

The Director General

Maisons-Alfort, 19 October 2016

## **OPINION**

### **of the French Agency for Food, Environmental and Occupational Health & Safety**

#### **on the assessment of the safety and effectiveness of water filter jugs**

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*ANSES undertakes independent and pluralistic scientific expert assessments.*

*ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.*

*It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.*

*It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).*

*Its opinions are published on its website.*

*This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 19 October 2016 shall prevail.*

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On 9 April 2015, ANSES issued an internal request to assess the safety and effectiveness of water filter jugs.

This internal request is included in ANSES's 2015 and 2016 work programmes, as part of its expert appraisal work on the assessment of treatment systems for drinking water (DW), including household treatment systems permanently connected to the consumer's tap as well as water filter jugs.

#### **1. BACKGROUND AND PURPOSE OF THE REQUEST**

Water filter jugs are household water treatment devices not connected to the DW supply system. They are meant to be used exclusively with DW and therefore are not designed to make non-potable water potable. The improvement of the organoleptic properties of water (chlorine taste in particular) and the removal of limescale and certain metals such as lead (Pb) are some of the claims made by manufacturers of water filter jugs.

The internal request intending to assess the safety and effectiveness of water filter jugs was issued in a context of reports submitted in 2009 to the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF)<sup>1</sup>, of questions put to Members of Parliament in France<sup>2</sup> and the European Union<sup>3</sup>, and of articles published in the media<sup>4</sup>.

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<sup>1</sup> DGCCRF draft request letter of 2011.

<sup>2</sup> Question No. 42021 (<http://2007-2012.nosdeputes.fr/question/QE/42021>).

<sup>3</sup> E-005272/2011 (<http://www.europarl.europa.eu/sides/getDoc.do?type=WQ&reference=E-2011-005272&language=FR>).

All of these queries show that questions still remain as to:

- whether there are any health risks to consumers related to the potential microbiological contamination of water filtered by the filter cartridge and/or the release of undesirable substances in filtered water (metals, in particular silver (Ag) in its dissolved or nanoparticulate form);
- the effective removal of contaminants found in DW such as nitrates, metals and pesticides;
- the discrepancy between actual conditions of use by users and the recommendations of the entities responsible for placing water filter jugs on the market.

In the fourth quarter of 2012, the DGCCRF undertook an exploratory investigation of domestic water treatment systems (water filter jugs and fixed filtration equipment<sup>5</sup>) in six regions and twelve *départements* of France (40 companies were visited<sup>6</sup>). This investigation showed that vigilance needed to be maintained, with regards to food contact materials (FCMs) and food safety. The DGCCRF's investigators reported difficulties obtaining relevant technical information from retailers (DGCCRF, 2014).

To date, no alerts involving water jugs have been reported *via* the RASFF<sup>7</sup>, RAPEX<sup>8</sup>, INFOSAN<sup>9</sup> or OECD<sup>10</sup> alert systems for the reporting of anomalies observed during inspections undertaken by the relevant administrative health services.

The Agency thus issued an internal request in order to:

- examine available studies and data collected in France and the European Union (ministries, consumer associations, scientific literature, manufacturers) on the use of water filter jugs in order to assess their safety and effectiveness;
- draft, if necessary, specifications for a new study on the safety and effectiveness of water filter jugs with regards to parameters likely to exceed the regulatory quality limits for DW<sup>11</sup> that may have a harmful effect on consumer health.

If a new study needed to be undertaken, this Opinion could be revised in light of the new data acquired.

**The work undertaken as part of this internal request did not deal with fixed filtration devices intended to be installed on taps or under sinks**, although they use similar technologies. Unlike water filter jugs and bottles, these devices fall under the regulations on materials and articles and treatment products and processes used in permanent facilities for the production, treatment and distribution of DW (Articles R. 1321-48 to R. 1321-54 of the French Public Health Code). Moreover, **filtration systems marketed for the home disinfection of water in emergency situations or for travellers are not covered in this expert appraisal.**

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E-007670/2011 (<http://www.europarl.europa.eu/sides/getDoc.do?type=WQ&reference=E-2011-007670&language=FR>).

E-003304/2012 (<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bWQ%2bE-2012-003304%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=FR>).

E-003529/2012 (<http://www.europarl.europa.eu/sides/getDoc.do?type=WQ&reference=E-2012-003529&language=FR>)

<sup>4</sup> Articles published in no. 481 of May 2010 of *Que Choisir* and in no. 461 of June 2011 of *60 Millions de Consommateurs*.

<sup>5</sup> Companies marketing jugs and jug cartridges, manufacturers of cartridges or cartridge components.

<sup>6</sup> <http://www.economie.gouv.fr/dgccrf/carafes-filtrantes-qualite-a-surveiller>.

<sup>7</sup> RASFF (Rapid Alert System for Food and Feed).

<https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1#>

<sup>8</sup> RAPEX (Rapid Alert System for dangerous non-food products).

<http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.search>

<sup>9</sup> INFOSAN (International Food Safety Authorities Network).

<sup>10</sup> OECD (Global portal on product recalls).

<http://globalrecalls.oecd.org/>

<sup>11</sup> Ministerial Order of 11 January 2007 on the quality reference values and limits for raw water and DW listed in Articles R. 1321-2, R. 1321-3, R. 1321-7 and R. 1321-38 of the French Public Health Code