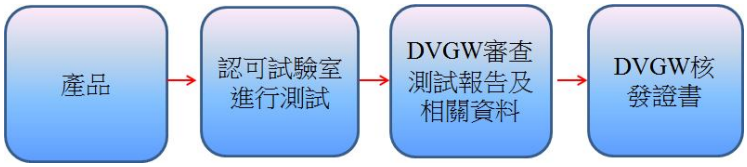


圖 6、德國 DVGW 水五金產品之驗證流程

圖 7、DVGW 所核發之證書範例

註 8：4MS 係由德國、英國、法國、荷蘭等 4 國共同簽署之對水龍頭輸入之相關檢測驗證協定，並同時開放給其他歐盟共同體作為該等產品輸入之依據。4MS 規定材質之正面表列如下：

(1)金屬材質正面表列：可接受與飲水接觸產品之金屬材料成分組成表(Common composition list acceptance of metallic materials used for products in contact with drinking water) 。(附錄 3)

(2)用於與飲水接觸產品之有機材料正面表列清單(Positive lists for organic materials used in products in contact with drinking water) 。(附錄 4)

下載網址

https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative

三、德國標準化協會(Deutsches Institut fur Normung e.V., DIN)

DIN 會議討論要點節錄如下：

會中一開始自我介紹，同時也介紹本局標準制定作業說明；水資源標準委員會(NAW)主席 Mr. Andreas 則於會中介紹 DIN 水資源標準委員會的運作及組織(附錄 5)。

DIN 旗下的水資源標準委員會，於 1950 年正式成立(但早於 1920 年代，已有水資源標準化的證據)。NAW 負責水資源相關領域之標準化工作，並促進水資源標準的推廣及應用，此項工作於環境(包括水、土壤及水質)委員會、水工程委員會、供水委員會及污水工程委員會中進行，NAW 亦協助將此領域標準推展至歐盟及世界標準化組織。

NAW 負責 415 個委員會(包括 181 個 DIN 標準委員會、71 個 CEN 歐洲標準委員會、163 個 ISO 國際標準委員會)，有 1393 位技術委員(技術委員的席次共 2450 位)，負責 578 個標準專案、標準總數約 2000 種，在德國有超過 8 千萬位利害關係者(stakeholder)。NAW 辦公室有

19 位員工，包括 1 位主管、11 位專案經理、7 位助理，其中專案經理於 2016 年參與 303 個會議。

NAW 組織分為 4 大主題領域，包括環境(廢棄物、土壤、水)，水利工程，污水處理技術，飲用水等，組織圖如下(圖 8)。

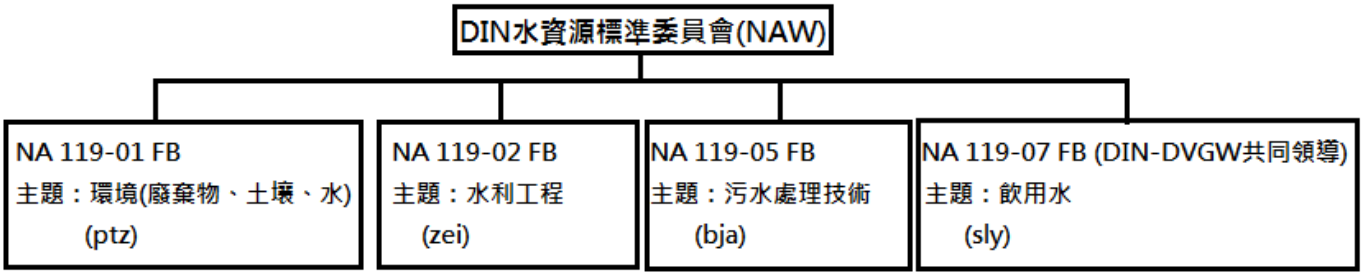


圖 8、NAW 組織圖

圖 9、拜會德國標準化協會(DIN)

四、德國聯邦環境局(Umweltbundesamt, UBA)

UBA 會議討論要點節錄如下：

德國聯邦環境局(Umweltbundesamt，UBA)為德國境內 4MS 規範之主要負責機構，該局兩位水處理專家解釋德國對於飲用水的管制如圖 10，飲用水的品質最低要求須符合歐盟飲用水標準[註9](附錄 6)，UBA 負責規範德國飲用水標準，定義目標邊界值(例如金屬與有機化合物

容許量邊界值)，產品材質正面表列規定，以及德國境內飲用水安全之責任。至於規範之細節，涉及標準部分則委由德國標準化協會(DIN)底下之各個技術委員會訂定，設備要求規範部分則委由德國燃氣與供水工業技術和科學協會(DVGW) 訂定，飲用水品質管理由供應者(即各區供水廠)負責，至於末端給水部分則透過各地方健康局獨立監控。

註 9：歐盟飲用水標準為 COUNCIL DIRECTIVE 98/83/EC 。(附錄 6)

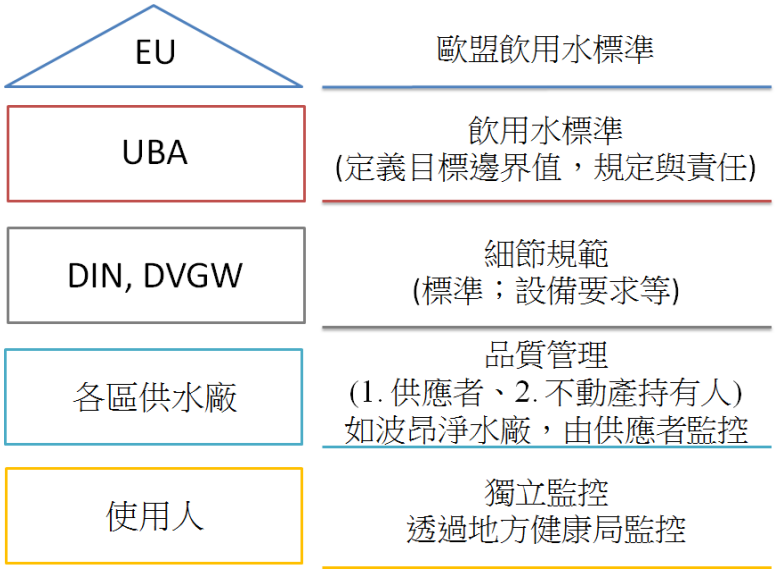


圖 10、德國飲用水相關之管制總覽

圖 11、拜會德國聯邦環境局(UBA)

除了水質專家以外，我們為更了解英、法、德及荷蘭四國共同制定與水接觸產品的金屬與有機化合物容許量之 4MS 規範(附錄 3、附錄 4)，金屬或有機材料可被 UBA 列為正面表列之測試流程，以及該規範與水五金驗證之關係，特別商請 Ms. Bettina Rickert 與 UBA 的材料專家 Dr. Thomas Rapp 聯繫，惟 Dr. Thomas Rapp 辦公室具參訪地點約 150 公里，因時間上的考量，我們無法親自拜訪，幸獲 Dr. Thomas Rapp 的首肯，進行了一場約 2 小時的視訊連線會議(圖 12)。

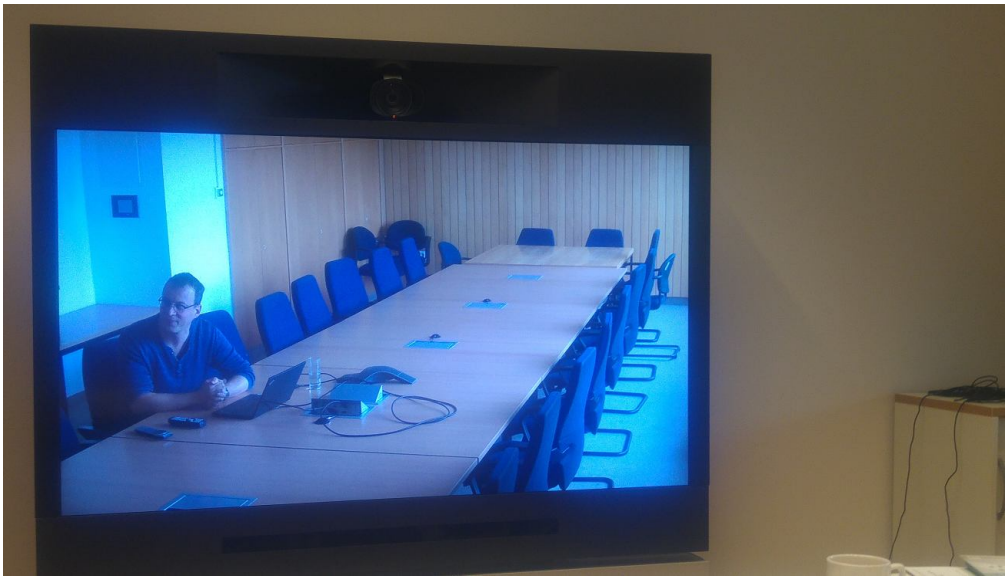


圖 12、與 Dr. Thomas Rapp 視訊連線會議

視訊連線會議內容主要是「Four Member States / 4MS」（以下簡稱 4MS）的一些近況以及 4MS 金屬材料的測試方法(附錄 7)，近年來也是有許多國家想加入 4MS，像是葡萄牙等，並且確認英國不會因為脫歐就脫離 4MS 的架構，使用 4MS 正面表列之金屬或是有機材料且該等材料在允許使用面積內之水五金產品，可以不需進行 26 週至 52 週的材料溶出性能測試，而可直接進行確認其為符合 4MS 正面表列材料之成品材質測試。

五、水技術中心(Technologiezentrum Wasser, TZW)

TZW 會議討論要點節錄如下：

DVGW 所屬之水技術中心(Technologiezentrum Wasser, TZW)為我們介紹該中心的檢驗技術(附錄 8)，同時也說明申請德國水五金產品測試報告之程序：業者需先提交產品之代表樣品及產品資料文件，例如：材料成分表、已符合 4MS 認可之材料清單與證明、產品爆炸圖(Product explosion map)與產品材料資訊表(Product Material Information，PMI)等，經 TZW 文件審查符合及代表樣品測試合格後出具產品測試報告。

德國之水五金產品測試之重要規範有 BS EN 15664-1[註 10]測試設備與程序規範、KTW[註 11]有機材料指引(附錄 9)、DIN EN 16058[註 12]水龍頭表面鍍鉻之鎳層釋出量相關測試方法等。

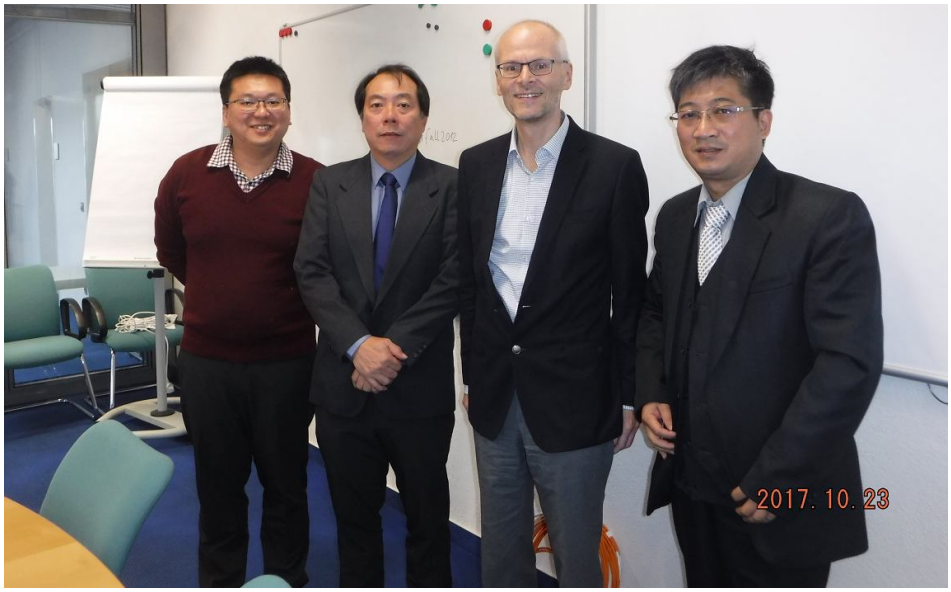


圖 13、拜會水技術中心(TZW)

註 10：BS EN 15664-1「Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of metal release - Part 1: Design and operation.」 (金屬材料對人類飲用水的影響-金屬釋放動態鑽機測試-第 1 部分：設計和操

作)。

註 11：KTW Guideline-Guideline on the hygienic assessment of organic materials in contact with drinking water. (KTW 指引-與飲用水接觸的有機物質的衛生評估指南)。(附錄 9)

註 12：DIN 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.」(金屬材料對人類飲用水的影響-鎳層表面塗層的動態鑽機測試-長期的測試方法)。

肆、心得與建議

一、心得

(一) 德國產業現況

這次的行程中，也透過各實驗室了解到德國市場的趨勢，市場的趨勢和德國人的性情有些許的關係，在德國傳統的搖桿式水龍頭(圖 14-A)還是佔有一席之地，另一個受到歡迎的水龍頭則是單把手水龍頭(圖 14-B)，對他們而言，傳統是好的，所以感應式龍頭就沒有這麼受到青睞。也有一個基本的理由，感應技術相對而言還沒這麼穩定，所以接受度也跟著比較低。

圖 14、搖桿式水龍頭與單把手水龍頭

雖然德國沒有要求水五金產品上市前須強制檢驗及通過驗證，然而消費者基於飲水安全考量，一般會選購通過驗證之水五金產品(例如包裝上貼附 DVGW 產品驗證標誌者)，故水五金產品輸歐時，若能取得 DVGW 之產品驗證，可獲得較高之市場接受度。

(二) 德國 DVGW 驗證流程

而就驗證情形而言，DVGW 的專家給了我們一個解釋，目前德國是採後市場機制，總共分為三個層級：

第一、廠商自我宣告，任何廠商只要符合 EN 817 就可以自我宣告材料符合 4MS 規範要求。

第二、廠商自我宣告材料符合 4MS 規範要求加上第三方公正單位驗證的測試報告，可靠度較第一種更高，多了第三方公正單位。

第三、廠商自我宣告材料符合 4MS 規範要求加上具有 DVGW 的證書與驗證標章，公信力更高。在歐盟境內 DVGW 的驗證標章，普遍收到民眾的信賴，除因 DVGW 所屬實驗室均是受良好的驗證管理的，公信力佳。

以德國市場而言，大部分民眾的採購順序是第三種方式>第二種方式>第一種方式。所以產品要在歐盟或德國市場暢行無阻，產品取得驗證將是最好的選擇。由圖 5 德國 DVGW 產品測試試驗室之認可流程及圖 6 德國 DVGW 水五金產品之驗證流程可以看到，要取得 DVGW 產品驗證需要通過三項測試，分別為「功能性測試(EN 817)」、「殘響性能(噪音)測試(ISO 3822-1)」、「飲水安全測試(DVGW W 270、W 574)」，雖然德國水五金(水龍頭)產品上市沒有要求一定要取的驗證(非強制檢驗之消費性商品)，但是飲用水安全是強制測試項目，所以上市產品必須要通過飲用水安全測試，那麼就可以整理出來測試市場為什麼依然蓬勃發展的原因了，第一、大部分民眾與大賣場會選擇通過驗證的產品。第二、飲用水安全測試是必須測試的項目，廠商一旦與自我宣告產品驗證項目不符，於後市場端被查驗出來，可不是下架、回收、銷毀及罰鍰而已，廠商還涉後續嚴峻刑罰。

(三) 美國與德國的驗證申請程序之比較

飲用水安全一直以來受到各先進國家的重視，分別針對水龍頭金屬材質、水龍頭有機材質以及水龍頭溶出污染物做出許多檢測規範，例如北美有名的美國國家衛生基金會(National Science Foundation, NSF)也是針對這些項目進行測試。而歐洲法規一樣在這方面有所著墨，近年來最著名的莫過於 4MS 這個合作關係了，德國指引的限制物質也是參考這項協議，美國水龍頭驗證流程程序與德國水龍頭驗證流程程序都須進行「功能性測試」、「殘響性能(噪音)測試」，最主要差異為水龍頭「飲用水安全測試」，以下將美國水龍頭驗證流程程序與德國水龍頭驗證流程程序，以供參考。

1. 美國水龍頭驗證流程程序

廠商需要先提交產品的相關訊息予以文件化，例如：代表測試產品、材料成分表、已認可材料清單與證書、產品爆炸圖與產品材料資訊表（product/ material information / PMI）等的相關文件資料，確認「代表測試產品」符合資格後，進行「19 天」的產品前處理測試(溶出試驗)，前處理所蒐集之測試液，依 NSF ANSI 61[註 13] 及 NSF ANSI 372[註 14] 之規範，實施「材質鉛含量」、「無機污染物溶出性能分析」與「有機污染物溶出性能分析」，上述兩項（無機污染物與有機污染物之溶出性能分析）統稱「毒理分析」。測試分析後之所有結果與數據，提交委員會審定核判。

註 13：NSF/ANSI 61「Drinking Water System Components - Health Effects(飲用水系統組件 – 健康影響)」。

註 14： NSF/ANSI 372「Drinking Water System Components - Lead Content (飲用水系統組件 – 鉛含量)」。

2. 德國水龍頭驗證程序：

德國飲用水安全測試第一個步驟也是文件審查，同樣的，需要廠商提出產品爆炸圖、材料成分表、許可材料的相關資訊證書與產品資訊表等產品訊息。然後從第二步驟開始，就可以看出不同之處了，在德國，如果材料是使用正面表列上的材料，就可以不需再進行材料試驗，當然，前提是在允許的使用面積內，接著

僅需要進行成品測試即可。最大的不同就是在這個地方，美國 NSF 測試只需進行 19 天的產品前處理測試，而德國需要進行 26 週(182 天)的測試，時間較美國測試長很多，因為德國實驗室認為 19 天所溶出的有機物質與金屬物質含量均太高，對產品而言較不公平，所以他們採計 26 週(182 天)的數值，以趨勢而言，後幾週溶出的污染物趨為平緩，對於產品而言，較為公平。另一層的意義則是，德國是要探討材料本質對水的影響，而不是短周期時間內溶出的污染物。

二、建議

為降低我國水五金產品輸歐盟之驗證成本，提升產業競爭力，建議未來或可朝下列方向之一協助本局飲水用水龍頭指定試驗室：

(一) 財團法人金屬工業研究發展中心申請成為 DVGW 亞洲區認可測試試驗室，則其所出具的測試報告可為我國廠商申請 DVGW 水五金驗證時所採認，惟須配合我國水五金業者亦採用符合 4MS 正面表列之金屬及有機材料。

(二) 財團法人金屬工業研究發展中心與 DVGW 所屬之 TZW 建立合作夥伴關係，由本局飲水用水龍頭指定試驗室進行水五金機械功能性及殘響性能(噪音)等物理性測試之檢驗能量，由 TZW 進行需使用德國當地自來水之飲用水安全測試及出具產品測試報告，惟此模式需再經 DVGW 同意採認雙方合作之報告。

附錄 1

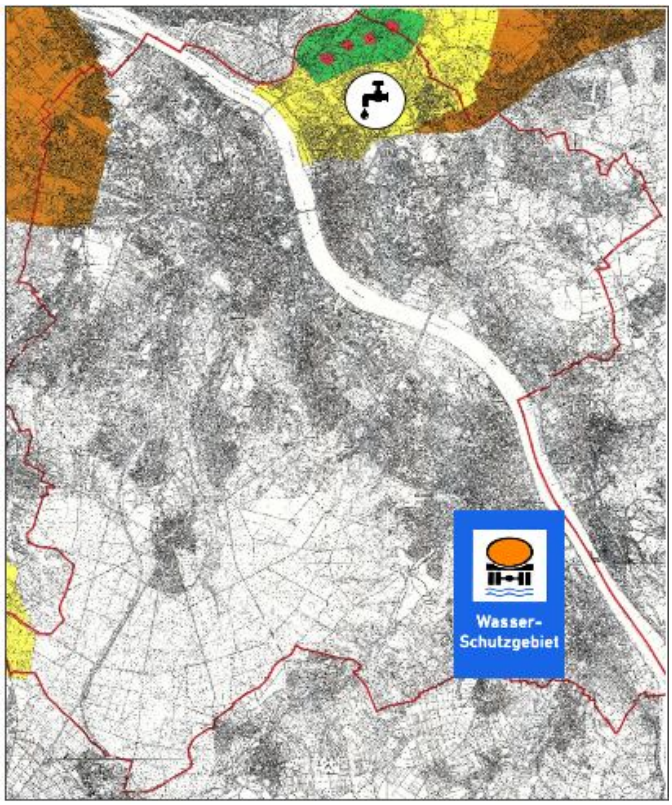
波昂環保局工作內容

1. 現行的環境保護政策與方法

波昂市目前統整了 1200 項與環境相關的營運企業，分別列管相關的固體垃圾，有毒的廢水與廢棄，也負責污水處理設備的安全測試。除了列管以外，更在波昂市內廢水排放有監測，當然，與臺灣相同，廢水也是有分級，可直接排放或廢水經處理後才排放。除此之外，也負責汙水處理設備的安全測試。在波昂市約有 250 間受到定期監控的企業，另外亦有 1000 間企業因特別原因受到監測。

2. 水域保護

本次計畫剛好是來探討飲用水相關議題， 波昂環保局基礎水域保護科 Mr. Hans 為我們說明了，目前德國用水之水源比例為 20%來自地表水，80%來自地下水。同時，我們於會中特別提出疑問，指台灣在抽地下水時，會有地層下陷的問題發生，但德國怎麼不會？Mr. Hans 說，德國地下水源非常豐富，且地表水也豐富，地質屬岩層結構亦與貴國不同，所以在德國沒有地層下陷問題。另外在水源保護方面也特別用心，圖附錄 1-1 為波昂市的水源保護區，可以看到總共有三個顏色，綠色部分為不能開發(農業也不行)，黃色部分為不能蓋工廠，可以蓋民宿，紅色部分則允許只能蓋輕工業。在綠色區塊連汽機車都只能是電動的，禁止以燃油為動力系統的汽機車，以確保環境不會受到汽油等石化產品的污染，可以想見德國政府對於水源保護之用心。我們可以由下面四圖(圖附錄 1-2、圖附錄 1-3、圖附錄 1-4、圖附錄 1-5)來看見波昂市由 1807 年到 1995 年的發展進程，在這兩百多年來，波昂市由一個小城鎮，變成目前的大城鎮。早期波昂市的供水管線為鉛管，目前波昂市(Bonn)的供水管線已全數更換完畢，大部分為銅管（因銅管具抑菌效能及導熱性佳），小部分為高分子材料管，這也是我們可以借鏡的地方。



圖附錄 1-1、波昂水資源保護區(綠色區塊為禁建，黃色區塊為僅可建立民居，紅色區塊為允許建立輕工業)

圖附錄 1-2、1807 年波昂市

圖附錄 1-3、1845 年波昂市

圖附錄 1-4、1958 年波昂市

圖附錄 1-5、1995 年波昂市

1.3 地表保護與舊有廢棄物處理

以前德國沒有特別規定垃圾處理的方式，所以都是採「掩埋法」，直到近年來，才開始處理以往的錯誤，像臺灣常說的「歷史共業」。這個歷史共業，可以說是吃力不討好，在這裡分享一個例子，可以看見紅框處為舊有的掩埋場，目前已改為學校，從掩埋場轉變為學校之處理步驟大致如下。

a. 空照圖對照，衛生層級分類(圖附錄 1-6)。

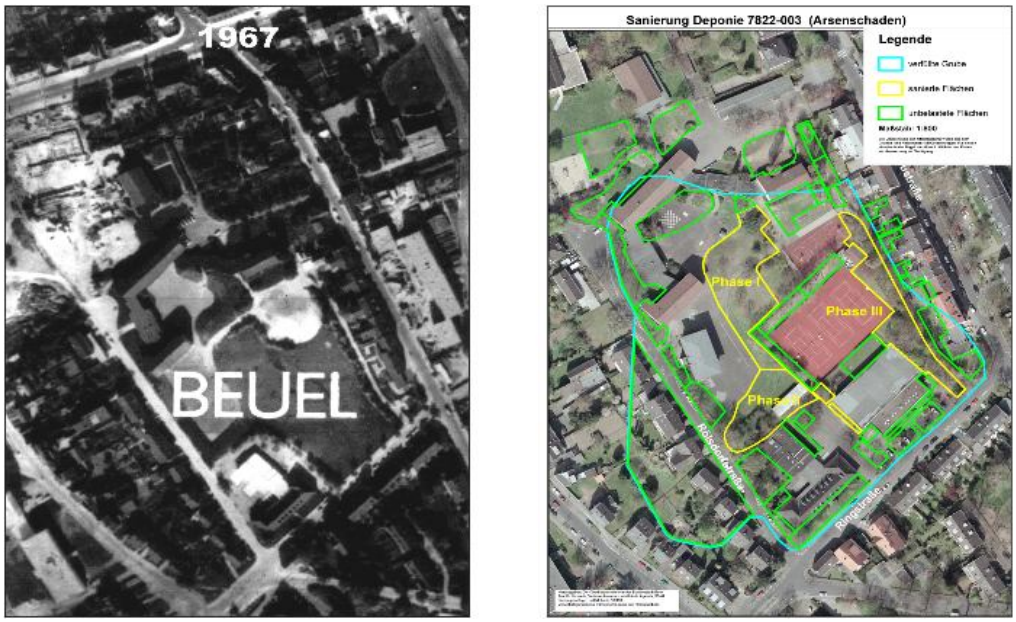
b. 地基研究，判定汙染程度。

c. 拆除現有建築，重新填土(圖附錄 1-7)。

d. 專業廢土處理。

e. 還原現場，重鋪土地與重建建築(圖附錄 1-8)。

由此可知，波昂市(Bonn)對於市內環保有多用心。



圖附錄 1-6、空照圖與衛生層級分類圖

圖附錄 1-7、拆除、填土

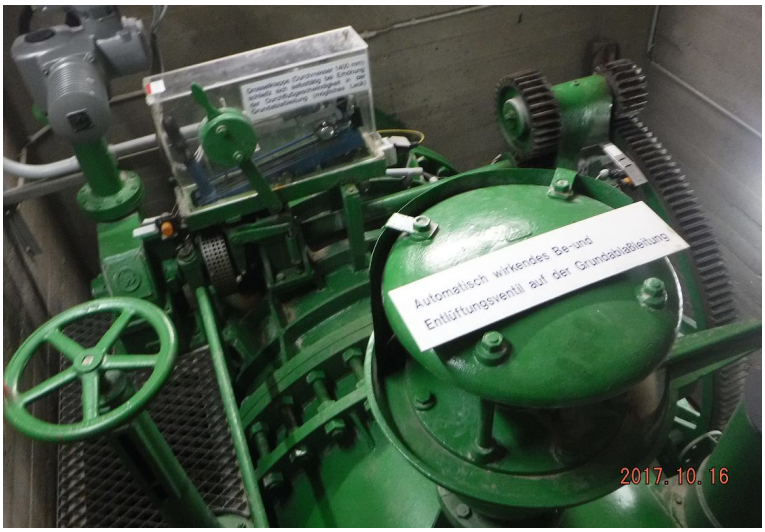
圖附錄 1-8、建造完工

附錄 2

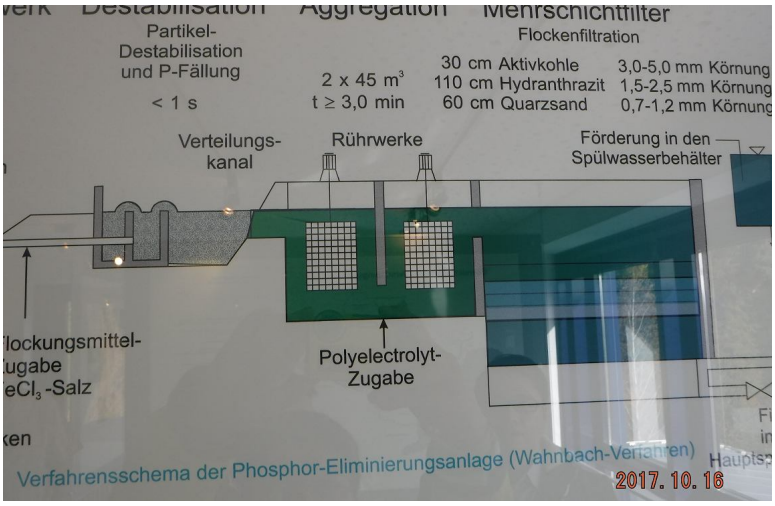
波昂市淨水廠的水淨化處理過程

波昂市淨水廠位於距離波昂市區大約 35 分鐘的水源保護區，淨水廠周遭果然如詩如畫(圖附錄 2-1)，也看到水淨化處理的過程，因為波昂水源保護區的水，含礦物質比較多，都屬於硬水，但是波昂淨水廠人員跟我們說，可以放心的飲用自來水，因為自來水的衛生標準與市售的瓶裝水是一樣的，所以不需要花錢去買瓶裝水。也看到了與人一般高的逆止閥，壩體及管路破損的防禦機制(圖附錄 2-2)。這邊因為土壤中磷含量特別高，所以他們有組裝出一台可以讓水中磷含量下降的機台，目前已經升級到第二代，也在淨化處理製程中，特別針對水中磷含量來處理，圖附錄 2-3 為讓水中磷含量下降機制的示意圖，圖附錄 2-4 為可運作之小型機台模型，可視為整個淨水廠設備之縮小版示意圖。參觀途中也有談到除菌的技術，淨水廠除菌的方法並非採用「臭氧」除菌或「紫外光」除菌，而是使用「次氯酸鈉」，惟次氯酸鈉本質不穩定且具爆炸性，所以使用時要特別注意。

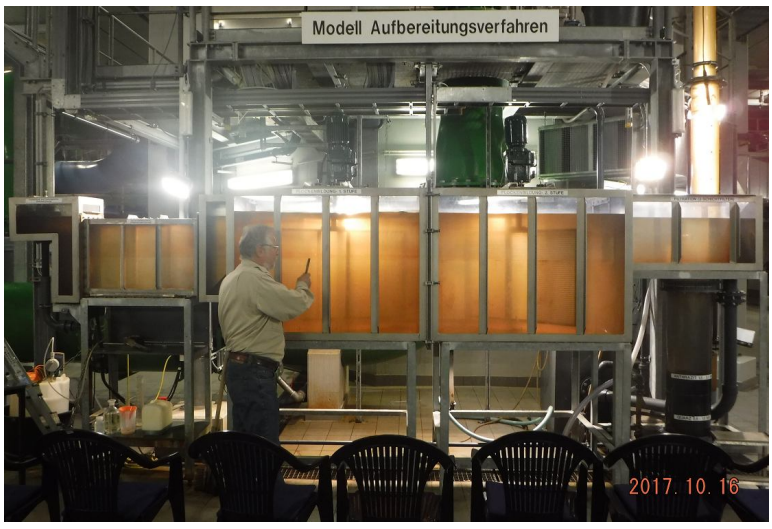
圖附錄 2-1、波昂市(Bonn)水資源保護區



圖附錄 2-2、管路破損的防禦機制



圖附錄 2-3、讓水中磷含量下降的機制



圖附錄 2-4、讓水中磷含量下降的機台模型

附錄 3

4MS 規定之金屬材質正面表列

ACCEPTANCE OF METALLIC MATERIALS USED FOR PRODUCTS IN CONTACT WITH DRINKING WATER

4MS Common Approach

Part A – Procedure for the acceptance

Part B – 4MS Common Composition List

Adopted by the 4MS Joint Management Committee

7th Revision:

05th January 2017

France, Germany, the Netherlands and the United Kingdom (4MS) work together in the framework of the 4MS Common Approach as laid down in the Declaration of Intent (January 2011). This common approach aims for convergence of the respective national approval schemes for materials and products in contact with drinking water.

The 4MS have adopted Part A of this document as a common basis for implementing the concept of accepting metallic materials in their national regulations. The document is subject to revisions agreed by the 4MS.

Part B of this document includes a Composition List of metallic materials accepted in all of the 4MS following the procedure described in Part A.

Further information may be obtained from any of the competent authorities of the 4MS.

Bundesministerium für Gesundheit (Deutschland)

Ministère du Travail, de l'Emploi et de la Santé (France)

Ministerie van Infrastructuur en Milieu (Nederland)

Department for Environment, Food and Rural Affairs (United Kingdom)

Part B – 4MS Common Composition List

Table of contents

1 Introduction

Awaiting a European acceptance scheme the 4 MS co-operate concerning the convergence of their national acceptance schemes for products in contact with drinking water. The national implementation of the procedure for the acceptance of metallic materials described in Part A allows the compilation of a common Composition List for metallic materials that are accepted in all 4 MS.

Metallic materials on this common Composition List can be used for products in contact with drinking water. For the acceptance of products made of metallic materials the composition of the metallic materials have to be check for compliance with the listed materials. Further product specific tests (e.g. nickel release from chromium plated taps) for the acceptance are under consideration in some of the 4MS.

2 Compilation of a common Composition List

For the inclusion of a material onto the common Composition List the material has to be tested according to the procedure in Part A.

The primary responsibility for assessment of materials will remain at the national level making use of established processes and the expert resources available there. Thus a manufacturer may approach a national regulatory body (or its appointed agencies) for evaluation of a new material. There are obvious practical advantages for a manufacturer in the 4MS countries to work with his "home" assessment body, but he would not be required to do so. Applicants from outside the 4MS area would be free to use any of the national arrangements.

The national arrangements will continue to operate largely as at present, but instead of producing findings and recommendations for local decision, will create assessment information and proposals in a common form (Opinions). These draft opinions will be reviewed by the appropriate bodies within each of the other MS, who will offer their comments. The aim will be to achieve agreement on where and how a material is listed and on any restrictions or other information that should be included in the listing.

3 Structure of the Composition List (see Part A 3.2)

The Composition List contains different categories of metallic materials.

A Category is defined as:

> a group of materials with the same characteristics in respect of their field of application, behaviour in contact with drinking water and restrictions with regard to water composition and/or surface area.

The Composition List contains the categories' range of compositions. A material falling within a category has to be tested individually for its acceptance on the list.

Each category has one reference material.

A Reference Material is defined as:

a material falling within a category for which the characteristics of metal release into drinking water are known and reproducible, the composition is strictly controlled and the elements of interest will be at or near the upper limit of acceptability. Possible effects of some constituents to inhibit the metal release have to be taken into account.

Under each category commercially available metallic materials accepted for use in PDW will be listed. The materials may only be used for certain products due to the restrictions with respect to the surface area (Table 1).

Table 1: Product groups for metallic materials

Product Group	Examples of products or parts of products	Assumed contact surface "a"
A	Pipes in buildings installation Uncoated pipelines in water supply systems	100%
B	Fittings, ancillaries in buildings installations (e.g. pump bodies, valve bodies, water meter bodies used in buildings installations)	10%
C	1. Components of products of product group B (e.g. the spindle of a pump or the moving parts in water meter in building installations). The sum of the surfaces in contact with drinking water of all these components has to be less than 10% of the total wetted surface of the product. 2. Fittings, ancillaries in water mains and water treatment works with permanent flow (e.g. pumps bodies, valves bodies used in water supply systems)	1%
D	Components of fittings and ancillaries in water mains in water treatment works (C2)	

4MS Composition List of accepted metallic materials

I Copper alloys

1 Copper-zinc alloys

1.1 Category

Constituents (% (m/m)):

Cu	Zn
≥ 57.0%	Remainder

Impurities (% (m/m)):

Al	Fe	Ni	Pb	Sn
≤ 0.1%	≤ 0.5%	≤ 0.2%	≤ 0.2%	≤ 0.5%

Each other impurity < 0.02%

1.2 Reference Material

Constituents (% (m/m)):

Cu	Zn
57.0% - 59.0%	Remainder

Impurities (% (m/m)):

Al	Fe	Ni	Pb	Sn
≤ 0.05%	≤ 0.3%	0.15% - 0.25%	0.15% - 0.25%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Cu, Ni, Pb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

1.3 Accepted Alloys

1.3.1

Notation	Product groups
CW509L* (CuZn40)	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn
59.5% - 61.5%	Remainder

Impurities (% (m/m)):

Al	Fe	Ni*	Pb*	Sn
≤ 0.05%	≤ 0.2%	≤ 0.2%	≤ 0.2%	≤ 0.2%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (23 Nov 2011)
UBA opinion (25 March 2013)

1.3.2

Notation	Product Group
CW510L* (CuZn42)	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn
57.0% - 59.0%	Remainder

Impurities (% (m/m)):

Al	Fe	Ni*	Pb	Sn
≤ 0.05%	≤ 0.3%	≤ 0.2%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (23 Nov 2011)
UBA opinion (25 March 2013)

1.3.3

Notation	Product Group
CW501L-DW* (CuZn10)	C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn
89.0% - 91.0%	Remainder

Impurities (% (m/m)):

Fe	Ni*	Pb	Sn
≤ 0.05%	≤ 0.2%	≤ 0.05%	≤ 0.1%

Each other impurity < 0.02%

1.3.4

Notation	Product Group
CW506L-DW* (CuZn33)	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn
66.0% - 68.0%	Remainder

Impurities (% (m/m)):

Fe	Ni*	Pb	Sn
≤ 0.05%	≤ 0.2%	≤ 0.05%	≤ 0.1%

Each other impurity < 0.02%

1.3.5

Notation	Product Group
CW507L-DW* (CuZn36)	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn
63.5% - 65.5%	Remainder

Impurities (% (m/m)):

Fe	Ni*	Pb	Sn
≤ 0.05%	≤ 0.2%	≤ 0.1%	≤ 0.1%

Each other impurity < 0.02%

1.3.6

Notation	Product Group
CW508L-DW* (CuZn37)	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn
62.0% - 64.0%	Remainder

Impurities (% (m/m)):

Al	Fe	Ni*	Pb	Sn
≤ 0.05%	≤ 0.1%	≤ 0.2%	≤ 0.1%	≤ 0.1%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (13 March 2016)

2 Copper-zinc-aluminum alloys

2.1 Category

Constituents (% (m/m)):

Cu	Zn	Al
≥ 57.0%	Rem.	0.1% - 0.3%

Impurities (% (m/m)):

Fe	Pb	Sn
≤ 0.3%	≤ 0.2%	≤ 0.3%

2.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	Al
57.0% - 59.0%	Rem.	0.1% - 0.2%

Impurities (% (m/m)):

Fe	Pb	Sn
≤ 0.3%	0.15% - 0.25%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Al, Cu, Pb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

2.3 Accepted Alloys

2.3.1

Notation	Product groups
CuZn42Al	B und C

Constituents (% (m/m))

Cu	Zn	Al
57.0% - 59.0%	Rem.	0.1% - 0.3%

Impurities (% (m/m))

Fe	Pb	Sn
≤ 0.3%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (16 March 2015)

3 Copper-zinc-arsenic alloys

3.1 Category

Constituents (% (m/m)):

Cu	Zn	As
≥ 61.0%	Reminder	0.02% - 0.15%

Impurities (% (m/m)):

Al	Fe	Mn	Ni	Pb	Sn
≤ 0.1%	≤ 0.5%	≤ 0.1%	≤ 0.3%	≤ 0.2%	≤ 0.5%

Each other impurity < 0.02%

3.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	As
61.5% - 63.5%	Remainder	0.10% - 0.15 %

Impurities (% (m/m)):

Al	Fe	Mn	Ni	Pb	Sn
≤ 0.1%	≤ 0.1%	≤ 0.1%	0.21% - 0.35%	0.15% - 0.25%	≤ 0.1%

Each other impurity < 0.02%

Elements for consideration in the migration water:
As, Cu, Ni, Pb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

3.3 Accepted Alloys

3.3.1

Notation	Product groups
CW511L (CuZn38As)	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn	As
61.5% - 63.5%	Remainder	0.02% - 0.15%

Impurities (% (m/m)):

Al	Fe	Mn	Ni	Pb	Sn
≤ 0.05%	≤ 0.1%	≤ 0.1%	≤ 0.3%	≤ 0.2%	≤ 0.1%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (28 March 2013)

4 Copper-zinc-arsenic-aluminium alloys

4.1 Category

Constituents (% (m/m)):

Cu	Zn	As	Al
≥ 61.0%	Remainder	0.02% - 0.15%	0.2% - 1.0%

Impurities (% (m/m)):

Fe	Mn	Pb	Sn
≤ 0.5%	≤ 0.1%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

4.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	As	Al
63.0% - 64.5%	Remainder	0.11% - 0.14%	0.2% - 0,4%

Impurities (% (m/m)):

Fe	Mn	Pb	Sn
≤ 0.3%	≤ 0.1%	0.15% - 0.25%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Al, As, Cu, Pb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

4.3 Accepted Alloys

4.3.1

Notation	Product groups
CuZn35Al-C	B and C

Constituents (% (m/m)):

Cu	Zn	As	Al
63.0% - 64.5%	Remainder	0.04% - 0.14%	0.2% - 0.7%

Impurities (% (m/m)):

Fe	Mn	Pb	Sn
≤ 0.3%	≤ 0.1%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA-opinion (29 July 2014)

5. Copper-zinc-arsenic-antimony-aluminum alloys

5.1 Category

Constituents (% (m/m)):

Cu	Zn	As	Sb	Al
≥ 60.0%	Rem.	0.02% - 0.10%	0.02% - 0.10%	0.02% - 1.0%

Impurities (% (m/m)):

Fe	Mn	Ni	Pb	Sn
≤ 0.5%	≤ 0.1%	≤ 0.2%	≤ 0.2%	≤ 0.5%

5.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	As	Sb	Al
62.0% - 65.0%	Rem.	0.03% - 0.04%	0.04% - 0.05%	0.45% - 0.58%

Impurities (% (m/m)):

Fe	Mn	Ni	Pb	Sn
≤ 0.2%	≤ 0.1%	0.12% - 0.20%	0.15% - 0.25%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Al, As, Cu, Ni, Pb, Sb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

5.3 Accepted Alloys

5.3.1

Notation	Product groups
CC771S (CuZn38AsSb)	B and C

Constituents (% (m/m))

Cu	Zn	As	Sb	Al
62.0% - 65.0%	Rem.	0.02% - 0.04%	0.02% - 0.05%	0.45% - 0,7%

Impurities (% (m/m))

Fe	Mn	Ni	Pb	Sn
≤ 0.2%	≤ 0.1%	≤ 0.20%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (10 July 2015)

6 Copper-zinc-lead alloys

6.1 Category

Constituents (% (m/m)):

Cu	Zn	Pb
≥ 57.0%	Remainder	0.2% - 3.5%

Impurities (% (m/m)):

Al	Fe	Ni	Si	Sn
≤ 0.3%	≤ 0.5%	≤ 0.2%	≤ 0.2%	≤ 0.5%

Each other impurity < 0.02%

6.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	Pb
57.0% - 59.0%	Remainder	1.9% - 2.2%

Impurities (% (m/m)):

Al	Fe	Ni	Si	Sn
≤ 0.2%	≤ 0.3%	0.05% - 0.15%	≤ 0.03%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Cu, Ni, Pb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

6.3 Accepted Alloys

6.3.1

Notation	Product groups
CW617N* (CuZn40Pb2) **CW612N* (CuZn39Pb2)**	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn	Pb*
57.0% - 60.0%	Remainder	1.6% - 2.2%

Impurities (% (m/m)):

Al	Fe	Ni*	Si	Sn
≤ 0.05%	≤ 0.3%	≤ 0.1%	≤ 0.03%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
German Co-normative Research Report RG_CPDW_01_074
Dossier John Nuttall (March 2006)

6.3.2

Notation	Product groups
CW614N* (CuZn39Pb3) **CW603N* (CuZn36Pb3)**	C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn	Pb
57.0% - 62.0%	Remainder	2.5% - 3.5%

Impurities (% (m/m)):

Al	Fe	Ni	Si	Sn
≤ 0.05%	≤ 0.3%	≤ 0.2%	≤ 0.03%	≤ 0.3%

Each other impurity < 0,02%

Basis for acceptance
German Co-normative Research Report RG_CPDW_01_074
Dossier John Nuttall (March 2006)

7 Copper-zinc-lead-aluminium alloys

7.1 Category

Constituents (% (m/m)):

Cu	Zn	Pb	Al
≥ 57.0%	Remainder	0.2% - 1.5%	0.2% - 1.0%

Impurities (% (m/m)):

Fe	Mn	Ni	Si	Sn
≤ 0.5%	≤ 0.05%	≤ 0.2%	≤ 0.05%	≤ 0.5%

Each other impurity < 0.02%

7.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	Pb	Al
58.0% - 63.0%	Remainder	1.2% - 1.4%	0.3% - 0.6%

Impurities (% (m/m)):

Fe	Mn	Ni	Si	Sn
≤ 0.3%	≤ 0.05%	0.15% - 0.25%	≤ 0.05%	≤ 0.5%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Al, Cu, Ni, Pb, Zn

Most critical test waters:
Test water 1 and 2 according to EN 15664-2

7.3 Accepted Alloys

7.3.1

Notation	Product groups
CC757S*(CuZn39Pb1Al-C)	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn	Pb*	Al
58.0% - 63.0%	Remainder	0.2% - 1.4%	0.3% - 0.9%

Impurities (% (m/m)):

Fe	Mn	Ni	Si	Sn
≤ 0.3%	≤ 0.05%	≤ 0.2%	≤ 0.05%	≤ 0.5%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (29 Aug 2014)

8 Copper-zinc-lead-arsenic-aluminium alloys

8.1 Category

Constituents (% (m/m)):

Cu	Zn	Pb	As	Al
≥ 61.0%	Remainder	0.2% - 2.2%	0.02% - 0.15%	0.02% - 1.0%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.5%	≤ 0.1%	≤ 0.2%	≤ 0.5%

Each other impurity < 0.02%

8.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	Pb	As	Al
61.0% - 63.0%	Remainder	1.4% - 1.6%	0.09% - 0.13%	0.5% - 0.7%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.3%	≤ 0.1%	0.15% - 0.25%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Al, As, Cu, Ni, Pb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

8.3 Accepted Alloys

8.3.1

Notation	Product groups
CC770S (CuZn36Pb-C)	B and C

Constituents (% (m/m)):

Cu	Zn	Pb	As	Al
62.0% - 64.0%	Remainder	0.2% - 1.6%	0.04% - 0.14%	0.5% - 0.7%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.3%	≤ 0.1%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (29 Jan 2014)

8.3.2

Notation	Product groups
CW626N (CuZn33Pb1.5AlAs)	B and C

Constituents (% (m/m)):

Cu	Zn	Pb	As	Al
64.0% - 66.0%	Remainder	1.2% - 1.7%	0.02% - 0.15%	0.8% - 1.0%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.3%	≤ 0.1%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (02 April 2013)

8.3.3

Notation	Product groups
CW625N (CuZn35Pb1.5AlAs)	B and C

Constituents (% (m/m)):

Cu	Zn	Pb	As	Al
62.0% - 64.0%	Remainder	1.2% - 1.6%	0.02% - 0.15%	0.5% - 0.7%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.3%	≤ 0.1%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (29 Jan 2014)

9 Copper-zinc-lead-arsenic-antimony-aluminum alloys

9.1 Category

Constituents (% (m/m)):

Cu	Zn	Pb	As	Sb	Al
≥ 60.0%	Rem.	0.2% - 1.1 %	0.02% - 0.10%	0.02% - 0.10%	0.02% - 1.0%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.5%	≤ 0.1%	≤ 0.2%	≤ 0.5%

9.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	Pb	As	Sb	Al
62.0% - 65.0%	Rem.	0.9% - 1.1%	0.03% - 0.04%	0.05% - 0.06%	0.45% - 0.58%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.2%	≤ 0.1%	0.15% - 0.25%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Al, As, Cu, Ni, Pb, Sb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

9.3 Accepted Alloys

9.3.1

Notation	Product groups
CC772S (CuZn36Pb1.5AsSbAl)	B and C

Constituents (% (m/m))

Cu	Zn	Pb	As	Sb	Al
62.0% - 65.0%	Rem.	0.2% - 1.1%	0.02% - 0.04%	0.03% - 0.06%	0.45% - 0,7%

Impurities (% (m/m))

Fe	Mn	Ni	Sn
≤ 0.2%	≤ 0.1%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (29 Aug 2014)

10 Copper-zinc-lead-arsenic-aluminium-silicon alloys

10.1 Category

Constituents (% (m/m)):

Cu	Zn	Pb	As	Al	Si
≥ 61.0%	Remainder	0.2% - 1.0%	0.02% - 0.10%	0.02% - 1.0%	0.02% - 0.5%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.5%	≤ 0.1%	≤ 0.2%	≤ 0.5%

Each other impurity < 0.02%

10.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	Pb	As	Al	Si
64.0% - 67.0%	Remainder	0.60% - 0.65%	0.07% - 0.08%	0.1% - 0.25%	0.1% - 0.2%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.3%	≤ 0.1%	0.15% - 0.25%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Al, As, Cu, Ni, Pb, Zn

Most critical test water:
Test water 1 and 2 according to EN 15664-2

10.3 Accepted Alloys

10.3.1

Notation	Product groups
CW725R*(CuZn33Pb1AlSiAs)	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Zn	Pb*	As	Al	Si
64.0% - 67.0%	Remainder	0.4% - 0.6%	0.04% - 0.08%	0.1% - 0.4%	0.1% - 0.3%

Impurities (% (m/m)):

Fe	Mn	Ni	Sn
≤ 0.3%	≤ 0.1%	≤ 0.2%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (27 July 2014)

11 Copper-tin-zinc-lead-nickel alloys

11.1 Category

Constituents (% (m/m)):

Cu	Sn	Zn	Pb	Ni
Remainder	4.0% - 13.0%	4.0% - 6.5%	0.2% - 3.0%	0.1% - 0.6%

Impurities (% (m/m)):

Fe	P	S	Sb
≤ 0.30%	≤ 0.04%	≤ 0.04%	≤ 0.10%

Each other impurity < 0.02%

11.2 Reference Material

Constituents (% (m/m)):

Cu	Sn	Zn	Pb	Ni
Remainder	4.0% - 4.2%	5.7% - 6.0%	2.8% - 3.0%	0.5% - 0.6%

Impurities (% (m/m)):

Fe	P	S	Sb
≤ 0.30%	≤ 0.04%	≤ 0.04%	0.09% - 0,15%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Cu, Ni, Pb, Sb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

11.3 Accepted Alloys

11.3.1

Notation	Product groups
CC499K* (CuSn5Zn5Pb2-C)	B and C

* Contents of certain elements are further restricted (see below)

Constituents (% (m/m)):

Cu	Sn	Zn	Pb*	Ni*
84.0% - 88.0%	4.0% - 6.0%	4.0% - 6.0%	0.2% - 3.0%	0.1% - 0.60%

Impurities (% (m/m)):

Fe	P	S	Sb
≤ 0.30%	≤ 0.04%	≤ 0.04%	≤ 0.10%

Each other impurity < 0.02%

Basis for acceptance
German Co-normative Research Report RG_CPDW_01_074
Dossier John Nuttall (March 2006)

12 Copper-zinc-silicon-phosphorous alloys

12.1 Category

Constituents (% (m/m)):

Cu	Zn	Si	P
60.0% - 80.0%	Remainder	0.5% - 5.5%	0.01% - 0.3%

Impurities (% (m/m)):

Al	Fe	Mn	Ni	Pb	Sn
≤ 0.1%	≤ 0.5%	≤ 0.05%	≤ 0.2%	≤ 0.1%	≤ 0.5%

Each other impurity < 0.02%

12.2 Reference Material

Constituents (% (m/m)):

Cu	Zn	Si	P
75.0% - 77.0%	Remainder	2.7% - 3.0%	0.02% - 0.06%

Impurities (% (m/m)):

Al	Fe	Mn	Ni	Pb	Sn
≤ 0.05%	≤ 0.3%	≤ 0.05%	0.15% - 0.25%	0.09% - 0.15%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Cu, Ni, Pb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

12.3 Accepted Alloys

12.3.1

Notation	Product groups
CW724R (CuZn21Si3P)	B and C

Constituents (% (m/m)):

Cu	Zn	Si	P
75.0% - 77.0%	Remainder	2.7% - 3.5%	0.02% - 0.10%

Impurities (% (m/m)):

Al	Fe	Mn	Ni	Pb	Sn
≤ 0.05%	≤ 0.3%	≤ 0.05%	≤ 0.2%	≤ 0.1%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (24 Feb 2012)

12.3.2

Notation	Product groups
CC768S (CuZn21Si3P)	B and C

Constituents (% (m/m)):

Cu	Zn	Si	P
75.0% - 77.0%	Remainder	2.7% - 3.5%	0.02% - 0.10%

Impurities (% (m/m)):

Al	Fe	Mn	Ni	Pb	Sn
≤ 0.05%	≤ 0.3%	≤ 0.05%	≤ 0.2%	≤ 0.1%	≤ 0.3%

Each other impurity < 0.02%

The content of boron and zirconium has to be less than 0.02%.

Basis for acceptance
UBA opinion (09 Jan 2014)

13 Copper-silicon-zinc-manganese-phosphorous alloys

13.1 Category

Constituents (% (m/m)):

Cu	Si	Zn	Mn	P
≥ 80.0%	0.5% - 5.5%	Remainder	0.01% – 0.2%	0.01% - 0.3%

Impurities (% (m/m)):

Al	Fe	Ni	Pb	Sn
≤ 0.3%	≤ 0.5%	≤ 0.1%	≤ 0.1%	≤ 0.5%

Each other impurity < 0.02%

13.2 Reference Material

Constituents (% (m/m)):

Cu	Si	Zn	Mn	P
Remainder	2.5% - 3.5%	8.0% - 10.0%	0.03% - 0.09%	0.05% - 0.10%

Impurities (% (m/m)):

Al	Fe	Ni	Pb	Sn
≤ 0.3%	≤ 0.3%	0.06% - 0.10%	0.06% - 0.10%	≤ 0.3%

Each other impurity < 0.02%

Elements for consideration in the migration water:
Cu, Mn, Ni, Pb, Zn

Most critical test water:
Test water 1 according to EN 15664-2

13.3 Accepted Alloys

13.3.1

Notation	Product groups
CC245E (CuSi4Zn4MnP-C)	B and C

Constituents (% (m/m)):

Cu	Si	Zn	Mn	P
Remainder	2.5% - 4.5%	1.0% -7.0%	0.03% - 0.09%	0.05% - 0.15%

Impurities (% (m/m)):

Al	Fe	Ni	Pb	Sn
≤ 0.3%	≤ 0.3%	≤ 0.10%	≤ 0.10%	≤ 0.3%

Each other impurity < 0.02%

13.3.2

Notation	Product groups
CC246E (CuSi4Zn9MnP-C)	B and C

Constituents (% (m/m)):

Cu	Si	Zn	Mn	P
Remainder	2.5% - 4.5%	7.0% - 11.0%	0.03% - 0.09%	0.05% - 0.15%

Impurities (% (m/m)):

Al	Fe	Ni	Pb	Sn
≤ 0.3%	≤ 0.3%	≤ 0.10%	≤ 0.10%	≤ 0.3%

Each other impurity < 0.02%

13.3.3

Notation	Product groups
CuSi4Zn4MnP	B and C

Constituents (% (m/m)):

Cu	Si	Zn	Mn	P
Remainder	2.5% - 4.5%	1.0% - 7.0%	0.01% - 0.09%	0.05% - 0.15%

Impurities (% (m/m)):

Al	Fe	Ni	Pb	Sn
≤ 0.3%	≤ 0.3%	≤ 0.10%	≤ 0.10%	≤ 0.3%

Each other impurity < 0.02%

13.3.4

Notation	Product groups
CuSi4Zn9MnP	B and C

Constituents (% (m/m)):

Cu	Si	Zn	Mn	P
Remainder	2.5% - 4.5%	7.0% - 11.0%	0.01% - 0.09%	0.05% - 0.15%

Impurities (% (m/m)):

Al	Fe	Ni	Pb	Sn
≤ 0.3%	≤ 0.3%	≤ 0.10%	≤ 0.10%	≤ 0.3%

Each other impurity < 0.02%

Basis for acceptance
UBA opinion (08 Jan 2016)

II Coppers

1 Copper

1.1 Category

Constituents (% (m/m)):

Cu	P
≥ 99.9%	≤ 0.04%

Impurities (% (m/m)):

Others total
≤ 0.1%

Each impurity < 0.02%

1.2 Reference Material

CW024A (CU-DHP)

Elements for consideration in the migration water:
None: No need for comparative testing

1.3 Accepted Alloys

Notation	Product groups
CW024A (Cu-DHP)	A -D

Constituents (% (m/m)):

Cu	P
≥ 99.9%	0.015% - 0.04%

Restrictions for the use of metallic materials with respect to water composition (health based)
The formation of the copper compounds on the surface of copper pipes and consequently the dissolution is strongly influenced by minor components of the water composition. In some water compositions, the rate of leaching of copper may be unacceptably high. Member States may need to offer guidance to the water industry and to suppliers and installers of copper pipe on restrictions that may need to be introduced on use of copper pipe in water compositions where excessive leaching of copper might occur.
Further research into the compatibility of copper with certain compositions of water needs to be carried out using harmonised procedures for investigation and evaluation.

Basis for acceptance
Research results and practical experience in several Member States are needed to characterise the conditions for safe use.

Note
The contamination of drinking water by copper pipes depends on several characteristics of water composition. There is no consensus view on their combined action and interaction at this time. In particular, there is inadequate information on the range of compositions of drinking water where non-compliance with the DWD is likely to occur.

2 Tinned copper pipes and tinned copper fittings

For tinned copper tubes and tinned copper fittings as base material copper according to 1 is used. On this substrate material a tin layer is deposited by different processes. By diffusion of copper ions into the tin layer the formation of an increasing intermetallic phase consisting of tin and copper (η-phase = Cu_6Sn_5) is formed.

2.1 Category

Constituents of the tin layer (% (m/m)):

Sn + Cu
≥ 99.90%

Impurities of the tin layer (% (m/m)):

As	Bi	Cd	Cr	Ni	Pb	Sb
≤ 0.01%	≤ 0.01%	≤ 0.01%	≤ 0.01%	≤ 0.01%	≤ 0.01%	≤ 0.01%

2.2 Reference Material

CW024A (CU-DHP)

2.3 Accepted Alloys

Notation	Product groups
CW024A (Cu-DHP) with a tin layer thickness of 1 µm	A-D

Constituents of the tin layer (% (m/m)):

Sn	Cu
> 90%	< 10%

Impurities of the tin layer (% (m/m)):

As	Bi	Cd	Cr	Ni	Pb	Sb
≤ 0.01%	≤ 0.01%	≤ 0.01%	≤ 0.01%	≤ 0.01%	≤ 0.01%	≤ 0.01%

Basis for acceptance

1. Leaching tests:
   a. Rig tests in representative German drinking waters, published: A. Baukloh, S. Priggemeyer, U. Reiter, B. Winkler, Chemically inner tinned Copper Pipes, Less Copper in Corrosive Drinking Waters, Metall 10-11 (1998) 592 - 600.
   b. Rig tests according to DIN 50931 (rig test): Technical report DVGW/TZW, 2000
2. Already existing approvals without restrictions in drinking waters
   a. Netherlands: according to BRL-K19005,
   b. Germany: according to DIN 50930, T6 and DVGW GW 392
   c. Denmark, ETA

III Steel / Iron

1 Galvanised steel

1.1 Category

Constituents of the zinc coating (% (m/m)):

Zn

Impurities of the zinc coating (% (m/m)):

As	Bi	Cd	Cr	Pb	Sb
≤ 0.02%	≤ 0.01%	≤ 0.01%	≤ 0.02%	≤ 0.05%	≤ 0.01%

1.2 Reference Material

Not required

1.3 Accepted Alloys

Notation	Product groups
Galvanised steel	A-D

Constituents of the zinc coating (% (m/m)):

Zn

Impurities of the zinc coating (% (m/m)):

As	Bi	Cd	Cr	Pb	Sb
≤ 0.02%	≤ 0.01%	≤ 0.01%	≤ 0.02%	≤ 0.05%	≤ 0.01%

Guidance on restrictions for the use of metallic materials with respect to water composition

The following formula is proposed as a means identifying water compositions where corrosion rates for galvanised steel is acceptable.

	pH ≥ 7.5 or free CO_2 ≤ 0.25 mmol/L
AND	Alkalinity ≥ 1.5 mmol/L
AND	S_1 < 2 (*definition of S_1 below*)
AND	Calcium ≥ 0.5 mmol/L
AND	Conductivity ≤ 600 µS/cm at 25°C
AND	S_2 <1 or S_2>3 (*definition of S_2 below*)

$$S_1 = \frac{c(Cl^-) + c(NO_3^-) + 2\,c(SO_4^{2-})}{c(HCO_3^-)}$$ concentrations in mmol/l

$$S_2 = \frac{c(Cl^-) + 2\,c(SO_4^{2-})}{c(NO_3^-)}$$ concentrations in mmol/l

Basis for acceptance

There are regulations with respect to water composition in France (DTU 60.1 / NF P 40-201) and in Germany (DIN 50930-3). These limits are based on practical experience but are expressed in different ways. The proposal covers mainly the same water compositions as both regulations. The proposal takes into account available results from research in Germany and co-normative research.
The proposal incorporates also the recommendations given EN 12502-3 with regard to the risk of localised corrosion. This localised corrosion frequently leads to deterioration in water quality as a result of corrosion products of iron.

The proposal is based on results that have been obtained with galvanised steel pipes with lead concentrations between 1.0% and 0.6% in the zinc layer, assuming a similar behaviour of pipes with lower lead concentrations.

2 Carbon steel

Carbon Steel for pipes and tanks

Carbon steel without permanent protective layers is not suitable for use in contact with drinking water.

Carbon Steel for ancillaries

Unprotected carbon steel can be used for specific applications (e.g. pumps, valves) and only for small surface in contact with water.

2.1 Category

Constituents (% (m/m)):

Fe	C	Cr	Mo	Ni
	≤ 2.11%	≤ 1.0%	≤ 1.0%	≤ 0.5%

Impurities (% (m/m)):

As	Cd	Pb	Sb
≤ 0.02%	≤ 0.02%	≤ 0.02%	≤ 0.02%

2.2 Reference Material

Not required

2.3 Accepted Alloys

Notation	Product groups
Carbon Steel	C2

Constituents (% (m/m)):

Fe	C	Cr	Mo	Ni
	≤ 2.11%	≤ 1.0%	≤ 1.0%	≤ 0.5%

Impurities (% (m/m)):

As	Cd	Pb	Sb
≤ 0.02%	≤ 0.02%	≤ 0.02%	≤ 0.02%

Basis for acceptance
Draft Italian Regulation
Calculation of possible impact on DW

3 Cast iron

Cast iron for pipes and tanks

Cast iron without permanent protective layers is not suitable for pipes and fittings in contact with drinking water.

Cast iron for ancillaries

Unprotected cast iron can be used for specific applications (e.g. pumps, valves) and only for very small surface in contact with water. Their composition needs to be regulated.

3.1 Category

Constituents (% (m/m)):

Fe	C	Cr	Mo	Ni
		≤ 1.0%	≤ 1.0%	≤ 6.0%

Impurities (% (m/m)):

As	Cd	Pb	Sb
≤ 0.02%	≤ 0.02%	≤ 0.02%	≤ 0.02%

2.2 Reference Material

Not required

2.3 Accepted Alloys

Notation	Product groups
Cast Iron	C2

Constituents (% (m/m)):

Fe	C	Cr	Mo	Ni
		≤ 1.0%	≤ 1.0%	≤ 6.0%

Impurities (% (m/m)):

As	Cd	Pb	Sb
≤ 0.02%	≤ 0.02%	≤ 0.02%	≤ 0.02%

Basis for acceptance
Draft Italian Regulation
French regulation
Calculation of possible impact on DW

4 Stainless steel

Stainless steels according to EN 10088 and EN 10283 can be applied for all product groups (A-D)

Restrictions:

Some stainless steels show a higher probability of occurrence of local corrosion (e.g. pitting or crevice corrosion) caused by the contact with certain drinking waters or in case of disinfection with high chlorine concentrations. For this purpose EN 16056 can be used to compare the passivity behaviour of the different stainless steel grades.

IV Platings

1 Tin plating applied by a galvanic process on the external surface

Components made of CW617N and CW612N (corresponding 4MS Composition List: I Copper alloys / 6.3.1) can be plated galvanically with a layer composition of copper and tin.

Restrictions:

- Bulk material CW617N and CW612N (corresponding 4MS Composition List: I Copper alloys / 6.3.1)
- Layer composition: 1.) Cu 2.) Sn
- applied process: galvanic tin plating
- Purity of the used anodes: ≥ 99,90 %

Additional requirement:

For the respective production process it has to be proven that the manufactured products are not contaminated with organic substances used in the galvanic process baths. This can be demonstrated by a migration test according to EN 12873-1. The evidence can be provided in the course of an approval/certification process of respective plated products. In this process a test of the metal release is not required. Additionally, a quality assurance scheme for the production process is required. In UK additional product tests might be necessary.

V Passive materials and copper alloys for product group D

In addition to the materials listed for the Product Groups A, B and C for components of the Product Group D further passive metallic materials and copper alloys can be used.

The copper alloys have to comply with:

- Cu, Zn, Si, Sn, P: no restrictions
- Al, Fe, Mn: max. 3.0% (m/m)
- Pb: max. 3.5% (m/m)
- Ni: max. 3.0% (m/m)
- As, Sb: max: 0.25% (m/m)
- All other: max. 0.1% (m/m)

附錄 4
4MS 規定用於與飲水接觸產品之有機材料正面表列清單

9 May 2017

4MS INITIATIVE
POSITIVE LISTS for ORGANIC MATERIALS
Used in Products in contact with Drinking Water

Introduction

An essential element of the regulatory arrangements for control of the hygienic performance of organic Products in contact with Drinking Water (PDW's) is the examination and approval of the substances used for the production of these products. The goal of the 4MS Initiative is to have a Positive List of substances that are permitted for the production of organic materials, which is accepted by all MS's. This is in addition to the substances authorized for use in food contact materials (FCM) according to Regulation (EU) No. 10/2011, as these are included as permissible for use in PDW's.

Candidate substances for this Positive List (the "Core List") are the substances on the existing national Positive Lists in use in France, Germany and the Netherlands, and which had been collated earlier in the "Combined List". The substances on the Combined List can only be transferred to the Core List after they have been reviewed, therefore the Combined List is the list of substances under review.

Core List (list of confirmed substances)

The 4MS Initiative has agreed procedures for the evaluation of organic substances in use in products in its report "Common Approach on Positive Lists for Organic Materials", published in December 2011, and revised in March 2016. The Common Approach sets out the process to be followed for the assessment and acceptance of substances. Substances approved by this procedure are included in the "Core List", which is the 4MS-Positive List of substances that can be used for the production of PDW's.

Substances from the Combined List which have been assessed according to the criteria for approval by one of the MS's, and for which the positive opinion was accepted by the other MS's, have been transferred now onto the Core List. The Core List therefore only contains confirmed substances. In addition, substances from the Combined List for which a favourable EFSA opinion was already available, or for which other adequate information was available, have also been transferred onto the Core List.

The first version of the Core List (list of confirmed substances) is now published, see Annex A.

Combined List (list of substances under review)

The first version of the Combined List was published in 2011. This was a compilation of substances that appeared on the national lists and which did not appear in the Union List of Regulation (EU) No. 10/2011 (referred to as: "FCM-List of 10/2011"). Pigments and colourants currently used in the MS's are not included in the Combined List. The Combined List is now updated and a revised version is now published, see Annex B.

The Combined List, as published in 2011, has been updated by the following actions:

- Substances have been removed from the List that are covered by Reg. EU 10/2011 (even though the name of the substance is not listed 'as such' in the FCM-List) and, therefore, they are already permitted for use in PDW.

This includes substances that are either individual substances that are covered by a group entry on the FCM-List, or they are salts (including double salts and acid salts) of acids, phenols or alcohols listed in the FCM-List, which according to Art.6 §3.a of Reg. (EU) 10/2011 are allowed, as far as these salts consist of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and/or zinc.

- Some substances have been removed from the List because they are not known to be used in certified PDW's, as checked by MS's. These 'obsolete' substances have been transferred to the '**Obsolete List**'.
- Substances for which a favourable EFSA opinion (excepted if the assessment was too old and that new toxicological endpoints have been suspected since the opinion), a positive '4MS opinion' or other adequate information to complete the assessment of this substance was already available, have been transferred to the Core List.
- New substances have been added to the Combined List, because they were added in one of the MS's to the national positive list after the first version of the Combined List was compiled, or they were inadvertently missing from this first version of the list.
- The substances have been classified according to the materials where they are commonly used. In due course deadline dates for submission of the dossier for substances will be added to annexes B and C based on material type. Dossiers can be submitted before deadline dates for any substance once information has been gathered and the 4MS will evaluate the dossier.

Obsolete List (list of obsolete substances)

Some substances from the Combined List that are not known to be used anymore in certified or approved PDW's, have been transferred onto the 'Obsolete List'. This List is found in Annex C. In situations where it appears that a substance has inadvertently been miss-classified as being 'obsolete', then this substance can be returned to the Combined List. Substances that are on the Obsolete List will eventually be deleted.

Actions required by Industry

Should Industry notice substances on the Obsolete List, which they still use in certified or approved products, Industry can inform the relevant MS, making reference to the certificate or approval. The substance will be returned to the Combined List.

For the substances on the Combined-List, Industry is asked to submit dossiers to provide data in accordance with the requirements as stated in the 4MS Common Approach on Positive List for Organic Materials, including relevant migration data into drinking water, to one of the 4MS's. The 4MS will provide the deadline dates for submission of dossiers for material types shortly.

Annex A - Core List (list of confirmed substances)

CORE LIST FOR ORGANIC MATERIALS COMING INTO CONTACT WITH DRINKING WATER - 9 MAY 2017

PM/REF No	CAS No	NAME	Use as additive or PPA	Use as monomer or other starting substance	Material	Technological function	MTC (mg/l)	MTC(T) [mg/l] (Group restriction No)	Restrictions and specification
-	-	monomers and other starting substances according to plastic regulation 10/2011		yes		monomer	1/20 SML		QM/QMA or other limits as in 10/2011
-	-	additives according to plastic regulation 10/2011	yes			additive	1/20 SML		QM/QMA or other limits as in 10/2011
-	-	polymeres according to PL's (i.e. all starting substances have to be listed in the PL's that apply to DWP), with a MW above 1000 Da	yes			polymeric additive	MTC's of all starting substances apply		QM/QMA or other limits as in 10/2011
-	-	amylose	yes		coatings	initiator			
37520	2634-33-5	1,2-benzisothiazol-3(2H)-one	yes		rubber, silicone	antifoaming, biocide in can preservation	0.025		no antimicrobial effects on the surface of the end product
-	7637-07-2	boron trifluoride	yes		plastics, rubber	catalyst		0.10 0.15	MTC(T) expressed as boron; MTC(T) expressed as fluoride
40430	109-63-7	boron trifluoride etherate	yes		plastics	catalyst		0.10 0.15	MTC(T) expressed as boron; MTC(T) expressed as fluoride
40594	75-65-0	tert-butanol	yes		coatings	solvent	0.5		
41200	7789-75-5	calcium fluoride	yes		plastics			0.15	MTC(T) expressed as fluoride
-	8007-24-7	cashew nut shell liquid, distilled (> 90% cardanol)	no	yes	coatings	hardener	0.0025		not for use as reactive diluent
14450/1	-	castor oil fatty acids, dehydrated							
14453	61790-39-4	castor oil fatty acids, hydrogenated		yes	coatings	monomer			
14505	9004-35-7	cellulose acetate		yes	coatings	monomer			
14512	9004-39-1	cellulose acetate propionate		yes	coatings	monomer			
43760	26172-55-4	5-chloro-2-methyl-2H-isothiazol-3-one	yes		coatings, silicone		0.0005		only to be used as in-can preservative; no antimicrobial effects on the surface of the end product
43730	55965-84-9	5-chloro-2-methyl-2H-isothiazol-3-one (CAS 26172-55-4) and 2-methyl-2H-isothiazol-3-one (CAS 2682-20-4), mixture (3:1)	yes		coatings	in can preservation			Restiction = 0.025 mg/dm²; only to be used as in-can preservative; no antimicrobial effects on the surface of the end product
-	21679-31-2	chromium(III)acetylacetonate	yes		plastics	adhesion		0.005	MTC(T) expressed as chromium
-	10025-73-7	chromium(III)chloride	yes		plastics	catalyst		0.005	MTC(T) expressed as chromium
-	11118-57-3	chromium oxide	yes		plastics	catalyst		0.005	MTC(T) expressed as chromium
-	7681-65-4	copper(I)iodide	yes					0.05 0.2	MTC(T) expressed as iodine MTC(T) expressed as copper
47060	110-05-4	di-tert-butyl peroxide		yes	plastics, rubber	crosslinker, aids to polymerization, vulcanisation agent	0.0001 0.5 0.015		peroxide tert-butanol methyl tert-butyl ether
66620	75-09-2	dichloromethane	yes		rubber, coatings	solvent			
48030	112-34-5	diethylene glycol monobutyl ether (DEGBE)	yes		coatings, silicone	solvent		0.15	MCT(T) for sum of (di)ethyleneglycol, monoalkyl (C1,C2,C4,C6) ethers and acetic acid, 2-ethoxyethyl ester
49160	127-19-5	dimethylacetamide	yes	no	plastics	solvent	0.0025		
56320	1323-83-7	distearic acid, diester with glycerol	yes		plastics				
53255	100-41-4	ethylbenzene	yes		coatings, silicone	solvent	0.03		
16993	111-76-2	ethyleneglycol monobutyl ether	yes	yes	coatings, silicone	solvent		0.15	MCT(T) for sum of (di)ethyleneglycol,monoalkyl (C1,C2,C4,C6) ethers and acetic acid, 2-ethoxyethyl ester
16999	112-25-4	ethyleneglycol monohexyl ether		yes	coatings	solvent		0.15	MCT(T) for sum of (di)ethyleneglycol,monoalkyl (C1,C2,C4,C6) ethers and acetic acid, 2-ethoxyethyl ester
17175	68938-15-8	fatty acids, coco hydrogenated		yes	coatings	monomer			

PM/REF No	CAS No	NAME	Use as additive or PPA	Use as monomer or other starting substance	Material	Technological function	MTC (mg/l)	MTC(T) [mg/l] (Group restriction No)	Restrictions and specification
18115/ 57520	31566-31-1	glycerol monostearate	yes	yes	rubber, coatings, silicone	processing aid/ additive			
59330	110-54-3	n-hexane (incl. structural isomers up to 40%; cyclohexane <3%)	yes	no		solvent	0.25		MTC does not need to be verified when process temperature > 100 °C
-	1333-74-0	hydrogen	yes		rubber	polymer modifier			
-	93685-81-5 (13475-82-6)	isododecane (main isomer: 2,2',4,6,6'-pentamethylheptane)	yes		plastics	phlegmatiser for organic peroxides	0.0025		
63240	8006-54-0	lanolin (pharmacopeia grade)	yes		coatings				
-	-	methacrylic acid, chromium (III) salt		yes	plastics	aids to polymerization, adhesion promoter for fillers		0.005 0.3	MTC(T) expressed as chromium, MTC(T) expressed as methacrylic acid
21827/66 655	78-93-3	methyl ethyl ketone	yes	yes	coatings, silicone	solvent	0.25		
66725	108-10-1	methyl isobutyl keton (4-methylpentan-2-one)	yes		coatings, silicone	solvent	0.25		
22190	2163-42-0	2-methylpropane-1,3-diol		yes	coatings	monomer	0.25		
-	7782-44-7	oxygen	yes	yes	plastics	catalyst			
23125	103-71-9	phenyl isocyanate		yes	coatings	monomer		ND (<0.0001)	QM= 1 mg/kg. QM and MTC(T) are both expressed as isocyanate moiety
23173	1314-56-3	phosphoric anhydride	yes	yes	coatings	monomer/ catalyst			
79550	9014-85-1	polyethyleneglycol-2,4,7,9-tetramethyl-5-decyn-4,7-diol ether	yes		coatings				Only to be used for sintered PTFE coatings
80160	37349-34-1	polyglyceryl-5 stearate	yes		coatings, silicone				
23680/81 280	9002-89-5	polyvinyl alcohol	yes	yes	plastics, rubber	emulsion polymerization aid, thickener, solvent			manufactured by sintering
-	12136-45-7	potassium oxide	yes		plastics	other additive			
24440	9000-59-3	shellac		yes	coatings	monomer			
-	7681-49-4	sodium fluoride	yes		plastics	antioxidant		0.15	MTC(T) expressed as fluor
-	1313-59-3	sodium oxide	yes						
-	-	stone wool (EC-No. 926-099-9)	yes	no	rubber	filler	-		Diameter > 1 µm (average diameter 5-30 µm)
-	7782-99-2	sulfurous acid	yes			additive			
93420	7646-78-8	tin(IV)chloride	yes		coatings				
93540	108-88-3	toluene			rubber, coatings, silicone	dispersive	0.06		the MTC is higher than the odour threshold
25573	16938-22-0	2,2,4-trimethylhexane-1,6 diisocyanate		yes	coatings	monomer		ND (<0.0001)	QM= 1 mg/kg. QM and MTC(T) are both expressed as isocyanate moiety
25574	15646-96-5	2,4,4-trimethylhexane-1,6-diisocyanate		yes		monomer		ND (<0.0001)	QM= 1 mg/kg. QM and MTC(T) are both expressed as isocyanate moiety
95870	-	wheat protein	yes						
26370	1330-20-7	xylene	yes		coatings, silicone	dispersive agent/solvent	0.05		the MTC is higher than the odour threshold
96180	-	zinc dust	yes		coatings	filler		0.25	MTC(T) expressed as zinc
96200	55799-16-1	zinc hydroxyphosphite	yes		coatings			0.25	MTC(T) expressed as zinc
96240	1314-13-2	zinc oxide	yes		rubber			0.25	MTC(T) expressed as zinc

Annex B - Combined List (list of substances under review)

COMBINED LIST FOR ORGANIC MATERIALS COMING INTO CONTACT WITH DRINKING WATER - 9 MAY 2017

PM/ REF No	CAS No	NAME	Use as additive or PPA	Use as monomer or other starting substance	Material	Technological function	MTC (mg/l)	MTC(T) [mg/l] (Group restriction No)	Restrictions and specification	Auth. MS	Deadline for submission of dossier
-	17501-44-9	acetyl acetonic acid, zirconium salt	yes		silicone	catalyst hardener			DE: [1]	DE	To be set
-	-	acrylic acid, esters with alcohols, monohydric, aliphatic, saturated, C1-C18		yes	coatings	monomer	0.3		MTC expressed as acrylic acid	NL	To be set
32920	-	adipic acid, esters with alcohols, monohydric, aliphatic, primary, saturated, (C6-C12)	yes	yes	plastics	plasticizer				NL	To be set
-	-	addition products of trivinylcyclohexane and alpha, omega-dihydrogen-polyhydrogenmethyldimethylsiloxanes	yes		silicone	monomer			DE: maximum quanities 10 % [1]	DE	To be set
-	-	alkadienes (C3-C8)		yes	coatings	monomer	ND		QM = 1 mg/kg in EP	NL	To be set
	-	alkoxysilanes with functional groups, e.g. vinyl, methacryl, amino or glycidyl groups,	yes		plastics	adhesion promoters for fillers			DE: max. 0.5 %, based on the filler, or max. 0.3 %, based on the plastic component	DE	To be set
-	-	alkylarylsulfonic acid	yes		plastics	emulgator			DE: max. 3%	DE	To be set
-	-	alkyl(C8-C18)dimethylbenzylammonium chloride	yes		lubricants					DE	To be set
-	-	alkyl(C8-C18)naphthalene sulfonates, sodium salts		yes	plastics	emulsifier		1.5	MTC(T) for the sum of sodium salts of alkyl(C8-C18)benzene sulfonates, alkyl(C8-C18)naphthalene sulfonates, alkyl(C8-C18)sulfates and alkyl(C8-C18)sulfonates	NL	To be set
-	-	alkyl(C1-C8)-silicic acid or orthosilicic acid with aliphatic monohydric alcohols (C2-C4) and the monomethyl ether of ethanediol (methylglycol) and their condensation products, esters of		yes	silicone	crosslinking agent			DE: max. use level 3 % [1]	DE	To be set
-	54326-11-3	aluminium hydroxide benzoate stearate		yes	lubricants	thickener					To be set
34800	-	amide of aliphatic carboxylic acids, C8-C22	yes		silicone	emulgator			DE: max. use level 1.5% [1]	DE	To be set
34960	-	3-aminocrotonic acid, esters with butyleneglycol	yes		coatings					FR	To be set
35040	-	3-aminocrotonic acid, esters with mono- or dihydric alcohols	yes		coatings					FR	To be set
-	1760-24-3	[3-(2-aminoethyl)aminopropyl]trimethoxysilane	yes	yes	plastics, coatings		0.0001			NL	To be set
-	-	aramid fiber	yes		rubber	filler-polymeric additive			DE: limited acceptance	DE	To be set
-	95-33-0	benzothiazyl-2-cyclohexylsulfenamide		yes	rubber	crosslinking agent			DE: limited acceptanceand additional requirements for S-cross-linking [2]	DE	To be set
-	4979-32-2	benzothiazyl-2-dicyclohexylsulfenamide		yes	rubber	crosslinking agent			DE:limited acceptance and additional requirements for S-cross-linking [2]	DE	To be set
-	-	benzoylperoxide		yes	silicone	aids to polymerization			DE: no peroxide on product surface [1]	DE	To be set
38600	78-63-7	2,5-bis(tert-butylperoxy)-2,5-dimethylhexane		yes	plastics, rubber, coatings	vulcanisation agent, aids to polymerization	0.0001		DE: no peroxide on product surface, limited acceptance	DE, FR, NL	To be set
38615 38625	25155-25-3 2212-81-9 2781-00-2	1,3-(and/or 1,4)-bis(tert-butylperoxyisopropyl)benzene		yes	plastics, rubber	vulcanisation agent, aids to polymerization	0.0001		DE: no peroxide on product surface, limited acceptance	DE, FR, NL	To be set
-	85-60-9	bis(2-methyl-4-hydroxy-5-tert-butylfenyl)butane	yes		rubber	antioxidant	0.015			NL	To be set
-	101-67-7	bis(4-octylphenyl)amine	yes		rubber	aging protection products	0.0025		DE: limited acceptanceand additional requirements for PAA and sec. amines [2]	DE, NL	To be set
-	39817-09-9	bisphenol-F-diglycidylether		yes	coatings	resin	0.0025 0.0025 0.0001 0.005		BFDGE and hydrolysis products Bisphenol F epichlorhydrine 3-monochloro-propane-1,2-diol	DE	To be set
-	7726-95-6	bromine		yes	rubber	monomer			DE: limited acceptance	DE	To be set
40640	98-29-3	4-tert-butylcatechol	yes		coatings, silicone					FR	To be set
-	3457-61-2	tert-butylcumylperoxide	yes		coatings, silicone	aid to polymerization			DE: no peroxide on the product surface [1]	DE, FR	To be set

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-	17540-75-9	4-sec-butyl-2,6-di-tert-butylphenol	yes		plastics, rubber	processing excipient, antioxidant			DE: limited acceptance	DE	To be set
-	88-18-6	2-tert-butylphenol		yes	plastics, coatings		0.0001			NL	To be set
-	25085-50-1	4-tert-butylphenol formaldehyde resin		yes	rubber	crosslinking agent	0.75 0.0025		formaldehyde 4-tert butylphenol; content of oligomers under 1000 Da 25%	DE	To be set
-	23847-08-4	caprolactamdisulfide	yes		rubber	accelerator		0.75	MTC as caprolactam DE:limited acceptance	DE	To be set
42240	-	carbon fibers	yes		rubber	filler			DE: [1]	DE, FR	To be set
14560	126-99-8	2-chloro-1,3-butadiene		yes	rubber	monomer	0.0001		DE: limited acceptance	DE	To be set
14877	2556-36-7	1,4-cyclohexanediisocyanate		yes	coatings	monomer		ND (<0.0001)	QM= 1 mg/kg. QM and MTC(T) are both expressed as isocyanate moiety	DE	To be set
-	-	cyclic organopolysiloxane with methylgroups, alone or n-alkyl (C2-C32)-group		yes	lubricants	basic oil			DE: [1]	DE	To be set
-	17796-82-6	N-(cyclohexylthio)phthalimide	yes		rubber	accelerator	NL: 0.15		DE: limited acceptance	DE, NL	To be set
13250	101-77-9	4,4'-diaminodiphenylmethane	yes	yes	coatings	monomer	0.0001			DE, FR, NL	To be set
-	9046-10-0	diaminopolypropylene glycol	yes		coatings	hardener	0.0025		MTC expressed as aminoethanol	NL	To be set
-	68953-84-4	N,N'-diaryl-p-phenylenediamine	yes		rubber		0.0001			NL	To be set
46440	94-36-0	dibenzoyl peroxide		yes	plastics, rubber, silicone	aids to polymerization, vulcanisation agent	0.0001		DE: no peroxide on product surface, limited acceptance	DE, FR, NL	To be set
47060	171090-93-0	3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionic acid, esters with linear or branched alcohols (C13-C15)	yes		rubber	antioxidant				DE	To be set
47060	110-05-4	di-tert-butyl peroxide		yes	rubber	aids to polymerization, vulcanisation agent	0.0001			NL	To be set
-	6731-36-8	1,1-di-tert-butylperoxy-3,3,5-trimethylcyclohexane	yes	yes	plastics, rubber	initiator, cross linking agents	0.0001		DE: no peroxide on the product surface, limited acceptance	DE, NL	To be set
-	96-76-4	2,4-di-tert-butylphenol	yes		rubber	processing excipient			DE: limited acceptance	DE	To be set
-	128-39-2	2,6-di-tert-butylphenol			rubber	processing excipient			DE: limited acceptance	DE	To be set
-	-	α,ω-dicarboxylic acids (C6-C12), aliphatic, unbranched		yes						NL	To be set
-	133-14-2	2,4-dichlorobenzoyl peroxide		yes	coatings, silicone	crosslinking agent	0.0001		DE: no peroxide on the product surface, limited acceptance [1]	DE, FR, NL	To be set
15580	1653-19-6	2,3-dichloro-1,3-butadiene		yes	rubber	monomer	0.0001		DE: limited acceptance	DE	To be set
-	80-43-3	dicumyl peroxide		yes	plastics, rubber	aids to polymerization, vulcanisation agent	0.0001		DE: no peroxide on the product surface, limited acceptance	DE, FR, NL	To be set
15730	77-73-6	dicyclopentadiene		yes	rubber	monomer	NL: 0.0025 DE: 0.0001		DE: limited acceptance	DE, NL	To be set
47520	-	dicyclopentadiene-indene-styrene-vinyl-toluene-isobutylene-copolymer, hydrogenated	yes		coatings	additive		2.5		DE	To be set
48050	111-90-0	diethyleneglycol monoethyl ether	yes		coatings	solvent		0.15	MTC(T) for the sum of all of glycolmonoalkylethers	DE	To be set
-	140-01-2	diethylenetriaminepentaacetic acid pentasodium salt	yes		plastics	dispersive agent				NL	To be set
-	1047-16-1	5,12-dihydroquino(2,3-b)acridine-7,14-dione	yes		plastics, coatings	pigment				NL	To be set
49225	124-40-3	dimethylamine	yes		rubber, coatings	monomer	0.003			DE, FR	To be set
49235	108-01-0	dimethylaminoethanol	yes		coatings		0.9			FR	To be set
-	7005-47-2	2-dimethylamino-2-methyl-1-propanol	yes		plastics					FR	To be set
-	-	di(4-methyl-benzoyl)peroxide		yes	rubber, silicone	vulcanisation agent, crosslinking agent			no peroxide on product surface, limited acceptance	DE	To be set

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-	53880-86-7	dimethyldiphenylthiuram disulfide		yes	rubber	crosslinking agent			DE: limited acceptance and additional requirements for S-cross-linking [2]	DE	To be set
-	115-10-6	dimethyl ether	yes		coatings	propellant	<0.001			DE	To be set
-	68-12-2	N,N-dimethylformamide	yes		plastics, coatings	solvent?	0.025			NL	To be set
-	70131-67-8	dimethylsiloxane, hydroxy terminated		yes	rubber, lubricants	basic oil			DE: [1]	DE	To be set
50080	3806-34-6	dioctadecyl pentaerythritol diphosphite	yes		plastics	stabilizer				FR, NL	To be set
-	122-39-4	diphenylamine	yes		plastics, rubber	catalyst			max. use level 0.1%	NL	To be set
-	68411-46-1	diphenylamine, octylated	yes		rubber	anti-ageing			DE: limited acceptance and additional requirements on primary aromatic amines and secondary amines [2]	DE	To be set
51500	102-06-7	N,N-diphenylguanidine		yes	rubber	crosslinking agent			DE: limited acceptance and additional requirement for S-cross-linking [2]	DE	To be set
-	120-78-5	dithiobis(2-benzothiazole) / dibenzothiazyldisulfide		yes	rubber	crosslinking agent		NL: 0.15	MTC(T) for the sum of dithiobis(2-benzothiazole), 2,2'-dibenzothiazyl disulfide, mercaptobenzothiazole, and 2-(4-morpholino)thiobenzothiazole DE: limited acceptanceand additional requirements for S-cross-linking [2]	DE, NL	To be set
16920	87057-87-2	2-ethylbutane-1,4-diisocyanate		yes	coatings	monomer		ND (<0.0001)	QM= 1 mg/kg. QM and MTC(T) are both expressed as isocyanate moiety	DE, FR	To be set
16996	110-80-5	ethyleneglycol monoethyl ether	yes	yes	coatings, silicone	monomer, solvent/diluter		0.15	MTC(T) for sum of (di)ethyleneglycol,monoalkyl (C1,C2,C4,C6) ethers and acetic acid, 2-ethoxyethyl ester	DE	To be set
17002	109-86-4	ethyleneglycol monomethyl ether	yes	yes	coatings	solvent/diluter		0.15	MCT(T) for sum of (di)ethyleneglycol,monoalkyl (C1,C2,C4,C6) ethers and acetic acid, 2-ethoxyethyl ester	DE	To be set
54120	149-57-5	2-ethylhexanoic acid	yes		plastics	stabilizer, lubricant	0.0025			DE, FR, NL	To be set
-	17689-77-9	ethyltriacetoxysilane		yes	silicone	crosslinking agent			DE: [1]	DE	To be set
-	28106-30-1	ethylvinylbenzene	yes		plastics			0.0001	MTC(T) for the sum of ethylvinylbenzene and divinylbenzene (FCM No. 405)	NL	To be set
-	78-27-3	ethynylcyclohexanol	yes		coatings, silicone	solvent			DE: [1]	DE, FR	To be set
-	-	fatty acids (unbranched, saturated and unsaturated, with an even number of carbon atoms, C8-C22, with a maximum content of 2% unsaponifiable matter), as compounds with bis(2-hydroxyethyl)amine	yes	yes	plastics	antistatic, lubricant	1.5			NL	To be set
-	-	fatty acids (unbranched, saturated and unsaturated, with an even number of carbon atoms, C8-C22, with a maximum content of 2% unsaponifiable matter), amides of	yes	yes	plastics, rubber	lubricant, activator				NL	To be set
-	-	fatty acids (unbranched, saturated and unsaturated, with an even number of carbon atoms, C8-C22, with a maximum content of 2% unsaponifiable matter), esterified with alcohols, monohydric, primary, unbranched, saturated, C4-C18, as well as oleyl alcohol	yes	yes	plastics	lubricant				NL	To be set
-	-	fibers, natural and synthetic, with the exception of asbestos	yes		coatings	filler				FR, NL	To be set
13160 22552	9003-36-5	formaldehyde, polymer with 2-(chloromethyl)oxirane and phenol (Novolak glycidyl ether, NOGE) *	yes	yes	coatings	monomer	0.0025 0.0025 0.0001 0.006		NOGE bisphenol F epichlorohydrin 3-monochloro-propane-1,2-diol Only to be used in powder coatings	DE, NL	To be set
54970	9003-08-1	formaldehyde-2,4,6-triamino-1,3,5-triazine, copolymer	yes		coatings				DE: only sintered PTFE	FR	To be set
-	9006-24-0	formaldehyde-xylene, copolymer	yes		rubber	resin				FR	To be set

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-	-	glycerol esters with linear fatty acids satured or not with an even number of carbon C8-C20 and/or adipic acid, citric acid, oxystearin acid and ricinoleic acid	yes		coatings					FR	To be set
18370	592-45-0	1,4-hexadiene		yes	rubber	monomer		0.0006	MTCtap as sum for 1,4 and 1,5 hexadiene DE:limited acceptance	DE, NL	To be set
18400	592-42-7	1,5-hexadiene		yes	rubber	monomer		0.0006	MTCtap as sum for 1,4 and 1,5 hexadiene; DE:limited acceptance	DE, FR	To be set
-	16096-31-4	1,6 hexanediol diglycidyl ether	yes		coatings		0.0001			FR, NL	To be set
-	-	2-hydroxy-2-sulfinato acetic acid, disodium salt (50-60%), 2-hydroxy-2-sulfonato acetic acid, disodium salt (10-20%) and sodium sulfite (30-40%) (mixture)			plastics	aids to polymerization			max use level of 0.5%	DE	To be set
-	55406-53-6	3-Iodo-2-propynylbutylcarbamate	yes		rubber, coatings	accelerator				FR	To be set
62255	75-28-5	Isobutane	yes		lubricants					FR	To be set
18970	78-83-1	Isobutanol	yes		silicone	solvent			DE: [1]	DE	To be set
-	-	Isobutyl titanate	yes		silicone	catalyst			DE: [1]	DE, FR	To be set
64000	3999-01-7	linoleamide	yes		coatings, silicone	catalyst			DE: [1]	DE, FR	To be set
-	149-30-4	2-mercaptobenzothiazole	yes		rubber	accelerator		NL: 0.15	MTC(T) for the sum of dithiobis(2-benzothiazole), 2,2'-dibenzothiazyl disulfide, mercaptobenzothiazole, and 2-(4-morpholino)thiobenzothiazole; DE: limited acceptance and additional requirements to S-crosslinking [2]	DE, FR, NL	To be set
19977	60-24-2	2-mercaptoethanol	yes		plastics, rubber	other add.	0.0025			NL	To be set
-	68440-24-4	mercaptoethyl tallate	yes		plastics		1.5			NL	To be set
-	-	methacrylic acid, esters with alcohols, monohydric, aliphatic saturated, C1-C18		yes	rubber	monomer	0.3		expressed as methacrylic acid	NL	To be set
-	115-19-5	methyl-2-butyn-3-ol-2	yes		coatings, silicone	inhibitor			DE: [1]	DE, FR	To be set
21754	15520-10-2	2-methyl-1,5-diaminopentane		yes	coatings	hardener	0.005			DE	To be set
-	7786-17-6	2,2-methylenebis(4-methyl-6-nonylphenol)	yes		plastics, rubber	antioxidant	0.0001			FR, NL	To be set
21823	598-09-4	methylepichlorhydrin		yes	coatings	monomer	0.0001			DE	To be set
-	96-29-7	methyl ethyl ketone oxime	yes		coatings	blocking agents	NL: 0.12		DE: only for hot curing coatings	DE, NL	To be set
66715	693-98-1	2-methylimidazole	yes		coatings	additive	0.0025			DE	To be set
-	534-26-9	2-methylimidazoline	yes		coatings		0.0001			NL	To be set
22065	34813-62-2	2-methylpentane-1,5-diisocyanate		yes	coatings	monomer		ND (<0.0001)	QM= 1 mg/kg. QM and MTC(T) are both expressed as isocyanate moiety	DE	To be set
-	201687-58-3	methyltin-2-mercaptoethyl tallate	yes		plastics		0.009			NL	To be set
-	4253-34-3	methyltrisacetoxysilane		yes	silicone	crosslinking agent			DE: [1]	DE	To be set
-	-	methyltrisbutanoximosilane		yes	silicone	crosslinking agent			DE: [1]	DE	To be set
-	-	methyltriscyclohexylaminosilane		yes	silicone	crosslinking agent			DE: [1]	DE	To be set
-	-	methyltris-sec.-butylaminosilane		yes	silicone	crosslinking agent			DE: [1]	DE	To be set
-	-	mono- and/or polytitanic acid, butyl ester (butyltitanate, butylpolytitanate), as necessary, with the monoethylether of ethanediol (ethyleneglycol) in the ratio 1:1			silicone	aids to polymerization			DE: [1]	DE	To be set
67260	108-90-7	monochlorobenzene	yes		plastics, coatings		0.001			FR, NL	To be set
-	-	mono-n-octyltin tris(maleic acid half ester), prepared with C1-C18, primary, unbranched, saturated alcohols		yes	plastics	stabilizer, antioxidant		0.06	expressed as tin; sum of mono-n-octyltin-compounds	NL	To be set
-	-	mono-n-octyltin tris[monoalkyl(C1-C18) maleate]	yes		plastics	stabilizer, antioxidant		0.06	expressed as tin; sum of mono-n-octyltin-compounds	NL	To be set
67840	-	montanic esters with ethylene glycol and/or 1,3-butanediol and/or glycerol	yes		plastics					NL	To be set

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-	26530-20-1	2-octyl-2H-isothiazole-3-one	yes		rubber	preservative				FR	To be set
69648	-	organopolysiloxanes, containing methylgroups on each silicon atom which can be partially replaced by alkenyl(C2-C32)groups, alkyl (C2-C32)groups, hydroxylgroups, hydrogen, disubstituted alkylamines and/or hydroxylated alkylgroups, acetoxy and/or alkoxy groups and their condensation products with polyethyleneglycol and/or polypropyleneglycol, fluorinated alkylgoups, and phenylgroups	yes	yes	coatings, silicone	monomer, polymeric additive				FR	To be set
-	-	organopolysiloxanes, linear and branched, with methyl groups alone and/or n-alkyl(C2-C32)-, and/or phenyl-2, and/or vinyl-, and/or hydroxyl-, and/or alkoxy(C1-C4)-, and/or hydrogen-, and/or carboalkoxyalkyl(-(CH2)2-17-C(O)-O-(CH2)0-17CH3)-, and/or hydroxyalkyl(C1-C3)-groups	yes	yes	silicone	monomer, polymeric additive			DE: [1]	DE	To be set
-	-	organopolysiloxanes, linear or branched, as mentioned PM/REF No. 69648, but in addition with up to max. 5 % hydrogen and/or alkoxy(C2-C4) and/or carboalkoxyalkyl (-(CH2)2-17-C(O)-O-(CH2)0-17CH3)- and/or hydroxyalkyl(C1-C3) groups attached to the silicon atom	yes	yes	silicone	monomer or polymeric additive			DE: [1]	DE	To be set
-	-	organopolysiloxanes,linear or branched and/or cyclic, with methyl groups alone or with n-alkyl(C2-C32), phenyl-2 and/or hydroxyl groups attached to the silicon atom, and their condensation products with polyethylene and/or polypropyleneglycol	yes	yes	silicone	monomer or polymeric additive			DE: [1]	DE	To be set
	68083-14-7 73138-88-2 68440-81-3	organopolysiloxanes, linear or branched with methyl- or phenylgroups		yes	plastics, lubricants	basic oil			DE: [1]	DE	To be set
76721	9016-00-6 63148-62-9 68037-74-1	organopolysiloxanes, linear or branched with methylgroups		yes	plastics, lubricants	basic oil			DE: [1]	DE	To be set
-	-	organopolysiloxanes with vinyl groups attached to the silicon atom	yes	yes	silicone	monomer or polymeric additive			DE: [1]	DE	To be set
71120	8012-95-1 8042-47-5	paraffin oil	yes		plastics, rubber					FR	To be set
-	-	paraffin, solid, including synthetic paraffin		yes	plastics, rubber	lubricant, plasticizer				NL	To be set
-	614-45-9	peroxybenzoic acid, tert-butyl ester	yes		plastics, coatings		0.0001			NL	To be set
-	15520-11-3	peroxycarbonic acid, bis(4-tert-butylcyclohexyl) ester	yes		plastics, coatings	initiator	0.0001		DE: no peroxide on product surface [1]	DE, NL	To be set
-	16111-62-9	peroxycarbonic acid, bis(2-ethylhexyl) ester	yes		plastics	initiator	0.0001		DE: no peroxide on product surface [1]	DE, NL	To be set
-	927-07-1	peroxypivalic acid, tert-butyl ester	yes		plastics		0.0001			NL	To be set
-	3006-82-4	peroxy-2-ethylhexanoic acid, tert-butyl ester	yes		plastics, rubber		0.0001		DE: no peroxide on product surface [1]	DE, NL	To be set
-	7775-27-1	peroxydisulfuric acid, disodium salt	yes		plastics		0.0001			NL	To be set
-	26748-41-4	peroxyneodecanoic acid, tert-butyl ester	yes		plastics		0.0001			NL	To be set
72048	7727-21-1	peroxydisulfuric acid, dipotassium salt	yes		plastics	initiator	0.0001		DE: no peroxide on product surface [1]	DE, NL	To be set
-	-	petroleum hydrocarbon resins (cyclopentadiene type), hydrogenated	yes		rubber	resin, additive	FR: 0.15			DE, FR	To be set
-	64741-56-6	petroleum residues, vacuum distilled	yes		rubber	resin				FR	To be set
-	92062-05-0	petroleum residues, thermal cracked vacuum	yes		rubber	resin				FR	To be set
-	68610-06-0	phenols, butylated, isobutylated or octylated	yes		rubber	antioxidant				FR	To be set

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-	61788-44-1	phenols, styrenated	yes		rubber, coatings	antioxidant			DE: limited acceptance	DE, FR	To be set
-	936-49-2	2-phenylimidazol		yes	coatings	hardener	0.0025			DE	To be set
23060	104-49-4	1,4-phenylene diisocyanate		yes	coatings	hardener		ND (<0.0001)	QM= 1 mg/kg. QM and MTC(T) are both expressed as isocyanate moiety	DE	To be set
-	7774-80-3	phenyl-o-tolyl-phenylenediamine	yes		rubber	protecting agent	0.0001			NL	To be set
73680	126-73-8	phosphoric acid, tributyl ester	yes		rubber	antifoaming				FR	To be set
-	10294-56-1	phosphorous acid	yes		rubber	antioxidant				NL	To be set
-	54771-30-1	phosphorous acid, dinonylphenyl bis(nonylphenyl) ester	yes		plastics	plasticizer	0.3			FR, NL	To be set
74960	84-61-7	phthalic acid, dicyclohexyl ester	yes		plastics	plasticizer, pigment batches	0.3			DE, FR	To be set
-	110-85-0	piperazine	yes		plastics	monomer	0.075		DE: will be deleted in coatings	DE, NL	To be set
-	-	platinum complexes	yes		silicone	catalyst			DE: [1]	DE, FR	To be set
76461	9003-01-4	polyacrylic acid	yes		rubber					FR	To be set
76520	9003-29-6	polybutene	yes	yes	rubber, lubricants	antifoaming, basic oil			DE: [1]	DE, FR	To be set
76530	68937-10-0	polybutene, hydrogenated		yes	lubricants	basic oil			DE: [1]	DE	To be set
-	-	polyalcoxyesters of acids, fatty with an even number of carbon (C8-C24)	yes		plastics					FR	To be set
76680	68132-00-3	polycyclopentadiene	yes		plastics	resin				FR	To be set
76685	68037-01-4	poly 1-decene hydrated		yes	lubricants	basic oil			impurities of hydrocarbons with number of Carbon smaller than 30 not more than 1,5 %, free of naphthene, aromatics and PAH	DE	To be set
76690	-	polydienic resin, synthetic		yes						FR	To be set
-	-	polydimethyl siloxanes and polydimethyl silicones, 3-aminopropyl-group terminated, polymers with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	yes	yes	silicone	monomer or polymeric additive			DE: [1] Specific restrictions for 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane and 1-amino-3-aminomethyl-3,5,5-trimethylcyclohexane according 10/2011	DE	To be set
-	-	polydimethyl siloxanes and polydimethyl silicones, 3-aminopropyl-group terminated, polymers with bis(4-isocyanatocyclohexyl)methane	yes	yes	silicone	monomer or polymeric additive			DE: [1] Specific restrictions for bis(4-isocyanatocyclohexyl)methane and bis(4-aminocyclohexyl)methane according to 10/2011	DE	To be set
-	-	polyethylene glycol ethers of monohydric aliphatic alcohols (C12-C20) and of alkylphenols (C2-C9)	yes		silicone				DE: [1]	DE	To be set
-	- / 9002-98-6	polyethyleneamine and polyethyleneimine	yes		coatings					FR	To be set
-	-	polyethylene aminostearamide ethylsulfate	yes		coatings					FR	To be set
-	28208-80-2	poly(ethylene-co-acrylic acid), zinc salt		yes	plastics					FR	To be set
77360	9005-07-6	polyethyleneglycol dioleate	yes		coatings	additive				DE	To be set
-	-	polyethylene oxide (8-14), esterified with lauric acid, oleic acid, ricinoleic acid and/or stearic acid		yes						NL	To be set
-	-	polyethylene oxide, molecular weight > 200 (pEO)	yes		plastics	lubricants, other add.				NL	To be set
-	-	polyethylene oxide(4-14)ether of octyl- and/or nonylphenol	yes		plastics, rubber	emulgator	0.25			NL	To be set
-	-	polyethylene oxide(4-14)ethers of monohydric, primary, unbranched, saturated C12-C18 alcohols	yes		plastics	plasticizer	0.25			NL	To be set
80360	9003-27-4	polyisobutene	yes	yes	rubber, lubricants	polymeric additive, basic oils			composition according CR (EU) No. 10/2011, molecular weight >1000Da	DE, FR	To be set
-	-	polypropylene oxide, esterified with lauric acid, oleic acid, ricinoleic acid and/or stearic acid								NL	To be set
-	-	polysaccharides	yes		rubber	thickener				FR	To be set
-	-	poly(styrene-co-maleic anhydride)	yes		plastics					FR	To be set
-	9003-53-6	polystyrene (with pentane as expansion agent)	yes		rubber	resin				FR	To be set
81120	-	polyterpenes	yes		lubricants					DE, FR	To be set

PM/ REF No	CAS No	NAME	Use as additive or PPA	Use as monomer or other starting substance	Material	Technological function	MTC (mg/l)	MTC(T) [mg/l] (Group restriction No)	Restrictions and specification	Auth. MS	Deadline for submission of dossier
81160	9002-84-2	polytetrafluoroethylene	yes		lubricants, coatings	polymeric additive	0.0025		MTC for the residual TFE	DE	To be set
-	-	polyvinyl alcohols, partially acetylated with < 20% acetyl groups and a K-value of > 40	yes	yes	coatings, silicone	emulgator				DE, FR	To be set
81325	25498-06-0	polyvinyl cyclohexane	yes		rubber	coagulating agent				FR	To be set
-	-	poly(vinyl methyl ether)	yes		plastics					FR	To be set
81870	35674-65-8	N,N''-1,3-propanediyl bis (N'-octadecylurea)	yes		coatings	defoamer		0.025		DE	To be set
-	108-32-7	propylene carbonate	yes		lubricants	additive				DE	To be set
83530	71011-24-0	quaternary ammonium compounds, benzyl(hydrogenated tallow alkyl)dimethyl, chlorides, compounds with bentonite	yes		lubricants	thickener				DE	To be set
83560	68953-58-2	quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, salts with bentonite	yes		lubricants	thickener				DE	To be set
-	-	reticulated cationic polyalkyleneamine a) epichlorhydric polyamide resin made from diaminopropylmethylamine and epichlorhydrin; b) epichlorhydric polyamide resin made from epichlorhydrin, adipic acid, caprolactam, diethylene triamine and/or ethylene diamine; c) epichlorhydric polyamide resin made from adipic acid,diethylene triamine and epichlorhydrin or a melt of epichlorhydrin and ammoniac; d) epichlorhydric polyamide-polyamide resin made from epichlorhydrin, dimethyladipate and diethylene triamine; e) epichlorhydric polyamide-polyamide resin made from epichlorhydrin, adipamide and diaminopropylmethylamine	yes		plastics					FR	To be set
85120	122-62-3	sebacic acid, bis(2-ethylhexyl) ester	yes		plastics	PA				FR	To be set
85280	52629-07-9	sebacic acid, bis(2,2,6,6-tetramethyl-4-piperidyl) ester	yes		plastics, lubricants	lubricant	0.3			FR, NL	To be set
-	-	sebacic acid, reaction product with stearylamide, neutralised with calciumhydroxide	yes	yes	lubricants	thickener				DE	To be set
24445	-	silanols, with at least one hydroxyl group and one or more methyl, vinyl or phenyl groups on every silicon atom		yes	rubber	monomers	0.0001			NL	To be set
69885	68988-56-7	silicium dioxide, reaction product with trimethylchlorsilane and isopropyl alcohol		yes	lubricants	thickener			DE: [1]		To be set
		silicone	yes		rubber	polymeric additive			DE: [1]	DE	To be set
-	9006-65-9	silicone oils (organopolysiloxanes with methyl and/or phenyl groups)	yes	yes	rubber, coatings, lubricants	polymeric additive, basic oils			DE: [1]	DE, FR	To be set
86440	-	sodium aluminate	yes		coatings					FR	To be set
61340	149-44-0	sodium hydroxymethanesulphinate	yes		plastics				max use level of 0.07%	DE	To be set
-	1561-92-8	sodium methallyl sulfonate	yes		plastics		0.25			NL	To be set
-	-	solvents (boiling point < 150°C) if elimated in final product	yes		coatings	solvent				FR	To be set
		solvents in factory made products	yes				0.0001			DE	To be set
-	-	sorbitol esters with linear fatty acids, saturated or not, with an even number of carbon C8-C20	yes	yes	coatings		0.0001			FR	To be set
-	-	stearic acid mono or di esters with ethanediol and/or ether bis(2-hydroxyethyl) and/or triethyleneglycol	yes		plastics	stabilizer				FR	To be set
-	-	stearoyl-palmitoyl-benzoyl-methane		yes	plastics					FR	To be set
-	68442-68-2	styrene, reaction product with diphenylamine	yes		rubber	stabilizer	0.0025		DE: limited acceptance and additional requirements for PAA and sec. Amines [2]	DE, NL	To be set
-	126-33-0	sulfolane	yes		plastics	solvent	0.0025			NL	To be set
-	7446-09-5	sulfur dioxide	yes		rubber	monomer				FR	To be set
-	61790-38-3	tallow acid, hydrogenated	yes		rubber	accelerator					To be set

PM/ REF No	CAS No	NAME	Use as additive or PPA	Use as monomer or other starting substance	Material	Technological function	MTC (mg/l)	MTC(T) [mg/l] (Group restriction No)	Restrictions and specification	Auth. MS	Deadline for submission of dossier
-	10591-85-2	tetrabenzylthiuram disulfide	yes		rubber	accelerator			DE: limited acceptance and additional requirements for S cross-linking [2]	DE, FR	To be set
-	5593-70-4	tetra-n-butyl titanate	yes		rubber, silicone	accelerator			DE: [1]	DE, FR	To be set
-	112484-41-0	tetraethylbutylphenol-formaldehydresin hydrobrominated	yes		rubber	crosslinking agent			DE: limited acceptance	DE	To be set
92400	97-77-8	tetraethylthiuram disulfide	yes		plastics, rubber	expanding agent/accelerator		NL: 0.05	MTC(T) for the sum of tetra(alkyl/aryl)thiuram disulfides and tetramethylthiuram monosulfide DE: limited acceptance and additional requirements for S cross-linking [2]	DE, FR, NL	To be set
-	811-97-2	1,1,1,2 -tetrafluoroethane	yes		plastics	expanding agent			max. use level 2.2 %	FR	To be set
-	3064-73-1	tetraisobutylthiuramdisulfide	yes		rubber			0.05	MTC(T) for the sum of tetra(alkyl/aryl)thiuram disulfides and tetramethylthiuram monosulfide		To be set
92480	38613-77-3	tetrakis(2,4-di-tert-butylphenyl)-2,4'-biphenylene diphosphonite	yes		plastics, rubber	antifoaming	0.9			NL	To be set
92685	126-86-3	2,4,7,9-tetramethyl-5-decyne-4,7-diol	yes		rubber	accelerator			max. use level 0.1 %	FR	To be set
-	26678-93-3	tetramethylbutylphenol-formaldehydresin	yes		rubber	crosslinking agent			DE: limited acceptance	DE	To be set
92720	137-26-8	tetramethylthiuram disulfide	yes		rubber	accelerator		NL: 0.05	MTC(T) for the sum of tetra(alkyl/aryl)thiuram disulfides and tetramethylthiuram monosulfide DE: limited acceptance and additional requirements for S cross-linking [2]	DE, FR, NL	To be set
-	97-74-5	tetramethylthiuram monosulfide	yes		rubber	accelerator		NL: 0.05	MTC(T) for the sum of tetra(alkyl/aryl)thiuram disulfides and tetramethylthiuram monosulfide	FR, NL	To be set
-	-	titanic acid, esters with isobutanol, n-butanol and the enolate of ethylacetoacetate	yes		silicone	catalyst			DE: [1]	DE	To be set
25208	26471-62-5	toluene diisocyanate		yes	coatings	monomer	0.06	ND (<0.0001)	QM= 1 mg/kg. QM and MTC(T) are both expressed as isocyanate moiety	DE, FR	To be set
-	104-15-4	p-toluenesulfonic acid	yes		rubber	accelerator	0.0005			FR	To be set
-	93-69-6	o-tolylbiguanidine	yes		rubber	accelerator	0.0001			FR, NL	To be set
25390	101-37-1	triallyl cyanurate	yes		rubber	activator	NL: 0.0001		DE: limited acceptance [1]	DE, NL	To be set
25405	1025-15-6	triallyl isocyanurate	yes		rubber	activator	NL: 0.0001		DE: limited acceptance	DE, NL	To be set
25445	28607-72-9	tricyclododecane diisocyanate		yes	coatings	hardener		ND (<0.0001)	QM= 1 mg/kg. QM and MTC(T) are both expressed as isocyanate moiety	DE	To be set
-	90-72-2	2,4,6-tri(dimethylaminomethyl)phenol	yes		rubber, coatings	activator	0.0001			NL	To be set
-	78-40-0	triethyl phosphate	yes		plastics, coatings		0.375			NL	To be set
-	26780-96-1	2,2,4-trimethyl-1,2-dihydrochinolin (polymerized)	yes		rubber	aging protection products			DE: limited acceptance	DE	To be set
-	-	trivinyl cyclohexane and α,ω-dihydrogenpolyhydro-genmethyldimethyl-siloxanes, addition products of	yes	yes	silicon rubber	monomer or polymeric additive			DE: max. use level 10 % [1]	DE	To be set
-	-	urea-formaldehyde condensation products	yes		plastics, coatings	macromolecular agent, polymer, resin, adhesive, hygroscopic agent			intermediate according coating guideline	DE, NL	To be set
-	-	vinyl esters of monohydric, saturated, aliphatic carboxylic acids, C2-C20		yes	plastics	monomer	0.0025			NL	To be set
-	3048-64-4	vinylnorbornene		yes	rubber	monomer	0.0025		DE: limited acceptance	DE, FR, NL	To be set
26230	88-12-0	vinylpyrrolidone	yes		plastics	lubricant				DE, NL	To be set
-	14726-36-4	zinc dibenzyldithiocarbamate	yes		rubber	accelerator		NL: 0.05	MTC(T) for the sum of all listed zino-(alkyl/aryl)dithiocarbamates DE: limited acceptance	DE, FR, NL	To be set

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-	136-23-2	zinc dibutyldithiocarbamate	yes		rubber	accelerator		NL: 0.05	MTC(T) for the sum of all listed zino-(alkyl/aryl)dithiocarbamates DE: limited acceptance and additional requirements for S cross-linking [2]	DE, FR, NL	To be set
96170	14324-55-1	zinc diethyldithiocarbamate	yes		rubber	accelerator		NL: 0.05	MTC(T) for the sum of all listed zino-(alkyl/aryl) dithiocarbamates	FR, NL	To be set
-	137-30-4	zinc dimethyldithiocarbamate	yes		rubber	accelerator		0.05	MTC(T) for the sum of all listed zino-(alkyl/aryl) dithiocarbamates	NL	To be set
-	136-53-8	zinc-di-2-ethylhexanoate	yes		silicone	hardener			QM = 1.5 % DE: [1]	DE, NL	To be set
-	84604-96-6	zinc diisononyldithiocarbamate	yes		rubber	cross-linking			DE: limited acceptance and additional requirements for S cross-linking [2]	DE	To be set
-	53801-45-9	zirconium oxide	yes		plastics, rubber	stabilizer, antioxidant, drying agent	NL: 0.1		MTC is expressed as zirconium	FR, NL	To be set

[1] BfR Recommendations may have additional requirements. When the UBA-Guidelines get mandatory evaluation criteria no reference to BfR-Recommendations could be set. Therefore the substances will be checked and the requirements will be set in the mandatory evaluation criteria.

[2] additional requirements in DE:

		Parameter	Restriction
rubber		formaldehyde	MTC_{tap} = 750 µg/l
		sum of Primary Aromatic Amines (PAA) (a.o. aniline, o-toluidine)	MTC_{tap} = ND (DL = 2 µg/l)
		sum of secondary amines1	MTC_{tap} = 250 µg/l
	s-crosslinking	2-mercaptobenzothiazole	QM = 400 µg/kg
		N-nitrosamines 2	MTC_{tap} = 0.3 mg/l
coatings (polyurethanes, polyamides and epoxy coatings)		PAA	MTC_{tap} = ND (DL= 0.1 µg/l)
plastics		PAA	MTC_{tap} = ND (DL= 0.1 µg/l)

Annex C - Obsolete List (list of obsolete substances)

OBSOLETE LIST FOR ORGANIC MATERIALS COMING INTO CONTACT WITH DRINKING WATER - 9 MAY 2017

PM/ REF No	CAS No	NAME	Use as additive or PPA	Use as monomer or other starting substance	Material	Technological function	MTC (mg/l)	MTC(T) [mg/l] (Group restriction No)	Restrictions and specification	Auth. MS	Deadline for submission of dossier
-	3179-56-4	acetyl cyclohexylsulfonyl peroxide	yes		plastics	initiator	0.0001		no peroxid on the product surface	NL, D	To be set
-	25551-14-6	1,1'-azobis(1-cyclohexanecarbonitrile)	yes		plastics	initiator			max. 0.2 %	NL, D	To be set
-	78-67-1	2,2'-azobis(isobutyronitrile)	yes		plastics	initiator				NL	To be set
-	2167-23-9	2,2-bis(tert-butylperoxy)butane	yes		plastics	aids to polymerization				D	To be set
-	1068-27-5	2,5-bis(tert-butylperoxy)-2,5-dimethyl-3-hexyne		yes	plastics	aids to polymerization	0.0001			NL, D	To be set
38625	2781-00-2	1,4-bis(tert-butylperoxyisopropyl)benzene	yes		plastics	visc. contr. agent	0.0001			NL	To be set
40630	2782-40-3	N-butylbenzamide	yes							Fr	To be set
-	136-51-6	calcium bis(2-ethylhexanoate) (= calcium octoate)	yes		plastics					Fr	To be set
14587	1204-28-0	4-(chloroformyl)phthalic anhydride		yes	coatings	monomer	0.0025		QMA =0.05 mg/dm^2; only for PTFE sintered	Fr	To be set
-	2568-90-3	dibutoxymethane (butylal)	yes		plastics					NL	To be set
-	87-97-8	2,6-di-tert-butyl-4-(methoxymethyl)phenol	yes		rubber	protecting agent	0.0001			NL	To be set
-	1067-33-0	dibutyltin diacetate	yes		coatings, silicone	catalyst				Fr	To be set
-	77-58-7	dibutyltin dilaurate	yes		coatings, silicone	catalyst				Fr	To be set
-	4253-22-9	dibutyltin sulfide	yes				0.002		expressed as tin	NL	To be set
-	1717-00-6	1,1-dichloro-1-fluoroethane	yes		plastics, coatings	expanding agent				Fr	To be set
-	68479-98-1	diethylmethylbenzenediamine	yes							Fr	To be set
-	109-31-9	dihexyl azelate	yes							Fr	To be set
48560	36265-41-5	dihydro-1,4-dimethyl-2,6-dicarbododecyloxy-3,5-pyridine	yes		plastics	stabilizer				Fr	To be set
49040	1115-01-1	9,10-dihydroxystearic acid, methyl ester	yes		plastics	lubricant				Fr	To be set
-	109-87-5	dimethoxymethane	yes		plastics	monomer				NL, D	To be set
49120	3271-22-5	2,4-dimethoxy-6-(1-pyrenyl)-1,3,5-triazine	yes		plastics	azurant				NL	To be set
-	-	dimethyldialkyl(C16 and/or C18)ammoniumacetate	yes		plastics					NL	To be set
75840	117-84-0	di-n-octyl phthalate	yes		plastics, rubber, coatings	plasticizer	0.11			NL	To be set
-	2432-87-3	di-n-octyl sebacate	yes		plastics, rubber	plasticizer	0.0001			NL	To be set
-	-	N,N'-dioleoyl diaminoethane	yes							Fr	To be set
-	5518-18-3	N,N'-dipalmitoyl diaminoethane	yes		coatings					Fr	To be set
-	971-15-3	di-N-pentamethylenethiuram hexasulfide			rubber			0.05	MTC(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of all di-N-pentamethylenethiuram sulfides	NL	To be set
-	120-54-7	di-N-pentamethylenethiuram tetrasulfide			rubber			0.05	MTC(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of all di-N-pentamethylenethiuram sulfides	NL	To be set
-	-	N,N'-distearoyl diaminoethane	yes		coatings					Fr	To be set
-	151-41-7	dodecylsulfate	yes		coatings, silicone					Fr	To be set
53040	35001-52-6	2-ethoxy-5-tert-butyl-2'-ethyloxalic acid bisanilide	yes		plastics					Fr	To be set
-	75-04-7	ethylamine	yes		plastics	catalyst				NL, D	To be set
-	143-06-6	hexamethylenediamine carbamate	yes		rubber	accelerator				Fr	To be set
-	1191-25-9	6-hydroxyhexanoic acid	yes					0.0025	MTC(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of 6-hydroxyhexanoic acid and caprolacton (FCM No 342)	NL	To be set
-	59118-78-4	2-mercaptoethyl oleate	yes		plastics	stabilizer, antioxidant	1.5			NL	To be set
-	96-45-7	2-mercaptoimidazoline	yes		rubber	accelerator	0.0025			NL	To be set
-	96-53-7	2-mercaptothiazoline	yes		rubber	accelerator	0.0001			NL, Fr	To be set
66000		3'-methoxy-4'-hydroxyphenyl-2-indole	yes		plastics	stabilizer				Fr	To be set
-	4088-22-6	N-methyldioctadecylamine	yes							NL	To be set
-	694-91-7	5-methylenebicyclo[2.2.1]hept-2-ene	yes	yes	rubber, coatings	monomer	0.0025			NL	To be set
22333	79-11-8	monochloroacetic acid		yes	coatings		0.0025			Fr	To be set
-	-	monoethanolamine laurylsulfate	yes		coatings					Fr	To be set

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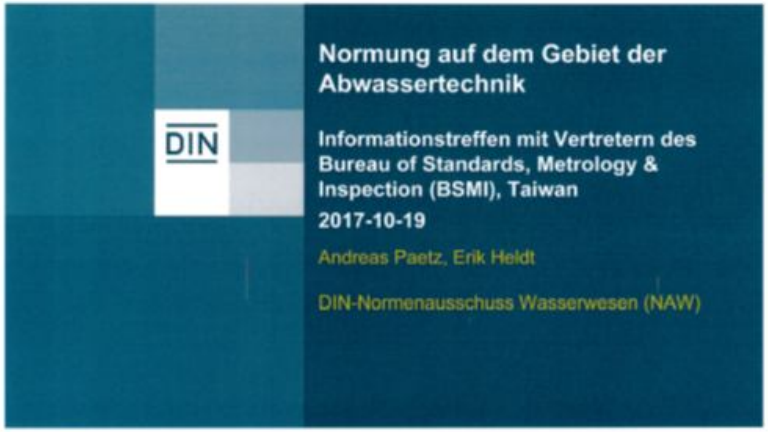
-	102-77-2	morpholinothio-2-benzothiazole	yes		rubber	accelerator		0.15	MTC(T) in this specific case means that the restriction shall not be exceeded by the sum of the migrations levels of dithiobis(2-benzothiazole), 2,2'-dibenzothiazyl disulfide, mercaptobenzothiazole, and 2-(4-morpholino)thiobenzothiazole	NL	To be set
-	-	myristyl polyethylene glycol (3-8) ether with oxyacetic acid		yes	plastics	antistatic				NL	To be set
67900	8030-30-6	naphtha	yes		plastics					Fr	To be set
-	9084-06-4	naphtalene sulfonic acid-formaldehyde condensation product, sodium salt	yes		plastics	emulgator PTFE		0.0001	only sintered products	NL, D	To be set
69120	142-77-8	oleic acid, butyl ester	yes		plastics					NL	To be set
-	1912-84-1	oleic acid, tin(II) salt	yes		plastics		0.0025			NL	To be set
-	-	2-heptadecyl-4,4-bis (methylenestearate) oxazoline	yes		coatings					Fr	To be set
70080	80-51-3	4,4'-oxybis(benzene sulfonyl hydrazide)	yes		plastics	blowing agent				Fr	To be set
70320	629-54-9	palmitamide	yes		coatings, silicone	catalyst				Fr	To be set
71710	98-77-1	pentamethylenedithiocarbamic acid, piperidine salt	yes		rubber	accelerator				Fr	To be set
-	13878-54-1	pentamethylenedithiocarbamic acid, zinc salt	yes		rubber	accelerator				Fr	To be set
-	79-21-0	peracetic acid	yes			initiator				Fr	To be set
-	107-71-1	peroxyacetic acid, tert-butyl ester	yes		plastics	initiator	0.0001			NL, D	To be set
-	1561-49-5	peroxycarbonic acid, dicyclohexyl ester	yes		plastics	initiator	0.0001			NL, D	To be set
-	26322-14-5	peroxycarbonic acid, dihexadecyl ester	yes		plastics	initiator	0.0001			NL, D	To be set
-	105-64-6	peroxycarbonic acid, diisopropyl ester	yes		plastics	initiator	0.0001			NL, D	To be set
-	53220-22-7	peroxycarbonic acid, ditetradecyl ester	yes		plastics	initiator	0.0001			NL, D	To be set
-	13122-18-4	peroxy(3,5,5-trimethylhexanoic acid), tert-butyl ester	yes		plastics	initiator	0.0001			NL, D	To be set
72105	-	phenols and/or cresols-styrene and/or alpha-methylstyrene and/or C3-C12 olefins, copolymers	yes		rubber		0.0001			NL,	To be set
-	-	N-phenyl-N'-isohexyl-p-phenylenediamine	yes	yes	rubber	protecting agent	0.0001			NL	To be set
72400	132-27-4	2-phenylphenol, sodium salt	yes		rubber	preservative			QM = 0.02%	Fr	To be set
72560	7144-65-2	3-(2-phenyl)phenoxy-1,2-epoxypropane	yes		plastics					Fr	To be set
74000	78-42-2	phosphoric acid, tris(2-ethylhexyl) ester	yes		plastics	filler / pigments batches				Fr, D	To be set
74800	-	phthalic acid, di-heptyl/nonyl ester	yes		rubber	plasticizer				Fr	To be set
75040	-	phthalic acid, diesters of hexadecanol and/or octadecanol	yes							Fr	To be set
75200	3648-61-1	phthalic acid, diheptylic ester	yes		plastics	plasticizer				Fr	To be set
-	68410-23-1 83487-96-1	polyaminoamide	yes		rubber, coatings	macromolecular agent	0.0001			NL	To be set
-	-	polyethylene oxide desorbitan monolaurate	yes		coatings	emulgator				NL	To be set
23710	63148-65-2	polyvinyl butyral	yes		plastics					Fr	To be set
-	11137-59-0	potassium aluminate	yes		rubber	buffering agent				Fr	To be set
-	74-98-6	propane	yes		plastics	pol.contr. agent				NL	To be set
-	-	reaction products of styrene and/or methylstyrene and/or alkenes (C3-C12) with phenol and/or methylphenol	yes		coatings	anchorage agent	0.0025			NL	To be set
83650	9006-34-8	resin acids and rosin acids, manganese salts	yes		coatings		0.03			Fr	To be set
83750	-	ricinoleic acid, amyl ester	yes		plastics					Fr	To be set
83760	-	ricinoleic acid, butyl ester	yes		plastics					Fr	To be set
83760	-	ricinoleic acid, ethyl ester	yes		plastics					Fr	To be set
-	-	rosin, dimerised, esters	yes		plastics					Fr	To be set
-	-	rosin, hydrogenated, esters	yes		plastics, rubber	plasticizer				Fr	To be set
86080	10101-52-7	silicic acid, zirconium salt	yes		plastics	lubricant, fillers				Fr,D	To be set
-	10026-04-7	silicon tetrachloride	yes		plastics	catalyst				NL, D	To be set
-	-	soybean oil, modified with sulfur	yes		plastics	lubricant				NL	To be set
89520	8045-34-9	stearic acid, esters with pentaerythritol	yes		plastics					Fr	To be set
89600	111-61-5	stearic acid, ethyl ester	yes		plastics					Fr	To be set
90000	646-13-9	stearic acid, isobutyl ester	yes		plastics					Fr	To be set
90480	6382-13-4	stearic acid, pentyl ester	yes		coatings					Fr	To be set
24560	111-63-7	stearic acid, vinyl ester		yes	plastics	monomer				D	To be set

PM/ REF No	CAS No	NAME	Use as additive or PPA	Use as monomer or other starting substance	Material	Technological function	MTC (mg/l)	MTC(T) [mg/l] (Group restriction No)	Restrictions and specification	Auth. MS	Deadline for submission of dossier
-	-	styrene (2 mol) condensed with 1 mol of a mixture of phenol and o-, m- and p-cresols; Brookfield viscosity of the end product at 25°C between 1400 and 1700 cP	yes		plastics	polymeric additive	0.0001			NL	To be set
-	1634-02-2	tetrabutylthiuram disulfide	yes		rubber	accelerator		0.05	MTC(T) in this specific case means that the restriction shall not be exceeded by the sum of the migrations levels of tetrabutylthiuram disulfide, tetraethylthiuram disulfide, tetramethylthiuram disulfide and tetramethylthiuram monosulfide	NL	To be set
92960	111-17-1	thiodipropionic acid	yes		plastics, coatings	antioxidant				NL, Fr	To be set
-	11130-18-0	titanium chloride	yes		plastics	catalyst				NL	To be set
-	7550-45-0	titanium tetrachloride	yes		plastics	other add.				NL	To be set
93790	102-82-9	tributylamine	yes		plastics	residue of catalyst	0.0001			NL, D	To be set
-	106-10-5	triethyleneglycol dioctanoate	yes							Fr	To be set
-	10380-08-2	triphosphoric acid	yes				0.0005			NL, Fr	To be set
-	7718-98-1	vanadium chloride	yes		plastics	catalyst		0.0025	MTC(T) expressed as vanadium	NL	To be set
-	11099-11-9	vanadium oxide	yes		plastics	catalyst		0.0025	MTC(T) expressed as vanadium	NL, D	To be set
72060	89-03-8	vaseline, pharmaceutical quality		yes	rubber	plasticizer				NL	To be set
26290	25013-15-4	vinyltoluene		yes	plastics	monomer/ additive				D	To be set
26215	100-69-6	2-vinylpyridine		yes	rubber	monomer				Fr	To be set
-	14634-93-6	zinc ethylphenyldithiocarbamate	yes		rubber	accelerator		0.05	MTC(T) in this specific case means that the restriction shall not be exceeded by the sum of all listed zinc-(alkyl/aryl) dithiocarbamates	NL	To be set

附錄 5

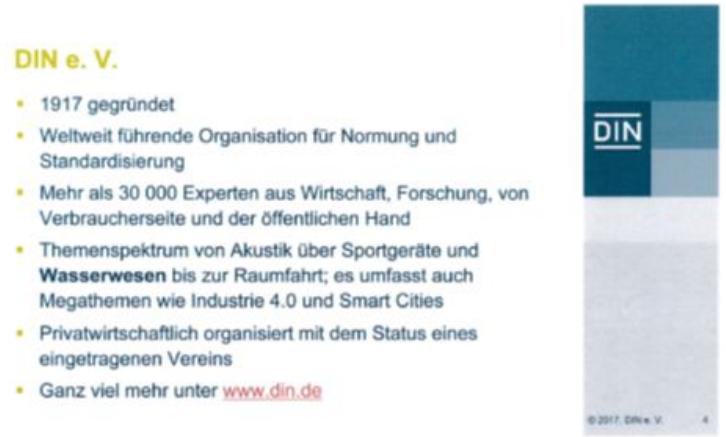
DIN 水資源標準委員會的運作及組織



簡報01

簡報02

簡報03



簡報04

DIN-Normenausschuss Wasserwesen (NAW)

- 1950 offiziell gegründet, aber frühe Zeugnisse wasserwirtschaftlicher Normung bereits seit den 1920er Jahren belegt (Schachtabdeckungen)
- 19 Mitarbeiter in der NAW-Geschäftsstelle (1 Geschäfts-führerin, 11 Projektmanager/innen, 7 Assistentinnen)
- Zuständig für 415 Gremien (181 DIN, 71 CEN, 163 ISO)
- Experten (national) 1 393 / 2 450 (Köpfe/Sitze)
- 578 Projekte (Normen und Standards) 2017 bearbeitet
- Teilnahme der Projektmanager 2016 an 303 Sitzungen
- Bestand etwa 2 000 Normen und Standards
- Ganz viel mehr unter www.naw.din.de

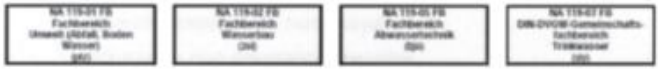
簡報05

DIN-Normenausschuss Wasserwesen (NAW)

Wie setzt sich der NAW zusammen?

簡報06

DIN-Normenausschuss Wasserwesen (NAW) Organigramm (verkürzt)



簡報07

Mehr als 80 000 000 Stakeholder in Deutschland !

- Wassergewinnung und -aufbereitung
- Wassertransport und –verteilung, Wasserzähler
- Wasserspeicherung
- Schwimm- und Badebeckenwasser
- **Abwasserableitung und –reinigung**
- **Klärschlammbehandlung, -verwertung und –beseitigung**
- Dienstleistungen – Benchmarking, Krisenmanagement
- Wasserbau – Deiche, Staudämme, Wehre, Schleusen
- Untersuchungsverfahren (Wasser, Boden, Abfall, Hydrometrie)

簡報08

Neue Normungsfelder – Innovative Themen

- Wasserwirtschaft 4.0 (Automatisierung, Digitalisierung, Big Data-Vernetzung, Datensicherheit)
- Ressourcen- und energieeffiziente Kläranlagen
- Vierte Reinigungsstufe
- Klimawandel und Siedlungsentwässerung
- Abscheidung und Speicherung von CO_2 (CCS, CCUS, EOR+CS)
- Geothermie
- Phosphorrückgewinnung
- Energie-/Wärmerückgewinnung aus Abwasser
- Mikroplastik

簡報09

RECHTLICHER HINTERGRUND – EU-WASSERRECHT, DEUTSCHES WASSERRECHT

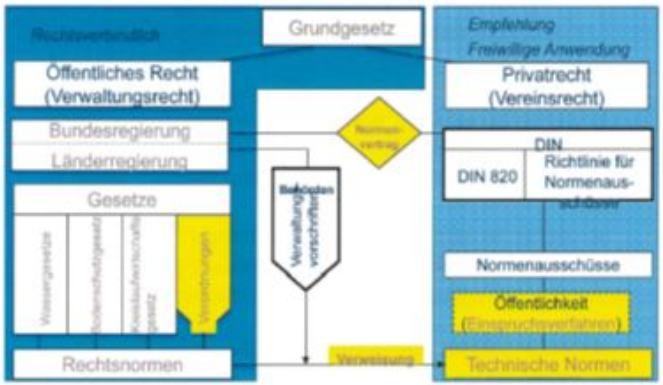
簡報10

Vertrag Bundesregierung/DIN vom 5.6.1975

- Bundesregierung erkennt DIN als nationale Normenorganisation in internationalen nichtstaatlichen Normenorganisationen an.
- DIN verpflichtet sich, das öffentliche Interesse zu berücksichtigen und dafür zu sorgen, dass Normen für Gesetze, Verwaltungsaufgaben und Verträge herangezogen werden können.
- DIN verpflichtet sich, Normungsanträge bevorzugt zu behandeln.

簡報11

Normen in der Rechtsordnung



簡報12

EU-Richtlinien mit Verweis auf Normen

- **2000/60/EG Wasserrahmenrichtlinie**
  - 91/271/EWG Behandlung von kommunalem Abwasser
  - 2006/18/EG Grundwasserrichtlinie
  - 2008/105/EG Umweltqualitätsnormen
  - 2009/90/EG Qualitätsrichtlinie
- **2008/98/EG Abfallrahmenrichtlinie**
  - 86/278/EWG Klärschlammrichtlinie
  - 1999/31/EG Deponierichtlinie

簡報13

Rechtsverordnungen mit Verweis auf Normen

Wasserhaushaltsgesetz (WHG)

Abwasserabgabengesetz (AbwAG)

- Abwasserverordnung (AbwV)
- Grundwasserverordnung (GrwV)
- Oberflächengewässerverordnung (OgewV)
- Trinkwasserverordnung (TrinkwV)
- Bundes-Bodenschutzverordnung (BBodSchV)
- Klärschlammverordnung (AbfKlärV)
- Deponieverordnung (DepV)

簡報14

ABWASSERTECHNIK

簡報15

Kläranlagen in Deutschland

- 96 % der Bevölkerung Deutschlands oder 78 Mio. Einwohner sind an die öffentliche Kanalisation angeschlossen.
- ~ 8 000 kommunale Abwasserentsorgungsunternehmen.
- Daneben gibt es Kläranlagen privater Industriebetriebe.
- Das Kanalnetz ist rund 515 000 km lang.
- Das Abwasser wird in über 10 000 Kläranlagen gereinigt.
- Das angefallene Abwasser wird zu fast 100 % in Kläranlagen behandelt.
- In den öffentlichen Kläranlagen werden jährlich rund 9,8 Milliarden m^3 Abwasser behandelt.

簡報16

Kläranlagen in Deutschland

- die über drei Reinigungsstufen verfügen:
  - eine mechanische Stufe,
  - eine biologische Stufe ohne gezielte Entfernung der Nährstoffe, wie Stickstoffe und Phosphate,
  - eine weitere biologische Stufe mit gezielter Entfernung der Nährstoffe.
- Die Gesamtzahl der biologischen Anlagen nimmt kontinuierlich zu.
  - 4. Reinigungsstufe (Mikroverunreinigungen, Mikroplastik)

簡報17

Reinigungsstufen in Kläranlagen

簡報18

Kläranlagen – Bemessungsgrundlagen I

- Der **Einwohnergleichwert (EGW)** dient als Referenzwert der Schmutzfracht in der Wasserwirtschaft. Er kann auf den Biochemischen Sauerstoffbedarf (BSB_5), den Chemischen Sauerstoffbedarf (CSB), den Stickstoff, den Phosphor, den gesamten organischen Kohlenstoff (TOC), die Schwebstoffe oder auf den Wasserverbrauch bezogen werden. Er gibt jeweils das Einwohneräquivalent der Tagesmengen dieser Stoffe bzw. Verbräuche im Abwasser von Industrie, Gewerbe, Landwirtschaft etc. an.

簡報19

Kläranlagen – Bemessungsgrundlagen II

- Die Summe aus der tatsächlichen **Einwohnerzahl (EZ)** und **Einwohnergleichwerten (EGW)** ergibt den für die Bemessung von Abwasserreinigungsanlagen wichtigen **Einwohnerwert (EW).**
- Es gilt: **EW = EZ + EGW**
- Mit Hilfe des **Einwohnerwertes (EW)** lässt sich die zu erwartende biologische Belastung von Kläranlagen abschätzen.

簡報20


Vielen Dank für Ihre Aufmerksamkeit
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簡報21

附錄 6

歐盟飲用水標準

COUNCIL DIRECTIVE 98/83/EC

of 3 November 1998

on the quality of water intended for human consumption

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community and, in particular, Article 130s(1) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 189c [4],

(1) Whereas it is necessary to adapt Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption [5] to scientific and technological progress; whereas experience gained from implementing that Directive shows that it is necessary to create an appropriately flexible and transparent legal framework for Member States to address failures to meet the standards; whereas, furthermore, that Directive should be re-examined in the light of the Treaty on European Union and in particular the principle of subsidiarity;

(2) Whereas in keeping with Article 3b of the Treaty, which provides that no Community action should go beyond what is necessary to achieve the objectives of the Treaty, it is necessary to revise Directive 80/778/EEC so as to focus on compliance with essential quality and health parameters, leaving Member States free to add other parameters if they see fit;

(3) Whereas, in accordance with the principle of subsidiarity, Community action must support and supplement action by the competent authorities in the Member States;

(4) Whereas, in accordance with the principle of subsidiarity, the natural and socio-economic differences between the regions of the Union require that most decisions on monitoring, analysis, and the measures to be taken to redress failures be taken at a local, regional or national level insofar as those differences do not detract from the establishment of the framework of laws, regulations and administrative provisions laid down in this Directive;

(5) Whereas Community standards for essential and preventive health-related quality parameters in water intended for human consumption are necessary if minimum environmental-quality goals to be achieved in connection with other Community measures are to be defined so that the sustainable use of water intended for human consumption may be safeguarded and promoted;

(6) Whereas, in view of the importance of the quality of water intended for human consumption for human health, it is necessary to lay down at Community level the essential quality standards with which water intended for that purpose must comply;

(7) Whereas it is necessary to include water used in the food industry unless it can be established that the use of such water does not affect the wholesomeness of the finished product;

(8) Whereas to enable water-supply undertakings to meet the quality standards for drinking water, appropriate water-protection measures should be applied to ensure that surface and groundwater is kept clean; whereas the same goal can be achieved by appropriate water-treatment measures to be applied before supply;

[1] OJ C 131, 30.5.1995, p. 5 and OJ C 213, 15.7.1997, p. 8.
[2] OJ C 82, 19.3.1996, p. 64.
[3] OJ C 100, 2.4.1996, p. 134.
[4] Opinion of the European Parliament of 12 December 1996 (OJ C 20, 20.1.1997, p. 133), Council common position of 19 December 1997 (OJ C 91, 26.3.1998, p. 1) and Decision of the European Parliament of 13 May 1998 (OJ C 167, 1.6.1998, p. 92).
[5] OJ L 229, 30.8.1980, p. 11. Directive as last amended by the 1994 Act of Accession.

(9) Whereas the coherence of European water policy presupposes that a suitable water framework Directive will be adopted in due course;

(10) Whereas it is necessary to exclude from the scope of this Directive natural mineral waters and waters which are medicinal products, since special rules for those types of water have been established;

(11) Whereas measures are required for all parameters directly relevant to health and for other parameters if a deterioration in quality has occurred; whereas, furthermore, such measures should be carefully coordinated with the implementation of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1] and Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [2];

(12) Whereas it is necessary to set individual parametric values for substances which are important throughout the Community at a level strict enough to ensure that this Directive's purpose can be achieved;

(13) Whereas the parametric values are based on the scientific knowledge available and the precautionary principle has also been taken into account; whereas those values have been selected to ensure that water intended for human consumption can be consumed safely on a life-long basis, and thus represent a high level of health protection;

(14) Whereas a balance should be struck to prevent both microbiological and chemical risks; whereas, to that end, and in the light of a future review of the parametric values, the establishment of parametric values applicable to water intended for human consumption should be based on public-health considerations and on a method of assessing risk;

(15) Whereas there is at present insufficient evidence on which to base parametric values for endocrine-disrupting chemicals at Community level, yet there is increasing concern regarding the potential impact on humans and wildlife of the effects of substances harmful to health;

(16) Whereas in particular the standards in Annex I are generally based on the World Health Organisation's 'Guidelines for drinking water quality', and the opinion of the Commission's Scientific Advisory Committee to examine the toxicity and ecotoxicity of chemical compounds;

(17) Whereas Member States must set values for other additional parameters not included in Annex I where that is necessary to protect human health within their territories;

(18) Whereas Member States may set values for other additional parameters not included in Annex I where that is deemed necessary for the purpose of ensuring the quality of the production, distribution and inspection of water intended for human consumption;

(19) Whereas, when Member States deem it necessary to adopt standards more stringent than those set out in Annex I, Parts A and B, or standards for additional parameters not included in Annex I but necessary to protect human health, they must notify the Commission of those standards;

(20) Whereas Member States are bound, when introducing or maintaining more stringent protection measures, to respect the principles and rules of the Treaty, as they are interpreted by the Court of Justice;

(21) Whereas the parametric values are to be complied with at the point where water intended for human consumption is made available to the appropriate user;

(22) Whereas the quality of water intended for human consumption can be influenced by the domestic distribution system; whereas, furthermore, it is recognised that neither the domestic distribution system nor its maintenance may be the responsibility of the Member States;

(23) Whereas each Member State should establish monitoring programmes to check that water intended for human consumption meets the requirements of this Directive; whereas such monitoring programmes should be appropriate to local needs and should meet the minimum monitoring requirements laid down in this Directive;

(24) Whereas the methods used to analyse the quality of water intended for human consumption should be such as to ensure that the results obtained are reliable and comparable;

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 96/68/EC (OJ L 277, 30.10.1996, p. 25).
[2] OJ L 123, 24.4.1998, p. 1.

(25) Whereas, in the event of non-compliance with the standards imposed by this Directive the Member State concerned should investigate the cause and ensure that the necessary remedial action is taken as soon as possible to restore the quality of the water;

(26) Whereas it is important to prevent contaminated water causing a potential danger to human health; whereas the supply of such water should be prohibited or its use restricted;

(27) Whereas, in the event of non-compliance with a parameter that has an indicator function, the Member State concerned must consider whether that non-compliance poses any risk to human health; whereas it should take remedial action to restore the quality of the water where that is necessary to protect human health;

(28) Whereas, should such remedial action be necessary to restore the quality of water intended for human consumption, in accordance with Article 130r(2) of the Treaty, priority should be given to action which rectifies the problem at source;

(29) Whereas Member States should be authorised, under certain conditions, to grant derogations from this Directive; whereas, furthermore, it is necessary to establish a proper framework for such derogations, provided that they must not constitute a potential danger to human health and provided that the supply of water intended for human consumption in the area concerned cannot otherwise be maintained by any other reasonable means;

(30) Whereas, since the preparation or distribution of water intended for human consumption may involve the use of certain substances or materials, rules are required to govern the use thereof in order to avoid possible harmful effects on human health;

(31) Whereas scientific and technical progress may necessitate rapid adaptation of the technical requirements laid down in Annexes II and III; whereas, furthermore, in order to facilitate application of the measures required for that purpose, provision should be made for a procedure under which the Commission can adopt such adaptations with the assistance of a committee composed of representatives of the Member States;

(32) Whereas consumers should be adequately and appropriately informed of the quality of water intended for human consumption, of any derogations granted by the Member States and of any remedial action taken by the competent authorities; whereas, furthermore, consideration should be given both to the technical and statistical needs of the Commission, and to the rights of the individual to obtain adequate information concerning the quality of water intended for human consumption;

(33) Whereas, in exceptional circumstances and for geographically defined areas, it may be necessary to allow Member States a more extensive timescale for compliance with certain provisions of this Directive;

(34) Whereas this Directive should not affect the obligations of the Member States as to the time limit for transposition into national law, or as to application, as shown in Annex IV,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Objective

1. This Directive concerns the quality of water intended for human consumption.

2. The objective of this Directive shall be to protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean.

Article 2

Definitions

For the purposes of this Directive:

1. 'water intended for human consumption' shall mean:

   (a) all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers;

   (b) all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality

of the water cannot affect the wholesomeness of the foodstuff in its finished form;

2. 'domestic distribution system' shall mean the pipework, fittings and appliances which are installed between the taps that are normally used for human consumption and the distribution network but only if they are not the responsibility of the water supplier, in its capacity as a water supplier, according to the relevant national law.

Article 3

Exemptions

1. This Directive shall not apply to:

(a) natural mineral waters recognised as such by the competent national authorities, in accordance with Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters [1];

(b) waters which are medicinal products within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [2].

2. Member States may exempt from the provisions of this Directive:

(a) water intended exclusively for those purposes for which the competent authorities are satisfied that the quality of the water has no influence, either directly or indirectly, on the health of the consumers concerned;

(b) water intended for human consumption from an individual supply providing less than 10 m^3 a day as an average or serving fewer than 50 persons, unless the water is supplied as part of a commercial or public activity.

3. Member States that have recourse to the exemptions provided for in paragraph 2(b) shall ensure that the population concerned is informed thereof and of any action that can be taken to protect human health from the adverse effects resulting from any contamination of water intended for human consumption. In addition, when a potential danger to human health arising out of the quality of such water is apparent, the population concerned shall promptly be given appropriate advice.

Article 4

General obligations

1. Without prejudice to their obligations under other Community provisions, Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean. For the purposes of the minimum requirements of this Directive, water intended for human consumption shall be wholesome and clean if it:

(a) is free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health, and

(b) meets the minimum requirements set out in Annex I, Parts A and B;

and if, in accordance with the relevant provisions of Articles 5 to 8 and 10 and in accordance with the Treaty, Member States take all other measures necessary to ensure that water intended for human consumption complies with the requirements of this Directive.

2. Member States shall ensure that the measures taken to implement this Directive in no circumstances have the effect of allowing, directly or indirectly, either any deterioration of the present quality of water intended for human consumption so far as that is relevant for the protection of human health or any increase in the pollution of waters used for the production of drinking water.

Article 5

Quality standards

1. Member States shall set values applicable to water intended for human consumption for the parameters set out in Annex I.

2. The values set in accordance with paragraph 1 shall not be less stringent than those set out in Annex I. As regards the parameters set out in Annex I, Part C, the values need be fixed only for monitoring purposes and for the fulfilment of the obligations imposed in Article 8.

3. A Member State shall set values for additional parameters not included in Annex I where the protection

(1) OJ L 229, 30.8.1980, p. 1. Directive as last amended by Directive 96/70/EC (OJ L 299, 23.11.1996, p. 26).
(2) OJ 22 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

of human health within its national territory or part of it so requires. The values set should, as a minimum, satisfy the requirements of Article 4(1)(a).

Article 6

Point of compliance

1. The parametric values set in accordance with Article 5 shall be complied with:

(a) in the case of water supplied from a distribution network, at the point, within premises or an establishment, at which it emerges from the taps that are normally used for human consumption;

(b) in the case of water supplied from a tanker, at the point at which it emerges from the tanker;

(c) in the case of water put into bottles or containers intended for sale, at the point at which the water is put into the bottles or containers;

(d) in the case of water used in a food-production undertaking, at the point where the water is used in the undertaking.

2. In the case of water covered by paragraph 1(a), Member States shall be deemed to have fulfilled their obligations under this Article and under Articles 4 and 8(2) where it can be established that non-compliance with the parametric values set in accordance with Article 5 is due to the domestic distribution system or the maintenance thereof except in premises and establishments where water is supplied to the public, such as schools, hospitals and restaurants.

3. Where paragraph 2 applies and there is a risk that water covered by paragraph 1(a) would not comply with the parametric values established in accordance with Article 5, Member States shall nevertheless ensure that:

(a) appropriate measures are taken to reduce or eliminate the risk of non-compliance with the parametric values, such as advising property owners of any possible remedial action they could take, and/or

other measures, such as appropriate treatment techniques, are taken to change the nature or properties of the water before it is supplied so as to reduce or eliminate the risk of the water not complying with the parametric values after supply;

and

(b) the consumers concerned are duly informed and advised of any possible additional remedial action that they should take.

Article 7

Monitoring

1. Member States shall take all measures necessary to ensure that regular monitoring of the quality of water intended for human consumption is carried out, in order to check that the water available to consumers meets the requirements of this Directive and in particular the parametric values set in accordance with Article 5. Samples should be taken so that they are representative of the quality of the water consumed throughout the year. In addition, Member States shall take all measures necessary to ensure that, where disinfection forms part of the preparation or distribution of water intended for human consumption, the efficiency of the disinfection treatment applied is verified, and that any contamination from disinfection by-products is kept as low as possible without compromising the disinfection.

2. To meet the obligations imposed in paragraph 1, appropriate monitoring programmes shall be established by the competent authorities for all water intended for human consumption. Those monitoring programmes shall meet the minimum requirements set out in Annex II.

3. The sampling points shall be determined by the competent authorities and shall meet the relevant requirements set out in Annex II.

4. Community guidelines for the monitoring prescribed in this Article may be drawn up in accordance with the procedure laid down in Article 12.

5 (a) Member States shall comply with the specifications for the analyses of parameters set out in Annex III.

(b) Methods other than those specified in Annex III, Part 1, may be used, providing it can be demonstrated that the results obtained are at least as reliable as those produced by the methods specified. Member States which have recourse to alternative methods shall provide the Commission with all relevant information concerning such methods and their equivalence.

(c) For those parameters listed in Annex III, Parts 2 and 3, any method of analysis may be used provided that it meets the requirements set out therein.

6. Member States shall ensure that additional monitoring is carried out on a case-by-case basis of substances and micro-organisms for which no parametric value has been set in accordance with Article 5, if there is reason to suspect that they may be present in amounts or

numbers which constitute a potential danger to human health.

Article 8

Remedial action and restrictions in use

1. Member States shall ensure that any failure to meet the parametric values set in accordance with Article 5 is immediately investigated in order to identify the cause.

2. If, despite the measures taken to meet the obligations imposed in Article 4(1), water intended for human consumption does not meet the parametric values set in accordance with Article 5, and subject to Article 6(2), the Member State concerned shall ensure that the necessary remedial action is taken as soon as possible to restore its quality and shall give priority to their enforcement action, having regard *inter alia* to the extent to which the relevant parametric value has been exceeded and to the potential danger to human health.

3. Whether or not any failure to meet the parametric values has occurred, Member States shall ensure that any supply of water intended for human consumption which constitutes a potential danger to human health is prohibited or its use restricted or such other action is taken as is necessary to protect human health. In such cases consumers shall be informed promptly thereof and given the necessary advice.

4. The competent authorities or other relevant bodies shall decide what action under paragraph 3 should be taken, bearing in mind the risks to human health which would be caused by an interruption of the supply or a restriction in the use of water intended for human consumption.

5. Member States may establish guidelines to assist the competent authorities to fulfil their obligations under paragraph 4.

6. In the event of non-compliance with the parametric values or with the specifications set out in Annex I, Part C, Member States shall consider whether that non-compliance poses any risk to human health. They shall take remedial action to restore the quality of the water where that is necessary to protect human health.

7. Member States shall ensure that, where remedial action is taken, consumers are notified except where the competent authorities consider the non-compliance with the parametric value to be trivial.

Article 9

Derogations

1. Member States may provide for derogations from the parametric values set out in Annex I, Part B, or set in accordance with Article 5(3), up to a maximum value to be determined by them, provided no derogation constitutes a potential danger to human health and provided that the supply of water intended for human consumption in the area concerned cannot otherwise be maintained by any other reasonable means. Derogations shall be limited to as short a time as possible and shall not exceed three years, towards the end of which a review shall be conducted to determine whether sufficient progress has been made. Where a Member State intends to grant a second derogation, it shall communicate the review, along with the grounds for its decision on the second derogation, to the Commission. No such second derogation shall exceed three years.

2. In exceptional circumstances, a Member State may ask the Commission for a third derogation for a period not exceeding three years. The Commission shall take a decision on any such request within three months.

3. Any derogation granted in accordance with paragraphs 1 or 2 shall specify the following:

(a) the grounds for the derogation;

(b) the parameter concerned, previous relevant monitoring results, and the maximum permissible value under the derogation;

(c) the geographical area, the quantity of water supplied each day, the population concerned and whether or not any relevant food-production undertaking would be affected;

(d) an appropriate monitoring scheme, with an increased monitoring frequency where necessary;

(e) a summary of the plan for the necessary remedial action, including a timetable for the work and an estimate of the cost and provisions for reviewing;

(f) the required duration of the derogation.

4. If the competent authorities consider the non-compliance with the parametric value to be trivial, and if action taken in accordance with Article 8(2) is sufficient to remedy the problem within 30 days, the requirements of paragraph 3 need not be applied.

In that event, only the maximum permissible value for the parameter concerned and the time allowed to remedy the problem shall be set by the competent authorities or other relevant bodies.

5. Recourse may no longer be had to paragraph 4 if failure to comply with any one parametric value for a given water supply has occurred on more than 30 days on aggregate during the previous 12 months.

6. Any Member State which has recourse to the derogations provided for in this Article shall ensure that the population affected by any such derogation is promptly informed in an appropriate manner of the derogation and of the conditions governing it. In addition the Member State shall, where necessary, ensure that advice is given to particular population groups for which the derogation could present a special risk.

These obligations shall not apply in the circumstances described in paragraph 4 unless the competent authorities decide otherwise.

7. With the exception of derogations granted in accordance with paragraph 4 a Member State shall inform the Commission within two months of any derogation concerning an individual supply of water exceeding 1 000 m^3 a day as an average or serving more than 5 000 persons, including the information specified in paragraph 3.

8. This Article shall not apply to water intended for human consumption offered for sale in bottles or containers.

Article 10

Quality assurance of treatment, equipment and materials

Member States shall 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 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; the interpretative document and technical specifications pursuant to Article 3 and Article 4 (1) of Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products [1] shall respect the requirements of this Directive.

[1] OJ L 40, 11.2.1989, p. 12. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

Article 11

Review of Annexes

1. At least every five years, the Commission shall review Annex I in the light of scientific and technical progress and shall make proposals for amendments, where necessary, under the procedure laid down in Article 189c of the Treaty.

2. At least every five years, the Commission shall adapt Annexes II and III to scientific and technical progress. Such changes as are necessary shall be adopted in accordance with the procedure laid down in Article 12.

Article 12

Committee procedure

1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by a Commission representative.

2. The Commission representative shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt measures which shall apply immediately. However, if those measures are not in accordance with the committee's opinion, the Commission shall communicate them to the Council forthwith. In that event:

(a) the Commission shall defer application of the measures which it has adopted for a period of three months from the date of communication;

(b) the Council, acting by a qualified majority, may take a different decision within the time limit referred to in point (a).

Article 13

Information and reporting

1. Member States shall take the measures necessary to ensure that adequate and up-to-date information on the

quality of water intended for human consumption is available to consumers.

2. Without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment [1], each Member State shall publish a report every three years on the quality of water intended for human consumption with the objective of informing consumers. The first report shall cover the years 2002, 2003 and 2004. Each report shall include, as a minimum, all individual supplies of water exceeding 1 000 m³ a day as an average or serving more than 5 000 persons and it shall cover three calendar years and be published within one calendar year of the end of the reporting period.

3. Member States shall send their reports to the Commission within two months of their publication.

4. The formats and the minimum information for the reports provided for in paragraph 2 shall be determined having special regard to the measures referred to in Article 3(2), Article 5(2) and (3), Article 7(2), Article 8, Article 9(6) and (7) and 15(1), and shall if necessary be amended in accordance with the procedure laid down in Article 12.

5. The Commission shall examine the Member States' reports and, every three years, publish a synthesis report on the quality of water intended for human consumption in the Community. That report shall be published within nine months of the receipt of the Member States' reports.

6. Together with the first report on this Directive as mentioned in paragraph 2, Member States shall also produce a report to be forwarded to the Commission on the measures they have taken or plan to take to fultil their obligations pursuant to Article 6(3) and Annex I, Part B, note 10. The Commission shall submit, as appropriate, a proposal on the format of this report in accordance with the procedure laid down in Article 12.

Article 14

Timescale for compliance

Member States shall take the measures necessary to ensure that the quality of water intended for human consumption complies with this Directive within five years of its entry into force, without prejudice to Notes 2, 4 and 10 in Annex I, Part B.

[1] OJ L 158, 23.6.1990, p. 56.

Article 15

Exceptional circumstances

1. A Member State may, in exceptional circumstances and for geographically defined areas, submit a special request to the Commission for a period longer than that laid down in Article 14. The additional period shall not exceed three years, towards the end of which a review shall be carried out and forwarded to the Commission which may, on the basis of that review, permit a second additional period of up to three years. This provision shall not apply to water intended for human consumption offered for sale in bottles or containers.

2. Any such request, grounds for which shall be given, shall set out the difficulties experienced and include, as a minimum, all the information specified in Article 9(3).

3. The Commission shall examine that request in accordance with the procedure laid down in Article 12.

4. Any Member State which has recourse to this Article shall ensure that the population affected by its request is promptly informed in an appropriate manner of the outcome of that request. In addition, the Member State shall, where necessary, ensure that advice is given to particular population groups for which the request could present a special risk.

Article 16

Repeal

1. Directive 80/778/EEC is hereby repealed with effect from five years after the entry into force of this Directive. Subject to paragraph 2, this repeal shall be without prejudice to Member States' obligations regarding deadlines for transposition into national law and for application as shown in Annex IV.

Any reference to the Directive repealed shall be construed as a reference to this Directive and shall be read in accordance with the correlation table set out in Annex V.

2. As soon as a Member State has brought into force the laws, regulations and administrative provisions necessary to comply with this Directive and has taken the measures provided for in Article 14, this Directive, not Directive 80/778/EEC, shall apply to the quality of water intended for human consumption in that Member State.

Article 17

Transposition into national law

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within two years of its entry into force. They shall forthwith inform the Commission thereof.

When the Member States adopt those measures, these shall contain references to this Directive or shall be accompanied by such references on the occasion of their official publication. The methods of making such references shall be laid down by the Member States.

2. The Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 18

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Article 19

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 3 November 1998.

For the Council

The President

B. PRAMMER

ANNEX I

PARAMETERS AND PARAMETRIC VALUES

PART A

Microbiological parameters

Parameter	Parametric value (number/100 ml)
Escherichia coli (E. coli)	0
Enterococci	0

The following applies to water offered for sale in bottles or containers:

Parameter	Parametric value
Escherichia coli (E. coli)	0/250 ml
Enterococci	0/250 ml
Pseudomonas aeruginosa	0/250 ml
Colony count 22 °C	100/ml
Colony count 37 °C	20/ml

PART B

Chemical parameters

Parameter	Parametric value	Unit	Notes
Acrylamide	0,10	µg/l	Note 1
Antimony	5,0	µg/l	
Arsenic	10	µg/l	
Benzene	1,0	µg/l	
Benzo(a)pyrene	0,010	µg/l	
Boron	1,0	mg/l	
Bromate	10	µg/l	Note 2
Cadmium	5,0	µg/l	
Chromium	50	µg/l	
Copper	2,0	mg/l	Note 3
Cyanide	50	µg/l	
1,2-dichloroethane	3,0	µg/l	
Epichlorohydrin	0,10	µg/l	Note 1
Fluoride	1,5	mg/l	
Lead	10	µg/l	Notes 3 and 4
Mercury	1,0	µg/l	
Nickel	20	µg/l	Note 3
Nitrate	50	mg/l	Note 5
Nitrite	0,50	mg/l	Note 5
Pesticides	0,10	µg/l	Notes 6 and 7
Pesticides — Total	0,50	µg/l	Notes 6 and 8
Polycyclic aromatic hydrocarbons	0,10	µg/l	Sum of concentrations of specified compounds; Note 9
Selenium	10	µg/l	
Tetrachloroethene and Trichloroethene	10	µg/l	Sum of concentrations of specified parameters
Trihalomethanes — Total	100	µg/l	Sum of concentrations of specified compounds; Note 10
Vinyl chloride	0,50	µg/l	Note 1

Note 1: The parametric value refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.

Note 2: Where possible, without compromising disinfection, Member States should strive for a lower value.

For the water referred to in Article 6(1)(a), (b) and (d), the value must be met, at the latest, 10 calendar years after the entry into force of the Directive. The parametric value for bromate from five years after the entry into force of this Directive until 10 years after its entry into force is 25 µg/l.

Note 3: The value applies to a sample of water intended for human consumption obtained by an adequate sampling method (1) at the tap and taken so as to be representative of a weekly average value ingested by consumers. Where appropriate the sampling and monitoring methods must be applied in a harmonised fashion to be drawn up in accordance with Article 7(4). Member States must take account of the occurrence of peak levels that may cause adverse effects on human health.

Note 4: For water referred to in Article 6(1)(a), (b) and (d), the value must be met, at the latest, 15 calendar years after the entry into force of this Directive. The parametric value for lead from five years after the entry into force of this Directive until 15 years after its entry into force is 25 µg/l.

Member States must ensure that all appropriate measures are taken to reduce the concentration of lead in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

When implementing the measures to achieve compliance with that value Member States must progressively give priority where lead concentrations in water intended for human consumption are highest.

Note 5: Member States must ensure that the condition that [nitrate]/50 + [nitrite]/3 ≤ 1, the square brackets signifying the concentrations in mg/l for nitrate (NO_3) and nitrite (NO_2), is complied with and that the value of 0,10 mg/l for nitrites is complied with ex water treatment works.

Note 6: 'Pesticides' means:

- organic insecticides,
- organic herbicides,
- organic fungicides,
- organic nematocides,
- organic acaricides,
- organic algicides,
- organic rodenticides
- organic slimicides,
- related products (*inter alia*, growth regulators)

and their relevant metabolites, degradation and reaction products.

Only those pesticides which are likely to be present in a given supply need be monitored.

Note 7: The parametric value applies to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the parametric value is 0,030 µg/l.

Note 8: 'Pesticides — Total' means the sum of all individual pesticides detected and quantified in the monitoring procedure.

Note 9: The specified compounds are:

- benzo(b)fluoranthene,
- benzo(k)fluoranthene,
- benzo(ghi)perylene,
- indeno(1,2,3-cd)pyrene.

Note 10: Where possible, without compromising disinfection, Member States should strive for a lower value.

The specified compounds are: chloroform, bromoform, dibromochloromethane, bromodichloromethane.

For the water referred to in Article 6(1)(a), (b) and (d), the value must be met, at the latest, 10 calendar years after the entry into force of this Directive. The parametric value for total THMs from five years after the entry into force of this Directive until 10 years after its entry into force is 150 µg/l.

(1) To be added following the outcome of the study currently being carried out.

Member States must ensure that all appropriate measures are taken to reduce the concentration of THMs in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

When implementing the measures to achieve this value, Member States must progressively give priority to those areas where THM concentrations in water intended for human consumption are highest.

PART C

Indicator parameters

Parameter	Parametric value	Unit	Notes
Aluminium	200	µg/l	
Ammonium	0,50	mg/l	
Chloride	250	mg/l	Note 1
Clostridium perfringens (including spores)	0	number/100 ml	Note 2
Colour	Acceptable to consumers and no abnormal change		
Conductivity	2 500	µS cm^{-1} at 20 °C	Note 1
Hydrogen ion concentration	≥ 6,5 and ≤ 9,5	pH units	Notes 1 and 3
Iron	200	µg/l	
Manganese	50	µg/l	
Odour	Acceptable to consumers and no abnormal change		
Oxidisability	5,0	mg/l O_2	Note 4
Sulphate	250	mg/l	Note 1
Sodium	200	mg/l	
Taste	Acceptable to consumers and no abnormal change		
Colony count 22°	No abnormal change		
Coliform bacteria	0	number/100 ml	Note 5
Total organic carbon (TOC)	No abnormal change		Note 6
Turbidity	Acceptable to consumers and no abnormal change		Note 7

RADIOACTIVITY

Parameter	Parametric value	Unit	Notes
Tritium	100	Bq/l	Notes 8 and 10
Total indicative dose	0,10	mSv/year	Notes 9 and 10

Note 1: The water should not be aggressive.

Note 2: This parameter need not be measured unless the water originates from or is influenced by surface water. In the event of non-compliance with this parametric value, the Member State concerned must investigate the supply to ensure that there is no potential danger to human health arising from the presence of pathogenic micro-organisms, e.g. cryptosporidium. Member States must include the results of all such investigations in the reports they must submit under Article 13(2).

Note 3: For still water put into bottles or containers, the minimum value may be reduced to 4,5 pH units.

For water put into bottles or containers which is naturally rich in or artificially enriched with carbon dioxide, the minimum value may be lower.

Note 4: This parameter need not be measured if the parameter TOC is analysed.

Note 5: For water put into bottles or containers the unit is number/250 ml.

Note 6: This parameter need not be measured for supplies of less than 10 000 m^3 a day.

Note 7: In the case of surface water treatment, Member States should strive for a parametric value not exceeding 1,0 NTU (nephelometric turbidity units) in the water ex treatment works.

Note 8: Monitoring frequencies to be set later in Annex II.

Note 9: Excluding tritium, potassium -40, radon and radon decay products; monitoring frequencies, monitoring methods and the most relevant locations for monitoring points to be set later in Annex II.

Note 10:

1. The proposals required by Note 8 on monitoring frequencies, and Note 9 on monitoring frequencies, monitoring methods and the most relevant locations for monitoring points in Annex II shall be adopted in accordance with the procedure laid down in Article 12. When elaborating these proposals the Commission shall take into account *inter alia* the relevant provisions under existing legislation or appropriate monitoring programmes including monitoring results as derived from them. The Commission shall submit these proposals at the latest within 18 months following the date referred to in Article 18 of the Directive.

2. A Member State is not required to monitor drinking water for tritium or radioactivity to establish total indicative dose where it is satisfied that, on the basis of other monitoring carried out, the levels of tritium of the calculated total indicative dose are well below the parametric value. In that case, it shall communicate the grounds for its decision to the Commission, including the results of this other monitoring carried out.

ANNEX II

MONITORING

TABLE A

Parameters to be analysed

1. *Check monitoring*

The purpose of check monitoring is regularly to provide information on the organoleptic and microbiological quality of the water supplied for human consumption as well as information on the effectiveness of drinking-water treatment (particularly of disinfection) where it is used, in order to determine whether or not water intended for human consumption complies with the relevant parametric values laid down in this Directive.

The following parameters must be subject to check monitoring. Member States may add other parameters to this list if they deem it appropriate.

Aluminium (Note 1)

Ammonium

Colour

Conductivity

Clostridium perfringens (including spores) (Note 2)

Escherichia coli (E. coli)

Hydrogen ion concentration

Iron (Note 1)

Nitrite (Note 3)

Odour

Pseudomonas aeruginosa (Note 4)

Taste

Colony count 22 °C and 37 °C (Note 4)

Coliform bacteria

Turbidity

Note 1: Necessary only when used as flocculant (*).

Note 2: Necessary only if the water originates from or is influenced by surface water (*).

Note 3: Necessary only when chloramination is used as a disinfectant (*).

Note 4: Necessary only in the case of water offered for sale in bottles or containers.

(*) In all other cases, the parameters are in the list for audit monitoring.

2. *Audit monitoring*

The purpose of audit monitoring is to provide the information necessary to determine whether or not all of the Directive's parametric values are being complied with. All parameters set in accordance with Article 5(2) and (3) must be subject to audit monitoring unless it can be established by the competent authorities, for a period of time to be determined by them, that a parameter is not likely to be present in a given supply in concentrations which could lead to the risk of a breach of the relevant parametric value. This paragraph does not apply to the parameters for radioactivity, which, subject to Notes 8, 9 and 10 in Annex I, Part C, will be monitored in accordance with monitoring requirements adopted under Article 12.

TABLE B1

Minimum frequency of sampling and analyses for water intended for human consumption supplied from a distribution network or from a tanker or used in a food-production undertaking

Member States must take samples at the points of compliance as defined in Article 6(1) to ensure that water intended for human consumption meets the requirements of the Directive. However, in the case of a distribution network, a Member State may take samples within the supply zone or at the treatment works for particular parameters if it can be demonstrated that there would be no adverse change to the measured value of the parameters concerned.

Volume of water distributed or produced each day within a supply zone (Notes 1 and 2) m^3	Check monitoring number of samples per year (Notes 3, 4 and 5)	Audit monitoring number of samples per year (Notes 3 and 5)
≤ 100	(Note 6)	(Note 6)
> 100 ≤ 1 000	4	1
> 1 000 ≤ 10 000	4 + 3 for each 1 000 m^3/d and part thereof of the total volume	1 + 1 for each 3 300 m^3/d and part thereof of the total volume
> 10 000 ≤ 100 000		3 + 1 for each 10 000 m^3/d and part thereof of the total volume
> 100 000		10 + 1 for each 25 000 m^3/d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

Note 2: The volumes are calculated as averages taken over a calendar year. A Member State may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.

Note 3: In the event of intermittent short-term supply the monitoring frequency of water distributed by tankers is to be decided by the Member State concerned.

Note 4: For the different parameters in Annex I, a Member State may reduce the number of samples specified in the table if:

(a) the values of the results obtained from samples taken during a period of at least two successive years are constant and significantly better than the limits laid down in Annex I, and

(b) no factor is likely to cause a deterioration of the quality of the water.

The lowest frequency applied must not be less than 50 % of the number of samples specified in the table except in the particular case of note 6.

Note 5: As far as possible, the number of samples should be distributed equally in time and location.

Note 6: The frequency is to be decided by the Member State concerned.

TABLE B2

Minimum frequency of sampling and analysis for water put into bottles or containers intended for sale

Volume of water produced for offering for sale in bottles or containers each day (1) m^3	Check monitoring number of samples per year	Audit monitoring number of samples per year
≤ 10	1	1
> 10 ≤ 60	12	1
> 60	1 for each 5 m^3 and part thereof of the total volume	1 for each 100 m^3 and part thereof of the total volume

(1) The volumes are calculated as averages taken over a calendar year.

ANNEX III

SPECIFICATIONS FOR THE ANALYSIS OF PARAMETERS

Each Member State must ensure that any laboratory at which samples are analysed has a system of analytical quality control that is subject from time to time to checking by a person who is not under the control of the laboratory and who is approved by the competent authority for that purpose.

1. PARAMETERS FOR WHICH METHODS OF ANALYSIS ARE SPECIFIED

The following principles for methods of microbiological parameters are given either for reference whenever a CEN/ISO method is given or for guidance, pending the possible future adoption, in accordance with the procedure laid down in Article 12, of further CEN/ISO international methods for these parameters. Member States may use alternative methods, providing the provisions of Article 7(5) are met.

Coliform bacteria and *Escherichia coli (E. coli)* (ISO 9308-1)

Enterococci (ISO 7899-2)

Pseudomonas aeruginosa (prEN ISO 12780)

Enumeration of culturable microorganisms — Colony count 22 °C (prEN ISO 6222)

Enumeration of culturable microorganisms — Colony count 37 °C (prEN ISO 6222)

Clostridium perfringens (including spores)

Membrane filtration followed by anaerobic incubation of the membrane on m-CP agar (Note 1) at 44 ± 1 °C for 21 ± 3 hours. Count opaque yellow colonies that turn pink or red after exposure to ammonium hydroxide vapours for 20 to 30 seconds.

Note 1: The composition of m-CP agar is:

Basal medium

Tryptose	30 g
Yeast extract	20 g
Sucrose	5 g
L-cysteine hydrochloride	1 g
$MgSO_4 \cdot 7H_2O$	0,1 g
Bromocresol purple	40 mg
Agar	15 g
Water	1 000 ml

Dissolve the ingredients of the basal medium, adjust pH to 7,6 and autoclave at 121 °C for 15 minutes. Allow the medium to cool and add:

D-cycloserine	400 mg
Polymyxine-B sulphate	25 mg
Indoxyl-β-D-glucoside to be dissolved in 8 ml sterile water before addition	60 mg
Filter — sterilised 0,5% phenolphthalein diphosphate solution	20 ml
Filter — sterilised 4,5 % $FeCl_3 \cdot 6H_2O$	2 ml

2. PARAMETERS FOR WHICH PERFORMANCE CHARACTERISTICS ARE SPECIFIED

2.1. For the following parameters, the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness, precision and limit of detection specified. Whatever the sensitivity of the method of analysis used, the result must be expressed using at least the same number of decimals as for the parametric value considered in Annex I, Parts B and C.

Parameters	Trueness % of parametric value (Note 1)	Precision % of parametric value (Note 2)	Limit of detection % of parametric value (Note 3)	Conditions	Notes
Acrylamide				To be controlled by product specification	
Aluminium	10	10	10		
Ammonium	10	10	10		
Antimony	25	25	25		
Arsenic	10	10	10		
Benzo(a)pyrene	25	25	25		
Benzene	25	25	25		
Boron	10	10	10		
Bromate	25	25	25		
Cadmium	10	10	10		
Chloride	10	10	10		
Chromium	10	10	10		
Conductivity	10	10	10		
Copper	10	10	10		
Cyanide	10	10	10		Note 4
1,2-dichloroethane	25	25	10		
Epichlorohydrin				To be controlled by product specification	
Fluoride	10	10	10		
Iron	10	10	10		
Lead	10	10	10		
Manganese	10	10	10		
Mercury	20	10	20		
Nickel	10	10	10		
Nitrate	10	10	10		
Nitrite	10	10	10		
Oxidisability	25	25	10		Note 5
Pesticides	25	25	25		Note 6
Polycyclic aromatic hydrocarbons	25	25	25		Note 7

Parameters	Trueness % of parametric value (Note 1)	Precision % of parametric value (Note 2)	Limit of detection % of parametric value (Note 3)	Conditions	Notes
Selenium	10	10	10		
Sodium	10	10	10		
Sulphate	10	10	10		
Tetrachloroethene	25	25	10		Note 8
Trichloroethene	25	25	10		Note 8
Trihalomethanes — Total	25	25	10		Note 7
Vinyl chloride				To be controlled by product specification	

2.2. For hydrogen ion concentration the specified performance characterisatics are that the method of analysis used must be capable of measuring concentrations equal to the parametric value with a trueness of 0,2 pH unit and a precision of 0,2 pH unit.

Note 1 (*): Trueness is the systematic error and is the difference between the mean value of the large number of repeated measurements and the true value.

Note 2 (*): Precision is the random error and is usually expressed as the standard deviation (within and between batch) of the spread of results about the mean. Acceptable precision is twice the relative standard deviation.

(*) These terms are further defined in ISO 5725.

Note 3: Limit of detection is either:
- three times the relative within batch standard deviation of a natural sample containing a low concentration of the parameter,

  or
- five times the relative within batch standard deviation of a blank sample.

Note 4: The method should determine total cyanide in all forms.

Note 5: Oxidation should be carried out for 10 minutes at 100 °C under acid conditions using permanganate.

Note 6: The performance characteristics apply to each individual pesticide and will depend on the pesticide concerned. The limit of detection may not be achievable for all pesticides at present, but Member States should strive to achieve this standard.

Note 7: The performance characteristics apply to the individual substances specified at 25 % of the parametric value in Annex I.

Note 8: The performance characteristics apply to the individual substances specified at 50 % of the parametric value in Annex I.

3. PARAMETERS FOR WHICH NO METHOD OF ANALYSIS IS SPECIFIED

Colour
Odour
Taste
Total organic carbon
Turbidity (Note 1)

Note 1: For turbidity monitoring in treated surface water the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness of 25 %, precision of 25 % and a 25 % limit of detection.

ANNEX IV

DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW AND FOR APPLICATION

Directive 80/778/EEC Transposition 17.7.1982 Application 17.7.1985 All Member States except Spain, Portugal and new *Länder* of Germany	Directive 81/858/EEC (Adaptation due to accession of Greece)	Act of Accession of Spain and Portugal Spain: transposition 1.1.1986 application 1.1.1986 Portugal: transposition 1.1.1986 application 1.1.1989	Directive 90/656/EEC for new *Länder* of Germany	Act of Accession of Austria, Finland and Sweden Austria: transposition 1.1.1995 application 1.1.1995 Finland: transposition 1.1.1995 application 1.1.1995 Sweden: transposition 1.1.1995 application 1.1.1995	Directive 91/692/EEC
Articles 1 to 14			Application 31.12.1995		
Article 15	Amended with effect from 1.1.1981	Amended with effect from 1.1.1986		Amended with effect from 1.1.1995	
Article 16					
Article 17					Article 17(a) inserted
Article 18					
Article 19		Amended	Amended		
Article 20					
Article 21					

ANNEX V

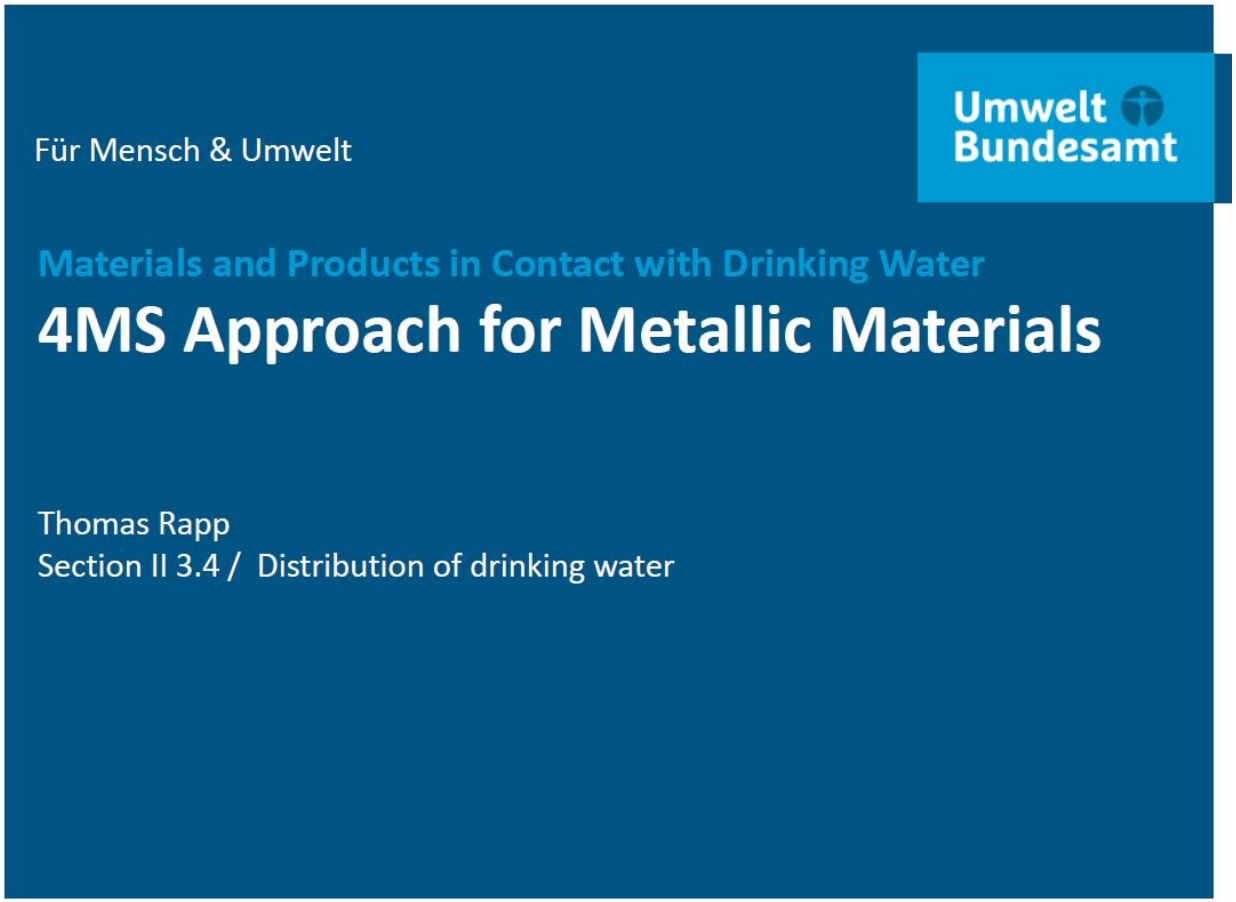
CORRELATION TABLE

This Directive	Directive 80/778/EEC
Article 1(1)	Article 1(1)
Article 1(2)	—
Article 2(1) (a) and (b)	Article 2
Article 2(2)	—
Article 3(1) (a) and (b)	Article 4(1)
Article 3(2) (a) and (b)	—
Article 3(3)	—
Article 4(1)	Article 7(6)
Article 4(2)	Article 11
Article 5(1)	Article 7(1)
Article 5(2) first sentence	Article 7(3)
Article 5(2) second sentence	—
Article 5(3)	—
Article 6(1)	Article 12(2)
Article 6(2) to (3)	—
Article 7(1)	Article 12(1)
Article 7(2)	—
Article 7(3)	Article 12(3)
Article 7(4)	—
Article 7(5)	Article 12(5)
Article 7(6)	—
Article 8	—
Article 9(1)	Article 9(1) and Article 10(1)
Article 9(2) to (6)	—
Article 9(7)	Article 9(2) and Article 10(3)
Article 9(8)	—
Article 10	Article 8

This Directive	Directive 80/778/EEC
Article 11(1)	—
Article 11(2)	Article 13
Article 12(1)	Article 14
Article 12(2) and (3)	Article 15
Article 13(1)	—
Article 13(2) to (5)	Article 17(a) (inserted by Directive 91/692/EEC)
Article 14	Article 19
Article 15	Article 20
Article 16	—
Article 17	Article 18
Article 18	—
Article 19	Article 21

附錄 7

4MS 金屬材料的測試方法



Overview

1 METAL RELEASE

2 4(5)MS APPROACH FOR METALS

3 CONCLUSIONS

Hygienic requirements for metals

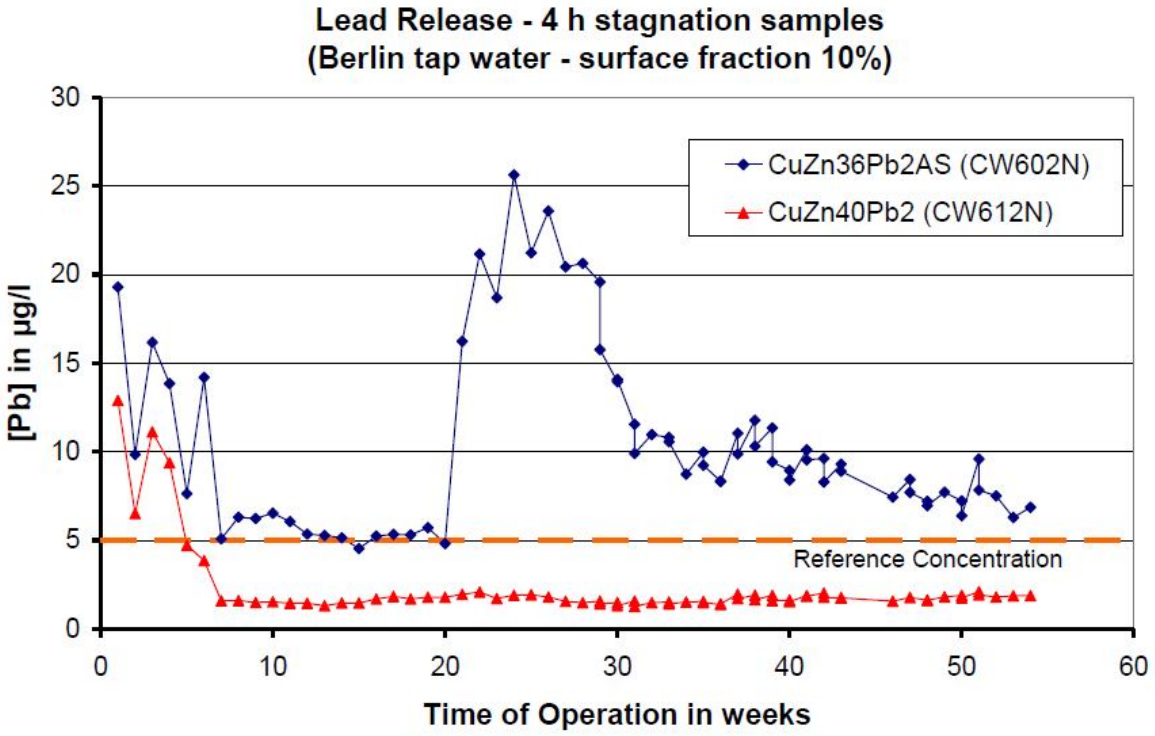
Metal Release

Depends on:

- Metal composition and surface characteristics
- Composition of drinking water
- Design of plumbing system
- Age of plumbing system
- Stagnation time

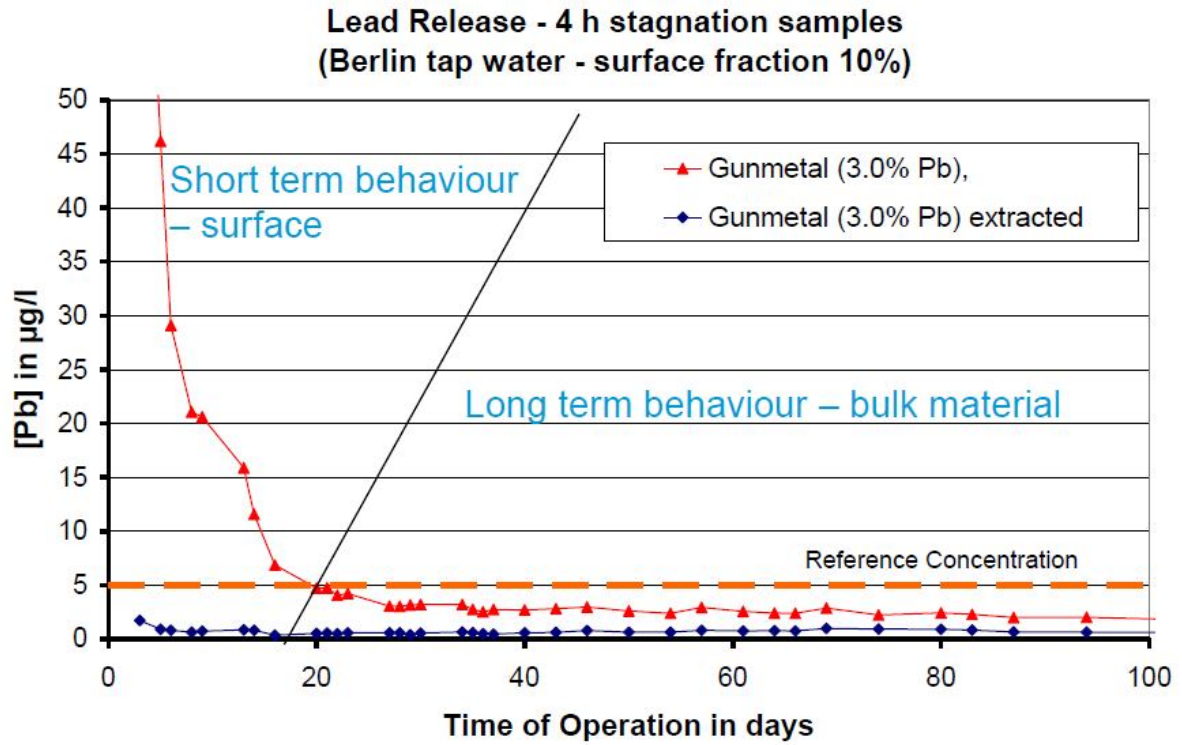
Hygienic requirements for metals

Metal Release



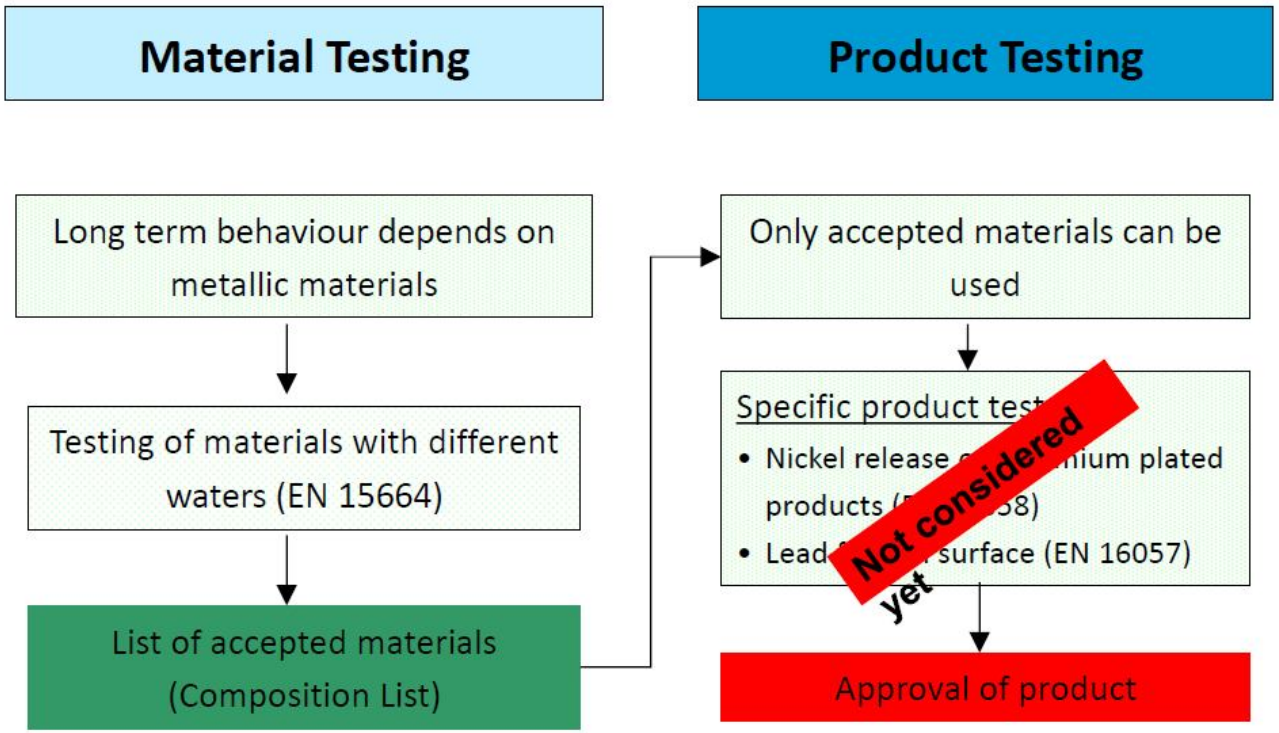
Hygienic requirements for metals

Metal Release



Hygienic requirements for metals

4(5)MS Approach for Metallic Materials



4(5)MS Approach for Metallic Materials

4 MS Common Approach: *Procedure for the Acceptance of Metallic Materials Used in Contact with Drinking Water*

1st revision 30th March 2011

Composition List: *3rd revision 20th December 2013*

www.umweltbundesamt.de/4MS.htm

4(5)MS Approach for Metallic Materials

List of accepted materials (Composition List)

- **Categories of materials (e.g. Copper-Zinc-Lead alloys)**
  - Reference material
  - Commercial alloys
- **Materials can be accepted for 3 product groups**
  - pipes,
  - fittings & ancillaries,
  - small parts in products

4(5)MS Approach for Metallic Materials

Procedure for the acceptance of materials for 4MS list

- **Acceptance in one of the MS acc. to 4MS concept**
  - Opinion will be circulated
  - Common acceptance

=> Common Composition List

Hygienic requirements for metals

4(5)MS Approach for Metallic Materials

Material test – EN 15664

Absolute Testing

For testing a **new reference material**

- Tests with 3 test waters
- Restricted composition

Comparative Testing

For testing a **commercial alloy** for an existing category

- Test against the reference material
- Test with 1 suitable test water
- Restricted composition of the test specimens

Hygienic requirements for metals

4(5)MS Approach for Metallic Materials

Material test – EN 15664-1

4(5)MS Approach for Metallic Materials

Material test – EN 15664-1

4(5)MS Approach for Metallic Materials

Material test – EN 15664-1

22 Flow periods per day (each 1 or 2 min)

Flow rate: 5 l/min

Total water flow: 145 l/d

Operation time: min. 26 weeks

Sampling: 8 samples after 0,5; 0,5; 1; 1; 2; 4; 8 and 16 h stagnation

4(5)MS Approach for Metallic Materials

Material test – EN 15664-2

Test Waters for Absolute Testing

	Characteristics	**pH**	$[HCO_3^-]$ in mmol/l	$[Cl^-] + [SO_4^{2-}]$ in mmol/l	**TOC in mg/l**
1	very hard, neutral water	7.1- 7.5	> 5	> 3	> 1.5
2	soft water, weakly acidic	6.7- 7.1	0.5- 1.3	-	-
3	soft water, alkaline	8.0- 8.4	0.7- 1.3	-	-

Hygienic requirements for metals

4(5)MS Approach for Metallic Materials

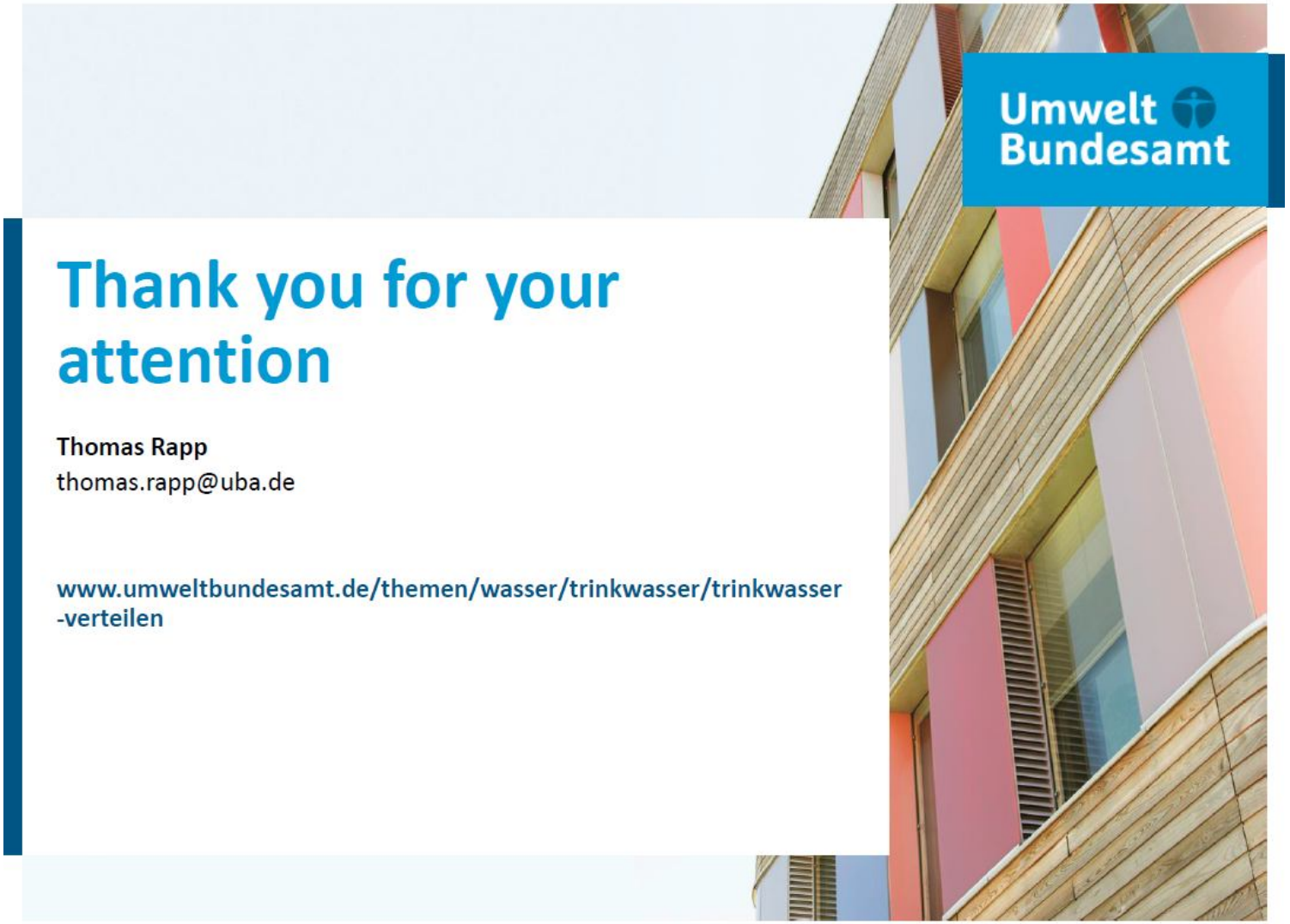
Acceptance criteria for Absolute Testing

Criteria	Acceptance Level
Compliance with reference concentrations	After 16 weeks (formation of corrosion layers)
Acceptable contribution to DWD parametric values (= reference concentration)	• 50%, if other source exist • 90%, if PDW are main source

Hygienic requirements for metals

Conclusion

- 4MS approach and common Composition List available
- National or European implementation necessary


Umwelt
Bundesamt
Thank you for your attention
Thomas Rapp
thomas.rapp@uba.de
www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen

附錄 8
TZW 檢驗技術

6

TZW
news

The Newsletter issued by TZW
The German Water Centre

Issue 6, 09/2017

DVGW

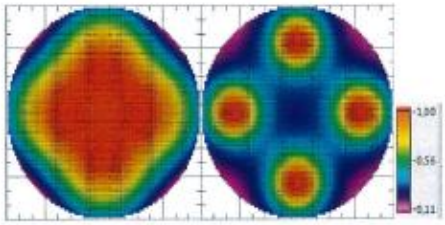
US AMERICAN AND GERMAN UV COOPERATION

Cooperative efforts between Carollo Engineers' UV validation facility in Portland, USA and TZW testing facility provide cost effective validation options for UV manufacturers.

The validation of ultraviolet (UV) disinfection systems has been key to its wider application for drinking water treatment over the past two decades. Regulatory approval is provided by different organisations in different parts of the globe. While in Europe regulatory acceptance is primarily governed by the German Technical and Scientific Association for Gas and Water (DVGW), in the United States the US Environmental Protection Agency (EPA) published the 2006 UV Disinfection Guidance Manual (UVDGM) for compliance with the standards of the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR).

Validation techniques differ between the various regulatory jurisdictions, and to gain global regulatory acceptance, UV equipment vendors must perform costly full-scale validation testing to meet the requirements of each. This often means vendors must ship UV equipment to more than one of the handful of validation test facilities worldwide, incurring substantial costs associated with installation, functional testing, biodosimetry testing and data analysis procedures stipulated by each regulatory jurisdiction.

The recently agreed collaboration between Carollo's Portland UV validation facility and the TZW testing facility in Germany allowed a major UV vendor to receive dual validation (US EPA UVDGM and DVGW) at a maximum flow of nearly 5,000 m³/h, not achievable by the German test facility, at the same time realising substantial cost savings by testing only at one facility. Further cooperative testing under the US EPA UVDGM protocol was conducted at the TZW test facility. This allowed two European vendors to conduct testing locally, thus reducing the costs associated with supporting validation testing in the United States, while achieving validation under US EPA UVDGM protocols.



Simulated distribution of UV LEDs

US EPA

Besides testing activities, TZW is involved in various research projects dealing with alternative UV sources, optimisation of energy efficiency and further fields of UV application like the treatment of industrial or municipal wastewater. In this context, a major research focus at TZW involves the replacement of currently dominant mercury vapor lamps by UV LEDs for disinfection purposes.

LED research

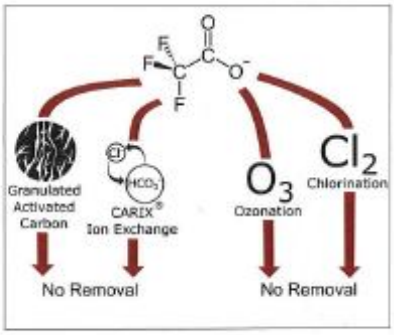
Jutta Eggers
Test Centre

Trifluoroacetate (TFA) challenges drinking water suppliers

Small, persistent and mobile organic trace contaminants increasingly attracted notice in TZW´s research over the last years. These chemicals are often difficult to analyse and to remove if present in water resources used for drinking water production.

Trifluoroacetic acid and its trifluoroacetate (TFA) salts are used for the synthesis of modern plant protecting agents and pharmaceuticals. TFA is the perfluorinated analogue of acetate and thus the perfluorinated carboxylate with the shortest possible chain length. Its direct anthropogenic emission in freshwaters is presumed to be low, but TFA occurs as an atmospheric transformation product upon photo-oxidation of fluorinated hydrocarbons containing trifluoromethyl moieties. Such compounds are used as refrigerants in air conditioning systems or as propellants. TFA is dislocated by precipitation and an average concentration of 0.14 µg/L in major German rivers has been reported more than a decade ago.

During screening of potable and surface waters in South-West Germany, outstanding TFA concentrations up to 100 µg/L were detected in a major stream, which led to the presence of more than 20 µg/L TFA in bank filtration based tap waters. Despite previously reported TFA-detections in tap waters, no information regarding treatment options were available.



Treatment behaviour

Several spatially resolved monitoring programs were conducted and an industrial discharger was identified as the point source of the extensive contamination. Commonly applied treatment options in waterworks like ozonation or filtration over granulated activated carbon proved to be inappropriate for TFA removal, whereas TFA might be partly removed by ion exchange and completely retained by reverse osmosis, with the high expenditure of energy, investment and operational costs. Further investigations identified wastewater treatment plants (WWTPs) as additional TFA dischargers. WWTP influents can even bear a TFA formation potential, when appropriate CF_3-containing precursors are present. Biological degradation and ozonation batch experiments with chemicals of different classes proved that there are more, yet overlooked sources and pathways of TFA.

formation potential

Heinz-Jürgen Brauch, Karsten Nödler, Marco Scheurer
Analysis and Water Quality

SIGN – SIno-German water supply Network

The quality of water is threatened by a variety of contaminants due to anthropogenic activities worldwide. A drastic example of such water pollution is the Taihu (Tai lake) in China. A German and Chinese consortium successfully cooperates to achieve good water quality from the source to the tap.

The region around the Taihu has undergone rapid industrial and economic growth in the last few decades. Especially the megacities Suzhou and Wuxi show an unprecedented population growth since 2000. A side-effect of the industrial and economic development is the decrease of the surface water quality and thus the impairment of the drinking water quality. Therefore, a powerful consortium comprising 25 German and Chinese research facilities, companies, and concerned stakeholders was formed. Since 2015, the SIno-German water supply network (SIGN, www.water-sign.de) funded by the BMBF is working on the quality of the lake, which serves as main water resource, and on the quality of drinking water. Assuring the supply with good quality water requires that the whole water cycle is taken into account: A powerful sewer system, a competent management of water resources with adapted monitoring strategies, a capable water treatment process as well as an efficient distribution of the drinking water.

English/Chinese project brochure

water cycle

Within this project, TZW is not only taking care of the coordination between the German

and Chinese partners, but also working on actual research topics regarding biodegradation processes and water quality of the Taihu. Among these topics, one focus was placed on the understanding of intrinsic biodegradation and nutrient removal regarding the nitrogen cycle in functional zones of the Taihu. Increasing nitrate contamination – not only in China but worldwide – is associated with agricultural activities, posing a risk to environmental and human health. Microbial denitrification can contribute to nitrate elimination. At TZW, new molecular monitoring methods are developed.

denitrification

Charlotte Schäfer, Andreas Tiehm
Microbiology and Molecular Biology

Innovative secure sensor networks and model-based assessment tools

The project ResiWater, a French-German cooperative project, aims to increase the resilience of water infrastructures by means of enhanced sensors and secure sensor networks, self-learning monitoring tools, robust simulation models and training simulator.

Water Distribution Systems (WDSs) are constantly exposed to deliberate or accidental contaminations or may undergo a partially or full system collapse. This could be caused by terrorist attacks, cascade effects, major technical accidents or natural disasters. The project ResiWater aims to develop tools to prepare water utilities for crisis management and enhance their resilience with regards to three specific case studies: collapse of WDS, water quality deterioration and cascade effects between water, energy and IT infrastructures.

IT infrastructures

For the realisation four main steps were defined: The first task is the specification of critical case studies especially by participating water utilities from Germany and France to assess the resilience of WDS. The second task is the design of integrated and secure sensor networks. This includes amongst other things the evaluation of the combined usage of different water quality sensors (sensor-networks). For this purpose standard sensors were installed in a model of a drinking water distribution network as well as in real drinking water distribution networks of participating water utilities. The third task is the development of a self-learning module for abnormal event detection. Here actual sensor readings from the whole sensor network are evaluated automatically to detect unusual patterns (anomalies). A fourth task is the development of robust hydraulic and water quality simulation tools for modelling of extreme events, like bursting of pipes.

event detection

Martin Wagner
Distribution Networks

Development of a standard test method for evaluating the removal efficiency of UF membranes

Within a research project funded by DVGW, a lab-based standard test method for the characterisation of ultrafiltration membranes with regard to their removal efficiency for viruses during drinking water treatment was developed.

Ultrafiltration (UF) is an emerging technology for the removal of particles during drinking water treatment. For safeguarding the hygienic quality of drinking water, the removal efficiency for microbial contaminations like viruses is of special interest. By definition, a UF membrane must achieve a 4-log reduction for particles in the 20 to 30 nm range.

UF modules

Within this project, membrane fibers and membrane modules were tested. As a result of the project, it was proposed to perform the tests only with large-scale modules but not with lab-scale modules. In the test MS2 phages in concentrations up to 10^6 PFU/mL were used as test organisms. During the test, the membrane fibers and modules were rinsed with water that causes no fouling of the membrane, and a stock solution of phages was added for a filtration period of 2 hours. Samples of the feed were taken

at the beginning and the end of the test, while samples of the filtrate were taken four times during the filtration period. During the tests some of the modules were backwashed on a regular basis representing practical conditions in large scale UF plants. The results of more than 60 tests showed that the test method was sensitive enough to distinguish between MF and UF membranes and to detect modules with low removal efficiency due to membrane failure or defect potting. As a result of the research project, a standardised test procedure for the determination of removal efficiencies of UF membranes for viruses was proposed.

membrane failure

Pia Lipp, Frank Sacher
Technology and Economics

TZW's new building

With the new building the TZW Water Campus was officially opened on July 5th by a ceremonial act, which was attended by 300 people from the national and international water business. Hereby, the environment minister of Baden-Wuerttemberg, Franz Untersteller, highlighted the importance of TZW for the whole water sector.

With the extension of TZW's working space with office rooms, laboratories and pilot plant stations spread over 2,500 m² on five levels, innovation in the technology and molecular biology sector will be considerably enhanced.

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附錄 9

有機材料指引

KTW Guideline-Guideline on the hygienic assessment of organic materials in contact with drinking water. (KTW 指引-與飲用水接觸的有機物質的衛生評估指南)

German Environment Agency

As at: 07 March 2016

RECOMMENDATION

Guideline on the hygienic assessment of organic materials in contact with drinking water (KTW Guideline)[1,2]

Only the German version of this document is legally binding.

1 Scope

1.1 Validity of this guideline

This Guideline defines hygienic requirements for plastics and silicones used in contact with drinking water.

This Guideline replaces the KTW Guideline dated 07 October 2008. It can be used for the hygienic assessment of plastics such as polyethylene, polypropylene, polybutene, polyvinylchloride, post-chlorinated polyvinyl chloride, cross-linked polyethylene, polyamide, polyurethane, polyester, and silicones. Furthermore, it contains requirements for the assessment of the testing in accordance with EN 16421 to prove the hygienic safety with regard to microbial growth.

Specific guidelines and recommendations have been published for the hygienic assessment of other organic materials:

For thermoplastic elastomers, the TPE Transitional Recommendation[3] on the hygienic assessment of products made from thermoplastic elastomers (TPEs) in contact with drinking water should be applied. In the case of non-covalent cross-linked TPEs this in turn refers back to this KTW Guideline.

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[1] Notified in accordance with Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations (OJ. L 204 dated 21.07.1998, p. 37), last amended under Section 26. 2 of Regulation (EU) No. 1025/2012 of the European Parliament and the Council dated 25 October 2012 (OJ. L 316 dated 14.11.2012, p. 12)

[2] Last amended on 07 March 2016, notified under 2013/470/D

[3] Recommendation on the provisional hygienic assessment of products made from thermoplastic elastomers in contact with drinking water (TPE Transitional Recommendation): https://www.umweltbundesamt.de/sites/default/files/medien/376/dokumente/recommendation_on_the_provisional_hygienic_assessment_of_products_made_from_thermoplastic_elastomers_in_contact_with_drinking_water.pdf

German Environment Agency
Section II 3.4
Heinrich-Heine-Str. 12
08645 Bad Elster

www.umweltbundesamt.de

For organic coatings and similar products, such as impregnating resins, grouting material, adhesives, aqueous plastic dispersions, plastic coatings, cementitious coatings with a polymer content > 25 % on the basis of epoxy resins, polyurethanes, polyamides, polyesters, polyacrylates or their mixtures, the "Guideline for the hygienic assessment of organic coatings in contact with drinking water (Coating Guideline)"[4] has been published.
For lubricants, the "Guideline for the hygienic assessment of lubricants in contact with drinking water (sanitary lubricants) (Lubricants Guideline)"[4] has been published.
For elastomers, the "Guideline for the hygienic assessment of elastomers in contact with drinking water (Elastomer Guideline)"[4] has been published.
Cement-bound materials are to be tested in accordance with DVGW Code of Practice W 347 "Hygiene requirements for cement-bound materials intended for use in drinking water supply systems - testing and evaluation".

1.2 Legal status

This Guideline is a revised version of the KTW Guideline dated 07.10.2008. It is also merely a recommendation and not yet an evaluation criteria within the meaning of the German Drinking Water Ordinance (TrinkwV 2001) in the amended version of 05.12.2012. The guideline is not legally binding.
It represents the current state of scientific and technical knowledge with regard to the hygienic requirements on organic materials in contact with drinking water.
It is planned to transfer this KTW-Guideline into an evaluation criteria in accordance with Section 17 (3) of the Drinking Water Ordinance (TrinkwV 2001) in the amended version of 05.12.2012, which will be legally binding two years after its publication.
In accordance with Section 17 (5) TrinkwV 2001 it can be assumed that products and procedures meet the requirements of Section 17 if this has been confirmed by a certificate from a certifier accredited in the field of drinking water. Until completion and entry into force of the evaluation criteria for plastics und silicones in accordance with Section 17, (2) TrinkwV 2001, this Guideline relating to conformity assessment and confirmation of harmlessness of plastics and silicones to human health may be consulted.
If certificates from another Member State of the European Union, a signatory to the Agreement on the European Economic Area or from Turkey are consulted for the assessment of conformity or confirmation of health safety, then the following conditions have to be met:

- The testing of materials or products shall be carried out in accordance with EN test methods, where available, and shall at least comply with the level of protection for existing regulations for materials and products in contact with foodstuffs.
- The assessment system used shall be transparent.

1.3 Further requirements

Organic materials in contact with drinking water have to be suitable for their intended use. The requirements in the technical regulations shall apply independently from this Guideline. The compliance of a product in contact with drinking water made from organic materials with generally accepted rules of technology and the requirements of TrinkwV 2001 can be shown via certification by a certification body accredited in the field of drinking water.

[4] https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/guidelines-evaluation-criteria

2 Organic materials in accordance with this Guideline

2.1 Plastics

Plastics are organic materials consisting mainly of polymers. These polymers are macromolecular substances produced from monomers or other substances by polymerisation processes such as poly-addition, poly-condensation, etc.

In addition to the polymers produced from the monomers as the main constituents, plastics may contain additives to ensure certain properties in the course of the production process or in the end product.

Polymerisation aids may also be contained in plastic:

- "Aids to Polymerisation (AtP)" have an influence on the polymerisation (e.g. catalysts, promoters) and are used in very small quantities. They may be present in the end product, but are not intended for it.
- "Polymer Production Aids (PPA)" are adjuvants in the production of plastics that only have a function in the manufacturing process and are not intended to have an effect in the end product. However, they may be present in the end product.

Under foodstuffs legislation, the requirements for the production of materials and articles made of plastic are regulated in the Regulation on plastic materials and articles intended to come into contact with food (Regulation (EU) No. 10/2011). The starting substances listed there can also be used for the manufacture of plastic products intended to come into contact with drinking water.

Polymerisation aids, solvents and pigments are not covered by the Regulation (EU) No. 10/2011, and they remain subject to national law. Within the scope of this Guideline, reference is made to the BfR recommendations (cf. Table 1) on the assessment of polymerisation aids.

2.2 Cross-linked plastics

Cross-linked plastics have polymer chains that are linked to one another by means of covalent bonds. The cross-linking can be formed by various procedures: Cross-linked polyethylene can be produced with the aid of peroxides (PE-Xa), with the aid of silanes (PE-Xb) or by radiation (PE-Xc). Only some of the cross-linking reagents currently used are listed in the Regulation (EU) No. 10/2011. Within the scope of this Guideline, reference is made additionally to the BfR recommendation "XLVI. Cross-linked Polyethylene" on the assessment of cross-linking materials.

2.3 Recycled plastics

The use of recycled plastics is limited to the use of recycled residues and off cuts arising in the course of production itself that have not been contaminated and have not been brought into circulation. It shall be ensured that the composition of the recycled material is known and has been notified and checked.

2.4 Silicones

2.4.1 Silicone products

Silicones intended for use in the field of drinking water consist of reactive silicone polymers, fillers, cross-linking reagents, catalysts and if necessary inhibitors, unreactive silicone polymers as plasticisers, pigments, or adhesion promoters. The cross-linking of the reactive polymer to silicone elastomers can be achieved by free-radical cross-linking with peroxide, by addition curing with platinum catalysts, or by condensation. Depending on the technology used, a distinction is made between high-temperature vulcanisation (HTV) and room-temperature vulcanisation (RTV). In the case of RTV, a further distinction is made between RTV-1 (single part) and RTV-2 (two part) types. A special case is the LSR-types (LSR = liquid silicone rubber), which are similar to the addition cured RTV-2 types, but which are vulcanised (cross-linked) at a higher temperature. All types have in common that the vulcanisation (cross-linking) produces a wide-meshed, elastic network with stable silicone-oxygen chains (siloxane structure).

Silicones used for tubing, equipment and preformed seals (without bonding) have usually been cured at higher temperatures, i.e. are of HTV or LSR types.

Within the scope of this Guideline, reference is made in the case of silicones to the positive list of the BfR Recommendation XV.[5]

2.4.2 Injectable silicone sealants

Silicone sealants are silicone formulations of the RTV-1 type. In this case, curing (vulcanisation) usually takes place at room temperature under the influence of air humidity.

Depending on the curing agent, a general distinction is made between acidic types (acetic acid) and neutral types (alcohol, oxime).

[5] https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp

For the assessment of the composition of RTV-1 silicone sealants, reference can be made to the positive list of the BfR Recommendation XV. An additional positive list in Annex 1 Part 2 is currently being drawn up.

2.5 Multi-layer structures

Products that are used in contact with drinking water may have a multi-layer structure. This can involve a number of layers of plastics, or one or more plastic layers in combination with layers of other materials. Where appropriate, other guidelines shall also be taken into account for the hygienic assessment, e.g. the Coating Guideline for adhesives.

If a product contains a total barrier, then hygienic assessment shall be carried out solely for the material layer that are on the side in contact with the drinking water. A total barrier prevents diffusion of all substances towards the drinking water contact side (continuous aluminium layer with a thickness of at least 9 µm or glass).

In addition to the total barrier there are also functional barriers, e.g. a layer of an ethylene-vinyl alcohol copolymer. These only slow down the diffusion of the migrating substances. Therefore, in these cases all layers are to be assessed in accordance with the relevant Guideline.

The multi-layer composite materials and the multi-layer plastic materials shall meet the requirements of this Guideline (cf. Section 3). For these products, an extended warm water migration test[6,7] is also necessary in addition to the cold water migration test in order to determine the migration behaviour of the substances from the layers under investigation into the drinking water (cf. Section 3 und 4). Multi-layer products are to be tested as such.

3 Requirements on the products within the context of this Guideline

3.1 Requirements on the composition

All substances used for the manufacture of products must be included in one of the positive lists of Table 1 or in Annex 1 according to their technological function. In the case of prematurely vulcanised or graft polymers, this requirement shall also apply for their monomers and other starting substances as well as for the starting substances of any additives. This requirement does not apply for marginal products (cf. 3.6).

For substances not included in the above-mentioned positive lists, the De Minimis Guideline can be drawn on, provided that the conditions specified therein are fulfilled. Solvents are usually not included in the positive lists (cf. Table 1). They are required as "Polymer Production Aids" for the production of plastics. They are only contained in the end product in very small amounts. For the assessment of the solvent in the formulations, the De Minimis Guideline can be drawn on.[8]

[6] Care shall be taken that substances are not extracted from the material during the warm water test.

[7] Instead of the warm water testing, the possible transfer of substances can be modelled.

[8] An extension of the *De Minimis* Guideline is planned.

For multi-layer products with a total barrier, only the layers on the drinking water side are to be assessed. The layer coming into contact with the drinking water is to be assessed in accordance with this Guideline. If further layers are to be assessed, then the corresponding Guidelines shall be drawn on for the materials in question.

For multi-layer products with a functional barrier, all layers are to be assessed. The layer coming into contact with the drinking water is to be assessed in accordance with this Guideline. For the assessment of all the other layers, the appropriate Guideline shall be drawn on according to the type of material. For the production of the layers on the side away from the drinking water substances may be used that are not contained in the positive lists if their migration into the drinking water is non detectable with a limit of detection of 0.1 µg/l. The unlisted substances shall not be mutagenic, carcinogenic or toxic to reproduction (Annex I Sections 3.5 ,3.6, and 3.7 of Regulation (EU) No. 1272/2008) and shall not have a nanostructure.

Substances used for the production of organic materials in contact with drinking water shall have a technical quality and purity that is suitable for the planned and envisaged use of the product.

Table 1 Positive lists of accepted starting substances with any limitations

Organic materials		Positive lists and evaluations
Plastics	Monomers and additives	Regulation (EU) No. 10/2011[9], German Consumer Goods Ordinance[10], European evaluations of EFSA (previously SCF)[11]
	Colourants and fillers	BfR Recommendations[12]: IX.-Colourants for plastics and other polymers used in commodities- and LII.-Fillers
	Polymerisation aids	In accordance with the evaluations of BfR for Germany (BfR Recommendations II, III, V, VI, VII, X, XI, XII, XVI, XVII, XX, XXII, XXV, XXXIII, XXXIV, XXXV, XXXVII, XXXIX, XLII, XLIII, L, and LI) Regulation (EU) 10/2011[9], German Consumer Goods Ordinance[10], assessments of EFSA (previously SCF)[11]

[9] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF

[10] https://www.juris.de/purl/gesetze/_ges/BedGgstV_!_10

[11] http://www.efsa.europa.eu/en/publications.htm

[12] https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp

Organic materials		Positive lists and evaluations
	Curing agent for cross-linked polyethylene	National evaluations of BfR Recommendation XLVI: "Cross-linked polyethylene" Regulation (EU) No. 10/2011, German Consumer Goods Ordinance, European evaluations of EFSA (previously SCF)
	Biocide additive[13]	Biocides evaluated by EFSA/SCF Biocides may only be used as preservatives for products during storage.
	Other starting substances	Supplementary positive list in Annex 1 of this Guideline
Silicones	Starting substances	BfR Recommendation XV. silicones, Supplementary positive list in Annex 1 of this Guideline (in preparation)

3.2 Basic requirements

The external characteristics (odour/flavour/ turbidity/colour/foaming) of the migration water in accordance with EN 12873-1 or EN 12873-2 shall not be changed.

For the ***cold water test***, the following threshold odour number (TON) and threshold flavour number (TFN) limits apply:

TON and TFN < 2	for the 3rd migration period in accordance with EN 1420-1, in the case of extension of the migration tests the 9th migration period in accordance with EN 1420-1.

For the ***warm water test***:

TON and TFN ≤ 4	for the 7th migration period in accordance with EN 1420-1, in the case of extension of the migration test the 22nd migration period in accordance with EN 1420-1.

In addition, the TON and TFN from tests in accordance with EN 1420-1 must not show an upward trend[14].

[13] Bringing the biocide onto the market is regulated in Regulation (EU) No. 528/2012.

[14] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

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For the release of organic substances, measured as total organic carbon (TOC) the following applies:

For the ***cold water test:***

$DWPLL_{TOC} = 0.5$ mg/l

$c_{Tap} \leq DWPLL_{TOC}$ for the 3rd migration period in accordance with EN 12873-1 (or EN 12873-2), or in the case of extension of the migration test the 9th migration period in accordance with EN 12873-1 (or EN 12873-2).

For the ***warm water test*** the following applies:

$DWPLL_{TOC} = 0.5$ mg/l

$c_{Tap} \leq DWPLL_{TOC}$ for the 7th migration period in accordance with EN 12873-1 (or EN 12873-2), or in the case of extension of the migration test the 22nd migration period in accordance with EN 12873-1 (or EN 12873-2).

The TOC is determined as non-purgeable organic carbon (NPOC) in accordance with EN 1484.

In addition, the measured concentrations in the migration water in accordance with EN 12873-1 (or EN 12873-2) must not show an upward trend[15].

3.3 Additional requirements

The additional requirements in Table 2 for plastics and in Table 3 for silicones shall apply. These requirements do not apply for marginal products (cf. 3.6)

If the applicable additional requirement presents a migration limit in the form of a Drinking Water Positive List Limit value (definition cf. 3.4), then the migration shall be investigated in accordance with 4.3.1 and compared with the given DWPLL value.

For the ***cold water test*** the following applies:

$c_{Tap} \leq DWPLL$ for the 3rd migration period in accordance with EN 12873-1 (or EN 12873-2), in the case of extension of the migration test the 9th migration period in accordance with EN 12873-1 (or EN 12873-2).

For the ***warm water test*** the following applies:

$c_{Tap} \leq DWPLL$ for the 7th migration period in accordance with EN 12873-1 (or EN 12873-2), in the case of extension of the migration test the 22nd migration period in accordance with EN 12873-1 (or EN 12873-2).

In addition, the measured concentrations in the migration water in accordance with EN 12873-1 (or EN 12873-2) must not show an upward trend.[15]

[15] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

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Table 2 Additional requirements for plastics

Substance/substance groups	DWPLL in µg/l	Analysis method[16]
Sum of primary aromatic amines (PAAs)[17] for plastics that contain PAAs or for which PAAs may be generated in the course of their production (e.g. polyamides, polyurethane)	ND [18] (0.1 µg/l)	Specific proof with GC-ECD/GC-MS with derivatisation[19]
For the use of substances from the following substance groups:		
Heavy metal catalysts	10 % of the limit value in the TrinkwV 2001 (e.g. chromium 5 µg/l, nickel 2 µg/l)	DEV[20]
Peroxides	No peroxide on the surface of the product	58th Announcement[21]
Fillers	Purity requirements in accordance with BfR Recommendation LII[22]	
Colourants	Requirements in accordance with BfR Recommendation IX[22].	
Polymerisation aid	Requirements in accordance with the BfR Recommendations (II., III., V., VI., VII., X., XI., XII., XVI., XVII., XX., XXII., XXV., XXXIII., XXXIV., XXXV., XXXVII., XXXIX., XLII., XLIII., L. and LI. BfR Recommendation)[22]	

[16] Other equivalent analytic methods may be used.

[17] Excepting PAAs authorised in Regulation EU 10/2011.

[18] Non detectable

[19] Analysis method: Pietsch et al (1996) Fresenius j. Anal. Chem. 355:164-173 or Pietsch et. al. (1997) Vom Wasser 88: 119-135

[20] German standard methods for the examination of water, waste water and sludge (DEV)

[21] German Federal Health Gazette 40 (1997)412

[22] Compliance of the substance in question with the purity requirements can be confirmed by a conformity declaration of the supplier.

Table 3 Additional requirements for silicones

Substance/substance groups	Requirement	Analysis method
Silicone oils	Purity requirements for the given starting substances[23], Note the quantity limit with regard to the formulation and migration limits	
Silicone resins		
Silicone elastomers		
Silicone elastomers	Volatile and extractable portions of not more than 0.5 % in each case	61st Announcement[24] or GC-MS-Screening[25]
Peroxides	No peroxide on the surface of the product	58th Announcement[26]

3.4 Requirements for individual substances in formulations

The positive lists specified in Table 1 and the evaluations of EFSA may contain limits on migration. In the context of this Guideline, migration limits are expressed in the form of a Drinking Water Positive List Limit (DWPLL).

The DWPLL is a provisional drinking water limit value for material-specific substances derived from human toxicology and serves to quantify an acceptable substance migration in the test system at the time specified in the Guideline.

The DWPLL is derived from the Tolerable Daily Intake (TDI) or Acceptable Daily Intake (ADI). A daily intake of 2 l of drinking water is assumed, with a body weight of 60 kg, and a 10 % proportion of the overall exposure for given substance through drinking water (WHO Concept).

The DWPLL value can also have been calculated from a specific migration limit (SML) of Regulation (EU) No. 10/2011 using the formula DWPLL = 1/20 SML of the German Federal Environment Agency (UBA), or has been derived by the UBA in cooperation with the German Federal Institute for Risk Assessment (BfR) in accordance with the principles of the EFSA.

[23] Compliance of the substance in question with the purity requirements can be confirmed by a conformity declaration of the supplier.

[24] German Federal Health Gazette 46 (2003) 362

[25] KOCH, Andreas: Gaschromatographische Verfahren zum Nachweis der Freisetzung von Inhaltsstoffen aus Polymermaterialien im Trinkwasserkontakt. 1st Ed. Osnabrück: Der Andere Verlag, 2004 -ISBN 3-89959-225-5

[26] German Federal Health Gazette 46 (2003) 362

The DWPLL values are calculated from the SML values as shown in Table 4.

Table 4 Deriving a DWPLL value

Level	Applicable for	Limit
0	Humans	TDI [mg/kg BW d][27]
1	Drinking water	$DWPLL = \frac{TDI \cdot 60 kgBW}{2l/d} \cdot 0.1$ $[mg/l] = \frac{[mg/kgBW \cdot d] \cdot kgBW}{[l/d]}$ DWPLL= 1/20 SML

If in Regulation (EU) No. 10/2011 a SML value is specified as "non detectable", e.g. for acrylonitrile, the limit of detection is 0.1 µg/l.

All substances with a migration limit that are contained in the product shall be tested for their migration in accordance with 4.3. The concentration determined in the test shall be used to calculate the maximum concentration to be expected at the tap, c_{Tap} (cf. 4.3.3). These requirements do not apply for marginal products (cf. 3.6).

Instead of the experimental investigation, the migration can also be estimated with the aid of the Modelling Guideline[28] (cf. 4.3.2).

It is not necessary to test substances with a specific migration limit (SML) in Regulation (EU) No. 10/2011 whose SML-value multiplied by the ratio of the carbon molar mass of the substance (M_C) to the total molar mass (M_{total}) is greater than or equal to 10 mg/l. For the migration limit it is then sufficient to check the TOC parameter of the basic requirements.

$$SML \times \frac{M_C}{M_{total}} \geq 10\ mg/l$$

For substances with a QM or QMA limit in accordance with Regulation (EU) No. 10/2011, an examination of the residual content of the substance in the product is required. The QM and QMA limits apply whatever the product group of the organic material is.

If a substance with a QMA limit can be determined in the test water, then the requirement may also be tested with the aid of a migration test. In this case it is assumed that 1 kg of food is contained in a cube with a surface area of 6 dm², a SML value is then derived from the QMA value, from which in turn the DWPLL can be derived in accordance with Table 4:

$$DWPLL = {}^{1}/_{20} \times \text{QMA} \times {}^{6\text{dm}^2}/_{1\text{kg}}$$

[27] BW (body weight)

[28] Guideline for the mathematical estimate of the migration of individual substances from organic material in drinking water

For some substances, both a migration limit and a QM or QMA value is given. In such cases, only one limit is to be tested. However, preference should be given to the DWPLL value.

For the ***cold water test*** the following applies:

$c_{Tap} \leq$ DWPLL — for the 3rd migration period in accordance with EN 12873-1 (or EN 12873-2), or in the case of extension of the migration test the 9th migration period in accordance with EN 12873-1 (or EN 12873-2).

For the ***warm water test*** the following applies:

$c_{Tap} \leq$ DWPLL — for the 7th migration period in accordance with EN 12873-1 (or EN 12873-2), or in the case of extension of the migration test the 22nd migration period in accordance with EN 12873-1 (or EN 12873-2).

In addition, the measured concentrations must not show an upward trend[29].

3.5 Requirements for the testing of the growth of microorganisms

3.5.1 Various test methods

The enhancement of microbial growth is tested in accordance with EN 16421. The test can be carried out on material plates, end products, or parts of end products (for more details see EN 16421).

In 4.4, requirements are specified for the application of the various test methods in accordance with EN 16421.

3.5.2 Requirements for testing in accordance with the biomass production potential (BPP), measured by adenosine triphosphate (ATP) - Method 1

A product shall be deemed appropriate for contact with drinking water with respect to the enhancement of microbial growth if the
biomass production potential (BPP) ≤ 1000 pg ATP /cm².

3.5.3 Requirements for tests in accordance with the volumetric method - Method 2

a) Products which, in all investigated test periods, have only a firmly adhering surface colonisation (comparison between the contact culture /the swab of the test specimen and the negative control) or surface growth ≤ (0.05 + 0.02) ml/800 cm², meet the requirements of this Guideline and are suitable for general use in connection with drinking water.

[29] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

b) For products to be used for large contact area seals[30] a limit value applies of (0.12 + 0.03) ml /800 cm². With the exception of the first month one value (1a), values shall not exceed (0.12 + 0.03) ml /800 cm². The values plus measurement limit errors shall be constant or show a declining trend, i.e. 1c ≤ 1b and 3a ≤ 2a (cf. Table 5).

c) For products to be used for small-area seals[31], the limit value is (0.20 + 0.03) ml /800 cm². With the exception of the first month one value (1a), values shall not exceed (0.20 + 0.03) ml /800 cm². The values plus measurement limit errors shall show a constant or declining trend, i.e. 1c ≤ 1b and 3a ≤ 2a (cf. Table 5).

d) For large contact area seals under b) and small contact area seals under c) the following additional assessment option applies on the basis of optional monthly values. The optional monthly values are only determined in those cases where materials or products are to be used as large contact area or small contact area seals and where the first month one value (1a) is below the relevant limit value, but the second month one value (1b) is above it (cf. Annex 6).

e) Products which show no surface growth and no surface colonisation (comparison of the contact culture /the swab of the test specimen with the negative control), do not meet the requirements of this Guideline for use in connection with drinking water.

[30] Large contact area seals and sealing filler for expansion joints; expansion units, equalisation pieces, and silencers; slides (tapered seals with seal coating); flaps, if the slider is coated; air valves if the ball is coated; membranes of pressure reducers; hydrants, if the stop valve is coated; plunger valves

[31] Other seals and adhesives (but not tile adhesives). All pipe connections not specified in D1 with elastic sealing elements, such as flange gaskets, screw-Tyton and plug-in sleeves, rolling rubber ring and rotating ring seals, fittings. All shut-off devices not specified as large contact area seals, such as slides with enclosed or surrounding seals, housing seals, spindle seals and tapered seals (with inserted profile seal). All flaps and non-return valves not specified as large contact area seals, if the flap surfaces are not coated. All valves not specified as large contact area seals

Table 5 Overview for assessment without optional monthly values

Type of material/ product	1-Monthly samples			2-Monthly sample	3-Monthly sample
	Sample 1a	Sample 1b	Sample 1c	Sample 2a	Sample 3a
All materials for general use in the field of drinking water (3.5.3 a)	All values ≤ (0,05 + 0,02) ml / 800 cm²				
Materials to be used as large seals (3.5.3 b, d)	If 1a ≥ 1b, 1a will not be subject to evaluation (in case 1a is much smaller than 1b cf. "optional monthly values")		All values ≤ (0.12 + 0.03) ml / 800 cm² where 1c ≤ 1b and 3a ≤ 2a		
Materials to be used as small seals (3.5.3 c, d)	If 1a ≥ 1b, 1a will not be subject to evaluation (in case 1a is much smaller than 1b cf. "optional monthly values")		All values ≤ (0.20 + 0.03) ml / 800 cm² where 1c ≤ 1b and 3a ≤ 2a		

3.6 Marginal products

Products with a conversion factor smaller than or equal to 0.001 d/dm (cf. Table 6), can be regarded as marginal products. The starting substances of these products need not be assessed or included in one of the positive lists. Requirements for the migration of individual substances as well as additional requirements do not apply to these products and a corresponding test is therefore not necessary. However, basic requirements do apply (for TOC, odour, flavour, and external characteristics). Testing the enhancement of growth of microorganisms is necessary.

4 Testing

4.1 Formulation review

The formulation shall be declared in accordance with the disclosure sheet (Annex 2). All constituents of the formulation shall be entered on the disclosure sheet. The conformity of the formulation constituents with the positive lists in Table 1 and the supplementary positive list in Annex 1 shall be confirmed. Not only the entries of substances has to be checked, but also the stated restrictions on use, e.g. in terms of the technological function. For silicones and polymerisation aids, the relevant restrictions in accordance with der BfR Recommendations are also to be examined (e.g. maximum quantity to be used, residual contents).

For the examination of the formulation of multilayer products, the formulation of each layer shall be declared separately in accordance with the disclosure sheet in Annex 2. An explanation of the layer structure shall be provided. The appropriate Guidelines shall be used for the assessment of the individual layers corresponding to the type of material in each case. For products with a total barrier, the layers not on the drinking water side of the barrier do not have to be assessed.

On the basis of the formulation presented, the test parameters shall be determined in accordance with Section 3.

4.2 Test pieces

The production process has an influence on the properties of a product. For this reason, tests of hygienic properties shall be carried out on the finished product or component.

Pipes, composite pipes, and single-layer and multi-layer hoses shall be tested by filling.

For products with the same formulation produced by the same method in a factory (e.g. injection-moulded parts, or seals of different shapes), the test can be carried out with a sample product representative of a series of products.

If it is not possible to test the finished product, the single layer materials can be tested using test plates measuring approximately 200 x 200 x 2 mm. The test plates shall have the same formulation and shall be produced according to the same temperature and time specifications as the product itself (Annex 4 of the Guideline).

Multi-layer materials, consisting of linings, intermediate layers, or inserts of individual substances, the individual components of which may have an influence by diffusion on the surface in contact with water, shall be tested as multilayer products or multilayer product components.

For testing in accordance with EN 16421, either material sheets, end products, or parts of end products may be used.

4.3 Testing migration

4.3.1 Carrying out migration tests

According to the scope of application of the product the migration test shall be performed as a cold water test at (23 ± 2) °C and if appropriate also as a warm water test (60 ± 2) °C or hot-water test (85 ± 2) °C.

The migration water samples are produced in accordance with the standards EN 1420-1, EN 12873-1, or EN 12873-2. Annex 3 provides a brief description of the migration test and includes additional requirements. The migration water samples are to be analysed for the parameters in accordance with the basic requirements, additional requirements, and formulation-specific requirements for an individual substance for the proposed product group. Careful records shall be kept of the testing process and the test results (cf. 4.3.4).

If c_{Tap} for one or more substances, the TOC value, TON or TFN in the 3rd migration period of the cold water test is above the test value (cf. 3.2) or shows an upward trend[32], then the testing can be extended to the 9th migration period in accordance with Annex 3.

If c_{Tap} for one or more substances, the TOC value, or TON and TFN in the 7th migration period of the warm water or hot water testing is above the test value (cf. 3.2) or indicates an upward trend[33], then the testing can be extended to the 22nd migration period in accordance with Annex 3.

For products made up of multiple layers, the warm water test shall be carried out with 22 migration periods[34]. This is intended to register substance migration from the outer layers.

Standardised methods shall be used to analyse the migration water samples. If no such methods currently exist for a certain substance, then an analysis method with a suitable sensitivity shall be used that allows the detection of the specified concentration. If no analytical methods are available for an individual substance, then the migration for this substance shall be estimated, e.g. in accordance with the Modelling Guideline.

4.3.2 Modelling

In place of the experimental test, migration for the formulation-dependent requirements for individual substances can also be assessed by means of the modelling guideline[35] if applicability of generally recognised diffusion models based on scientific evidence and parameters was defined.

In the report of Simoneau[36] specific parameters for the most important organic materials being in food contact are contained.

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[32] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

[33] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

[34] Care shall be taken that substances are not extracted from the material during the warm water test. Instead of the warm water test the possible substance migration can be modelled.

[35] Guideline for the mathematical estimate of migration of individual substances from organic materials in the drinking water

[36] Simoneau C. (ed) (2010). Publication Office of the European Union, Luxembourg. JRC Scientific and Technical Report, EUR 24514 EN. "Applicability of generally recognised diffusion models for the estimation of specific

In the case of other organic materials used in contact with drinking water these parameters must be determined specifically for each material or product before modelling can be applied. Testing necessary for that purpose is also described in the above mentioned test.

A prerequisite for the modelling is the determination of the amount of the relevant substance in the product tested ($c_{P,0}$).

The method of analysis for determining $c_{P,0}$ for the polymer must be presented by the raw material supplier if there is no validated method available from the "Community Reference Laboratory for Food Contact Materials" or a standard. Alternatively $c_{P,0}$ can be used from the required quantity if the substance does not change during the manufacture and processing of the product.

Modelling must consider the respective test conditions (test temperature and test cycle) under this Guideline (see Annex 3). The concentration profile for the previous test period is used to calculate the migration for the following test period. This is described in detail in the modelling guideline.

If a product does not meet the requirements of the Guideline concerning individual substances to be tested after modelling of migration, proof can still be provided by way of experimental testing. The results of experimental tests must be weighted higher than those of the modelling.

4.3.3 Calculating the maximum concentration to be expected at the tap (c_{Tap})

The maximum concentrations to be expected at the tap (c_{Tap}) differ for the various product groups depending on the conversion factors given in Table 6:

$$c_{Tap} = \frac{F_c \times c_m}{A/V \times t}$$

where:

F_C: Conversion factor in Table 6

c_m: The concentration measured in the migration water in accordance with EN 12873-1

A/V: Surface area to volume ratio in accordance with EN 12873-1

t: Duration of the migration period in accordance with EN 12873-1

In Table 6, distinctions are made between the product groups pipes, containers, and fittings, with the requirements being further differentiated according to the place of use in the water distribution system. The fittings and seals are allocated to the relevant pipe dimensions.

migration in support of EU Directive 2002/72/EC" under

17 http://publications.jrc.ec.europa.eu/repository/handle/111111111/14935

Table 6 Product groups with the relevant conversion factors

Product group	Conversion factor Fc in d/dm
Pipes with DN[37] < 80 mm (service and domestic pipes)	20
Pipes with 80 mm ≤ DN < 300 mm (distribution pipes)	10
Pipes with DN ≥ 300 mm (large distribution, mains)	5
Fittings for pipes with DN < 80 mm	4
Fittings for pipes with 80 mm ≤ DN < 300 mm	2
Fittings for pipes with DN ≥ 300 mm	1
Seals for pipes with DN < 80 mm	0.4
Seals for pipes with 80 mm ≤ DN < 300 mm	0.2
Seals for pipes with DN ≥ 300 mm	0.1
Containers in the drinking water installation including repair systems	4
Containers outside the drinking water installation including repair systems	1
Repair systems for containers in the drinking water installation with 1/100 of the surface area of the container	0.04
Repair systems for containers outside the drinking water installation with 1/100 of the surface area of the container	0.01
Small contact area components of materials for pipes with DN < 80 mm that are only installed in one place in the distribution system (e.g. plain bearing of a pump)	0.004
Small contact area components of materials for pipes with 80 mm ≤ DN < 300 mm, that are only installed in one place in the distribution system (e.g. plain bearing of a pump)	0.002
Small contact area components of materials for pipes with DN ≥ 300 mm, that are only installed in one place in the distribution system (e.g. plain bearing of a pump)	0.001

In Annex 5 of the KTW Guideline, typical products are assigned to the product groups given in Table 6.

[37] Internal diameter - ID

4.3.4 Test report

A test report shall be produced including the complete test results in accordance with Tables 4 and 5 of Annex 3 of the Guideline and attached as Annex I to the report. Compliance with the requirements for individual substances (DWPLL values) that are subject to confidentiality are recorded as the number of substances and the note "Test value complied with". The test report shall consist of the following annexes:

Annex I: Table with the full test results (cf. Annex 3 to the Guideline), if necessary with documentation of the modelling

Annex II: Declaration of the formulation (Annex 2 to the Guideline, completed and signed by the producer/ applicant and the test laboratory),

Annex III: Records of the production of the test specimen

Annex IV: Records of the test procedure (cf. 4.3),

Annex V: Selection and parameters for the analytical methods used or parameters for the modelling.

Confidential data are not included.

For the test on the enhancement of microbial growth, a test report shall be produced in accordance with EN 16421.

4.4 Requirements for testing in accordance with EN 16421 (microbial growth)

The test of products regarding the enhancement of microbial growth is carried out in accordance with EN 16421. The following limitations apply for the use of the three methods described in the standard.

Method 3 (MDOD method) has a limit of detection that is too high in comparison with the other methods. The method is not suitable for testing products that are to be used with drinking water that is free of disinfectant agents. In Germany, drinking water is distributed in many cases without the addition of chlorine or other disinfectant agents. For this reason, it is necessary in Germany to conduct a test using one of the other two methods (BPP method or volumetric method).

The BPP Method (Method 1) is not suitable for testing multi-layer composite products, because in the test the surface that would not normally come into contact with drinking water when in use is also exposed to the test water.

Multi-layer composite products are tested with Method 2 in the test module for pipes and hoses.

The volumetric method (Method 2) is not suitable for testing a lubricant or grease.

5 Conformity certification

5.1 General

The conformity of a product with the requirements of this Guideline may be confirmed by a test report or certificate. The confirmation of conformity is to be carried out with the

1+ System in accordance with the EU Construction Products Regulation (Regulation (EU) No. 305/2011). This requires external inspection of manufacturing plant[38].

5.2 Application

In order to receive an attestation of conformity according to this Guideline for products in contact with drinking water the applicant must provide the test laboratory with the formulation components (indication of all substances with the percentage by weight, the CAS No. and technological function (e.g. stabiliser) (template for formulation declaration in Annex 2). For products made up of multiple layers, the formulations shall be given for all layers (e.g. lining, adhesive).

The formulation details in accordance with Annex 2 can be provided separately by the producer of the product and the producer of the preparations, provided that the precise designation in each case allows a clear allocation to the product.

This shows the testing necessary for DWPLL values or the residual contents (QM, QMA) for individual substances in the product and purity requirements for the listed substances or substance groups.

In addition, the proposed product group (cf. Table 6) of the product shall be stated.

5.3 Test laboratory

Testing in accordance with this Guideline shall be carried out by a test laboratory accredited in accordance with ISO/IEC 17025 or by a certification body recognised by an accredited certifier.

5.4 Producing a test certificate

The test report or certificate shall contain the following closing paragraph:

"The product ... (precise designation) has been tested in accordance with the Guideline on the hygienic assessment of organic materials in contact with drinking water of the German Environment Agency and has passed the test for the proposed product group(s) ... in the temperature range up to ... °C."

Test certificates issued in accordance with this Guideline are valid for a period of 5 years.

Test reports or certificates for products of the same manufacturer that are produced in accordance with this Guideline may be extended for five years without further experimental testing provided that all requirements under Section 3 were met in the initial test and that the formulation of the relevant substance evaluations (restrictions in the positive lists) and the production of the product have not changed. Before extending the test certificate, the test laboratory shall ensure that the formulation, the production process, and the relevant positive list are unchanged.

[38] Implementing rules required for the external monitoring are specified in the technical regulations

As at: 07 March 2016

Annex 1 to the KTW-Guideline

Composition of the positive lists

The positive lists include the starting substances for the production of organic materials in contact with drinking water in tabular form. For plastics und silicones, this Guideline contains only supplementary positive lists (cf. Table 1).

Column 1 The EEC packaging reference number (Ref.-No.) from the Regulation (EU) No. 10/2011.

Column 2 The Chemical Abstracts Service Number (CAS Number).

Column 3 The name of the substance.

Column 4 DWPLL values as test criteria in the migration test (cf. 4.3).

Column 5 Residual content (QM) in the plastic, or area-related residual content (QMA), relative to a surface area of 6 dm2.

For some substances, limits are included both as a DWPLL value (derived in accordance with Section 3.4) and as a QM or QMA value. In these cases, only one limit shall be tested. Preference should be given to testing the DWPLL value.

The positive lists in Table 1 also contain substances (acids, alcohols, and phenols) that can occur in the form of salts. Since the salts are normally converted in the stomach into acids, alcohols, or phenols, it is possible to use salts of the listed acids, alcohols, or phenols. This means that the salts (including double salts and acid salts) of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium and zinc of the listed acids, phenols or alcohols are included. For the specified cations the migration limit shall be 10 % of the limit value under the TrinkwV 2011, Annexes 2 and 3 and the following limits as DWPLL values:

for barium	70[39] µg/l
for cobalt	1.0[40] µg/l
for zinc	300[41] µg/l

All fillers used shall comply with the purity requirements of BfR Recommendation LII[42].

All colourants used shall comply with the requirements of BfR Recommendation IX[42].

For the assessment of the aids to polymerisation used for the production of plastics and silicones, the relevant BfR Recommendations (Table 1) can be referred to (cf. Section 3.1).

[39] 10% of the WHO guidance value

[40] 10% of the LAWA-guidance value

[41] 10% of the WHO-guidance value

[42] https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp

Including new substances in the positive lists

The addition of a substance to the positive list is only permitted on application by a manufacturer (applicant) to the German Environment Agency pursuant to the rules of procedure[43] of the German Environment Agency for keeping the positive list of substances to manufacture organic materials in contact with drinking water (cf. UBA website: http://www.umweltbundesamt.de/wasser/themen/trinkwasser/verteilung.htm).

The positive list is updated approximately once per year.

To apply for an assessment of a substance to be added to the positive list a substance dossier has to be submitted containing information on transitions of the proposed substances, its contaminations and possible resulting reaction products (e.g. decomposition products of a stabiliser) into drinking water under the most unfavourable conditions. Data to be submitted are based on the questionnaire of the European Commission for plastics in contact with foodstuff ("Note for Guidance") which is divided into sections 1 to 8.

When applying for substances not only pure substances but also contaminations shall be considered. Test conditions of this Guideline have to be used for this migration test. In place of global migration the parameter "TOC " (total organic carbon) will be determined in accordance with the requirements of the Guideline.

Section 8 of the questionnaire describes the requirements for the toxicological data to be submitted, the scope of which depends on the migration level of the requested substance in deionised water. For migrations up to 2.5 µg/l it is to be shown that the substance is not mutagenic (mutagenicity test by OECD No. 471,473 and 476). For migrations exceeding 2.5 µg/l to 250 µg/l a 90-day oral feeding study and data on bioaccumulation are necessary in addition. If the migration exceeds 250 µg/l, the complete toxicological data set is required. Furthermore, all existing toxicological data must be presented.

When applying for substances to be added to the positive list for manufacture of organic materials in contact with drinking water the following 3 cases shall be distinguished. The procedure depends on which toxicological assessment is available for the substance.

1 There is no publicly available assessment of the substance by an authority or organisation.

2 There is an assessment of the substance by EFSA/SCF[44] for the use in plastics in case of food contact.

3 There is a publicly available assessment of the substance by another authority or organisation, e.g. WHO, ECHA.

In case 1 the whole questionnaire has to be filled in. In case 2 points 1 to 4 have to be filled in sufficiently and in case 3 the points 1 to 7 have to be filled in. Further details for application of substances are included in the rules of procedure of the German Environment Agency for

[43] http://www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen/bewertungsgrundlagen-leitlinien

[44] European Food Safety Authority (http://www.efsa.europa.eu/de/)/ Scientific committee on food

the management of the positive list of starting substances for organic materials in contact with drinking water.[45]

Within the framework of the mutual recognition in the 4MS process, substance assessments from other European member states may also be accepted provided that they were carried out in accordance with the requirements of the 4MS process[46]. These substances may also be added to the positive list (Annex 1 Parts 1 and 2).

Supplementary drinking-water specific positive lists for plastics and silicones in contact with drinking water

In addition to the positive lists in Table 1 in Section 3.1, Part 1 of Annex 1 contains additional starting substances for the production of plastics.

In addition to the positive list of BfR Recommendation XV. Silicones, Part 2 of Annex 1 contains further starting substances for the production of silicones.

[45] http://www.umweltbundesamt.de/sites/default/files/medien/419/dokumente/geringsfuegigkeits-leitlinie2011.pdf

[46] http://www.umweltbundesamt.de/wasser/themen/trinkwasser/4ms-initiative.htm

Part 1: Positive list of the starting substances for the production of plastics in accordance with this Guideline

Table 1 of Annex 1 — Starting substances for plastics evaluated by UBA or accepted within the framework of 4MS cooperation

PM-Ref-No.	CAS-No.	Name of substance	DWPLL in µg/l	QM or QMA

Part 2: Positive list of the starting substances for the production of silicones in accordance with this Guideline

Table 2 of Annex 1 — Starting substances for silicones evaluated by UBA or accepted within the framework of 4MS cooperation

PM-Ref-No.	CAS-No.	Name of substance	DWPLL in µg/l	QM or QMA

As at: 07 March 2016

Annex 2 to the KTW-Guideline

Form for the disclosure of a formulation

Address of the manufacturer: .....

Annex to test application dated ... by the company ...

Product or brand name: ....

Declaration of the formulation of the plastic or silicone in accordance with the Guideline on the hygienic assessment of organic materials in contact with drinking water of the German Environment Agency

This declaration is to be used to determine the scope of testing and the requirements for individual substances.

Please list all starting substances /components (polymer, fillers, processing aids, etc.) required for the production of the organic material. If there is more than one supplier for a certain starting substance these must be recorded individually.

The table must be completed in full.

Starting substance / Trade name	Chemical description	CAS-Number	Function of starting substance	Percentage by weight (in %)

All information will be treated confidentially.

page ___ of __ .

Signature of producer:

The formulation shall be disclosed using the form in Annex 2. In the table, all constituents of the formulation shall be included by the producer, including for example solvent and impurities. An updated safety data sheet for the substance or formulation can as a rule provide information about the purity of the substance and other substances contained in the formulation. In individual cases, the information is to be provided by suppliers.

If a product consists of multiple layers, then the formulation of each layer shall be disclosed for the evaluation of the formulation of the product.

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Annex 3 to the KTW Guideline

Performance of migration testing and odour/flavour testing of coating materials in contact with drinking water

Testing is to be done in accordance with DIN EN 1420-1 and DIN EN 12873-1, DIN EN 12873-2 by taking into account the options available in the European standards as follows:

I. Migration test at (23 ± 2) °C (cold water test) in accordance with DIN EN 12873-1 and -2

1. The test specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The specimens are pre-treated according to the following sequence:

   1 h flushing with tap water,

   24 h stagnation with test water at (23 ± 2) °C,

   1 h flushing with tap water,

   rinsing with test water.
3. Deionised water as defined in 5.1.2 DIN EN 12873-1 is used as test water.
4. At least two of the same specimens are used in the test and two blind tests are carried out.
5. Pipes and hoses with an internal diameter < 80 mm are tested by filling them. Pipes and hoses with an internal diameter 80 mm ≤ DN < 300 mm are tested by setting a glass cylinder with a S/V ratio of at least 5 dm^{-1}. Pipes and hoses with an internal diameter≥ 300 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of at least 5 dm^{-1}. Test plates are tested using a S/V ratio of at least 5 dm^{-1}. Fittings and other equipment are tested by immersing the products or immersing the test plates with a S/V ratio of at least 5 dm^{-1} (see table 3 of this Annex).
6. If pipes and hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. The migration waters of the first three migration periods of three days contact time each shall be used for further analyses as described below.
8. The parameters of the basic requirements (TOC, colour, turbidity and tendency to foaming) are tested on the migration waters of migration periods 1, 2 and 3.
9. Clarity, colour and tendency to foaming are tested visually on the undiluted migration water.
10. Mixed samples are created from the tests using the migration water from migration periods 1 and 3 respectively to determine the parameters with migration restriction stated in table 1 as additional requirements. These mixed samples are then tested. The control water from the migration periods must be tested at least once.
11. Mixed samples are created from the tests using the migration water from migration periods 1 and 3 respectively to determine the individual substances specific to the formulation. These mixed samples are then tested. The control water from the migration periods must be tested at least once.

12. When the cold water test is extended migration waters (mixed samples) of the fifth, seventh and ninth migration period shall be examined to determine the basic, additional and formulation-dependent requirements for individual substances (see table 1 of this Annex).

II. Migration test at elevated temperatures (60 ± 2) °C (warm water test) and (85 ± 2) °C (hot water test)) in accordance with DIN EN 12873-1 and -2

1. The test specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The test objects are pre-treated according to the following sequence:

   1 h flushing with tap water,

   24 h stagnation with test water at test temperature,

   1 h flushing with tap water,

   rinsing with test water.
3. Deionised water as defined in 5.1.2 DIN EN 12873-1 is used as test water.
4. At least two of the same specimens are used in the test and two blind tests are carried out simultaneously.
5. Pipes and hoses with an internal diameter < 80 mm are tested by filling them. Pipes and hoses with an internal diameter 80 mm ≤ DN < 300 mm are tested by setting a glass cylinder with a S/V ratio of at least 5 dm^{-1}. Pipes and hoses with an internal diameter≥ 300 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of at least 5 dm^{1}. Test plates are tested using a S/V ratio of at least 5 dm^{-1}. Fittings and other equipment are tested by immersing the products or immersing the test plates with a S/V ratio of at least 5 dm^{-1} (see table 3 of this Annex).
6. If pipes or hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. 7 migration periods shall follow the pre-treatment at test temperature (10 days of total contact time).
8. Migration waters of the first second, third, sixth and seventh migration periods shall be used for examining the parameters of the basic requirement (TOC, colour, turbidity and tendency to foaming). Clarity, colour and tendency to foaming are tested visually on the undiluted migration water.
9. Mixed samples are created from the tests using the migration water from migration periods 1 and 7 respectively to determine the parameters with migration restriction stated in table 1 as additional requirement. The mixed samples from the migration water from the 1st, 6th and 7th migration periods are then tested. The control water from the migration periods must be tested at least once.
10. The test for formulation-specific substances is conducted in the migrates of the 1st, 6th and 7th test periods (mixed samples from the tests). The control water from the migration periods must be tested at least once.
11. When the migration test at elevated temperatures is extended migration waters of the 11th, 12th, 16th, 17th, 21st and 22nd migration period (mixed samples from the test

runs) shall be tested to determine the basic, additional and formulation-dependent requirements of individual substances (cf. table 2).

III. Odour/flavour test at (23 ± 2) °C (cold water test) in accordance with DIN EN 1420-1 and DIN EN 1622

1. The test specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The test specimens are pre-treated according to the following sequence:

   1 h flushing with tap water,

   24 h stagnation with reference water at (23 ± 2) °C,

   1 h flushing with tap water,

   rinsing with reference water
3. The reference water must be in accordance with DIN EN 1420.
4. At least two of the same specimens are used in the test and two blind tests are carried out simultaneously.
5. Pipes and hoses with an internal diameter DN < 80 mm are tested by filling them. Pipes and hoses with an internal diameter DN≥ 80 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of 2.5 dm^{-1}. Test plates are tested using a S/V ratio of at least 2.5 dm^{-1}. Fittings and other equipment are tested by immersing the products or by immersing the test plates with a S/V ratio of at least 1.5 dm^{-1} small repair systems for containers with a S/V ratio of at least 0.2 dm^{-1} (see table 3 of this Annex).
6. If pipes and hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. The migration waters of the first three migration periods of three days contact time each are used to determine the odour/flavour threshold values. If the odour threshold value fails to meet the requirements the flavour threshold value need not be determined.
8. In several test series the migration waters from migration periods 1, 2 and 3 are combined into mixed samples.
9. The mixed samples from the migration water of the 1st and 2nd migration periods are tested tentatively[47] in the laboratory to determine the odour/flavour limits. The results are presented in the test report and marked accordingly.
10. The mixed sample of the migration water from the 3rd migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.
11. When the migration test is extended migration waters of the 5th, 7th and 9th migration period shall be tested. Odour and flavour threshold values of the migration waters of the 5th and 7th migration periods are determined tentatively. The results are presented in the test report and marked accordingly. The mixed sample of the migration water from the 9th migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.

[47] The tentative determination is a short test in which the migration water is diluted until no odour/flavour can be perceived.

12. To determine the odour/flavour thresholds, the unforced pair test is applied in accordance with DIN EN 1622 2006.

IV. Odour/flavour test at elevated temperatures (60 ± 2) °C (warm water test) and (85 ± 2) °C (hot water test)) in accordance with DIN EN 1420-1 and DIN EN 1622

1. The test specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The test objects are pre-treated according to the following sequence:

   1 h flushing with tap water,

   24 h stagnation with reference water at test temperature,

   1 h flushing with tap water,

   rinsing with reference water
3. The reference water must be in accordance with DIN EN 1420.
4. At least two of the same specimens are used in the test run and two blind tests are carried out simultaneously.
5. Pipes and hoses with an internal diameter DN < 80 mm are tested by filling them. Pipes and hoses with an internal diameter DN≥ 80 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of 2.5 dm^{-1}. Test plates are tested using a S/V ratio of at least 2.5 dm^{-1}. Fittings and other equipment are tested by immersing the products or by immersing the test plates with a S/V ratio of at least 1.5 dm-1, small-scale repair systems for tanks with a S/V ratio of at least 0.2 dm^{-1} (see table 3 of this Annex).
6. If pipes and hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. 7 migration periods shall follow the pre-treatment at test temperature. The migration waters of the 1st, 6th and 7th test periods are used to determine the odour-/flavour threshold values. If the odour threshold value fails to meet the requirements the flavour threshold value need not be determined.
8. In several test series the migration waters from migration periods 1, 6 and 7 are combined into mixed samples.
9. The mixed samples from the migration water of the 1st and 6th migration periods are tested tentatively in the laboratory to determine the odour/flavour threshold values. The results are presented in the test report and marked accordingly.
10. The mixed sample of the migration water from the 7th migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.
11. When the migration test is extended migration waters of the 11th, 12th, 16th, 17th, 21st and 22nd migration period shall be tested. Odour and flavour threshold values of the migration waters of the 11th, 12th, 16th, 17th and 21st migration periods are determined tentatively. The results are presented in the test report and marked accordingly. The mixed sample of the migration water from the 22nd migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.

12. To determine the odour/flavour thresholds, the unforced pair test is applied in accordance with DIN EN 1622.

Table 1 of Annex 3 Migration cycles of extended cold water test

Week	Migration cycle	Total contact time in days	End of migration period	Contact period in days per migration	Analysis
1	0 (pre-treatment)	1	Tuesday	1	No
1	1	4	Friday	3	Yes
2	2	7	Monday	3	Yes
2	3	10	Thursday	3	Yes
3	4	14	Monday	4	No
3	5	17	Thursday	3	Yes
4	6	21	Monday	4	No
4	7	24	Thursday	3	Yes
5	8	28	Monday	4	No
5	9	31	Thursday	3	Yes

Table 2 of Annex 3 Migration cycles of extended warm or hot water test

Week	Migration cycle	Total contact time in days	End of migration period	Contact period in days per migration	Analysis
1	0 (pre-treatment)	1	Tuesday		No
1	1	2	Wednesday	1	Yes
1	2	3	Thursday	1	Yes
1	3	4	Friday	1	Yes
2	4	7	Monday	3	No
2	5	8	Tuesday	1	No
2	6	9	Wednesday	1	Yes
2	7	10	Thursday	1	Yes
2	8	11	Friday	1	No
3	9	14	Monday	3	No
3	10	15	Tuesday	1	No
3	11	16	Wednesday	1	Yes
3	12	17	Thursday	1	Yes
3	13	18	Friday	1	No
4	14	21	Monday	3	No
4	15	22	Tuesday	1	No
4	16	23	Wednesday	1	Yes
4	17	24	Thursday	1	Yes
4	18	25	Friday	1	No
5	19	28	Monday	3	No
5	20	29	Tuesday	1	No
5	21	30	Wednesday	1	Yes
5	22	31	Thursday	1	Yes

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Table 3 of Annex 3 Minimum S/V ratio for the test runs

Test run / Area of use	Migration at 23°C	Migration at elevated temperature	Odour/flavour at 23°C	Odour/flavour at elevated temperature
Pipes DN < 80 mm	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)
Pipes 80 mm ≤ DN < 300 mm	S/V ≥ 5 dm^{-1} (fill or fill with inserted cylinder or fill pipe sections)	S/V ≥ 5 dm^{-1} (fill or fill with inserted cylinder or pipe sections)	S/V > 2.5dm^{-1} (fill)	S/V > 2.5 dm^{-1} (fill)
Pipes DN ≥ 300 mm	S/V ≥ 5 dm^{-1} (fill with inserted cylinder or of pipe section or immersed plates)	S/V ≥ 5 dm^{-1} (fill with inserted cylinder or pipe sections or immersed plates)	S/V ≥ 2.5 dm^{-1} (fill with inserted cylinder or pipe sections or immersed plates)	S/V ≥ 2.5 dm^{-1} (fill with inserted cylinder or pipe sections or immersed plates)
Fittings (ancillaries)	S/V ≥ 5 dm^{-1} (immersion of products or test plates)	S/V ≥ 5 dm^{-1} (immersion of products or test plates)	S/V ≥ 1.5 dm^{-1} (immersion of products or test plates)	S/V ≥ 1.5 dm^{-1} (immersion of products or immersed plates)
Seals	S/V ≥ 5 dm^{-1} (immersion of products or test plates)	S/V ≥ 5 dm^{-1} (immersion of products or test plates)	S/V ≥ 0.2 dm^{-1} (immersion of products or test plates)	S/V ≥ 0.2 dm^{-1} (immersion of products or plates)
Container, repair systems	S/V ≥ 5 dm^{-1} (immersion of test plates)	S/V ≥ 5 dm^{-1} (immersion of test plates)	S/V ≥ 2.5 dm^{-1} (immersion of test plates)	S/V ≥ 2.5 dm^{-1} (immersion of test plates)
Small contact area components for pipes DN < 300 mm	S/V ≥ 5 dm^{-1} (immersion of test plates)	S/V ≥ 5 dm^{-1} (immersion of test plates)	S/V ≥ 0.2 dm^{-1} (immersion of test plates)	S/V ≥ 0.2 dm^{-1} (immersion of test plates)
Small contact area components for pipes DN ≥ 300 mm	S/V ≥ 5 dm^{-1} (immersion of test plates)	-	S/V ≥ 0.2 dm^{-1} (immersion of test plates)	-

Table 4 of Annex 3 Table of test results for TOC in accordance with EN 12873-1 and -2

Product:

Date of test:

Test temperature:

Surface / volume ratio:

Conversion factor for the product to be assessed:

Number of migration periods:

Analysis method:

	Sequential number of the migration period n				
	1	2	3[48]	6	7
a_n^T					
$\overline{a}_n^T$					
b_n^T					
$\overline{b}_n^T$					
$\overline{c}_n^T = \overline{a}_n^T - \overline{b}_n^T$					
$\overline{\overline{c}}_{Tap\ n}^T$					

where

a_n^T is the concentration of a substance measured in a migration water sample in mg/l,

b_n^T is the concentration of a substance measured in blank water in mg/l,

$\overline{c}_n^T$ the concentration of the substance to be determined,

$\overline{\overline{c}}_{Tap\ n}^T$ is the maximum expected tap concentration of a migrating substance,

n is the sequential number of the migration period,

T is the test temperature

[48] The cold water test ends with the 3rd or 9th test period.

As at: 7 March 2016

Table 5 of Annex 3 — Table of test results for the additional requirements and the formulation-specific individual substance requirements in accordance with EN 12873-1 and-2

Product:

Date of test:

Test temperature:

Surface area to volume ratio:

Conversion factor for the product to be assessed:

Number of the migration period:

Analysed substance:

Analysis method:

	Sequential number of the migration period n			
	1	3[49]	6	7
α_n^T				
β_n^T				
$\chi_n^T = \alpha_n^T - \beta_n^T$				
$\overline{\overline{c_{Tap\ n}}}^T$				

Where:

α_n^T is the concentration of a substance measured in a mixed migration water sample in mg/l,

β_n^T is the concentration of a substance measured in the mixed blank water sample in mg/l,

χ_n^T is the concentration of the substance to be determined,

$\overline{\overline{c_{Tap\ n}}}^T$ is the maximum expected tap concentration of a migrating substance

,

n is the sequential number of the migration period,

T is the test temperature

[49] The migration test at elevated temperatures ends with the 7th or 22nd test period.

For the modelled concentrations a record should be produced of all the data entered (printout of the relevant software report) which shall form part of the test report. It shall include the parameters tested and the details of the test run (temperature, surface of the specimen, volume of the migration water sample, contact time).

The formulation-specific requirements are subject to confidentiality and cannot therefore be stated in the report. Proof that a test has been carried out on these parameters and that the requirements have been met is reported in the test report as follows: "Formulation constituent subject to confidentiality; reference value complied with."

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As at: 7 March 2016

Annex 4 to the KTW Guideline

Disclosure sheet for recording the production of the product or test plates

The following data shall be included:

1. Address of applicant,
2. Accurate designation of the plastic/silicone (for unambiguous allocation in terms of application, formulation statement, test record, and test report),
3. Location of production of the test plates or the product (e.g. factory, laboratory, or construction site),
4. Address of producer, name of the responsible employees,
5. Date of production of the test plates or the product,
6. Method of production of the test plates or the products (e.g. injection moulding),
7. Production or curing conditions (time, temperature),
8. Mixing procedure, e.g. milling, kneading,
9. Special conditions to be observed e.g. annealing,
10. If relevant: composition of the multilayer product
11. Deviations of the test plate production from the product production (if relevant).

The products and the test plates shall be packed in suitable diffusion-resistant packaging materials (e.g. aluminium foil, glass) and stored in such a way as to avoid contamination with other substances.

As at: 7 March 2016

Annex 5 to the KTW-Guideline

Table 1 of Annex 5 Overview of various products and their allocation to the product groups

Product group	Products
Pipes: DN < 80 mm 80 mm ≤ ID-DN < 300 mm ID-DN ≥ 300 mm	Pipes and hoses of plastics Plastic pipe lining Pipes from composite materials Cable in drinking water supply pipes Hoses in the drinking water installation (except connecting hoses for washing machines or dishwashers) Hoses for the temporary transport of drinking water
Fittings for pipes: DN < 80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	Valves Stop-cocks Meters Fittings Housings for filters in a drinking water installation Power cable (e.g. for submerged pumps) Linings for slider housings Membranes for expansion vessels (ID-DN<80 mm) Connecting hoses for washing machines and dishwashers
Seals for pipes: DN<80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	Seals for pipes and hoses Seals for fittings
Tanks: in a drinking water installation outside a drinking water installation Repair systems for containers and tanks	Plastic tanks and cladding in the drinking water supply system Tanks in the drinking water installation Tanks in the water works Repair systems for tanks in the waterworks
Small contact area components for pipes: DN ≥ 300 mm, only installed in one place in the distribution system	Plain bearing of a pump

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Annex 6 to the Coating Guideline

Assessment of test in accordance to DIN EN 16421 – Procedure 2 (volumetric procedure) by using optional monthly values

1. General information

Optional monthly values are only determined in those cases where products are to be used as large or small seals and where the first one-month value (1a) is within the corresponding threshold values, the second one-month value (1b) is over this value (cf. table 1). Then the optional monthly values, forth one-month-value (1d) as well as second two-month-value (2b) shall be determined (cf. table 1) and used for assessment. The first one-month-value (1a) shall not be taken into account for the assessment. Assessment of the overall results shall be done without considering the value 1a (cf. table 1).

2. Large seals

With the exception of the second one-month value (1b) all values must not exceed (0.12 + 0.03) ml /800 cm². Values plus measurement tolerance must show a constant or falling trend, i.e. value 1d must be ≤ 1c, the value 2b ≤ 2a and value 3a must be ≤ 2a (cf. table of Annex 6).

3. Small seals

With the exception of the second one-month value (1b) all values must not exceed (0.20 + 0.03) ml /800 cm². Values plus measurement tolerance must show a constant or falling trend, i.e. value 1d must be ≤ 1c, the value 2b ≤ 2a and value 3a must be ≤ 2a (cf. table of Annex 6).

Table 1 of Annex 6 Overview of assessment by using optional monthly values

	1-Monthly samples				2-Monthly samples		3-Monthly sample
Type of material/ product	**Sample 1 a**	**Sample 1 b**	**Sample 1 c**	**Sample 1 d**	**Sample 2a**	**Sample 2 b**	**Sample 3 a**
Products to be used as large seals (3.5.3 d)	1a much smaller than 1b and 1a below threshold value	Where 1b ≥ 1c, 1b shall not be used for assessment	All values ≤ (0.12 + 0.03) ml / 800 cm² where 1d ≤ 1c and 2b ≤ 2a and 3a ≤ 2a				
Products to be used as small seals (3.5.3 d)	1a much smaller than 1b and 1a below threshold value	Where 1b ≥ 1c, 1b shall not be used for assessment	All values ≤ (0.20 + 0.03) ml / 800 cm² where 1d ≤ 1c and 2b ≤ 2a and 3a ≤ 2a				

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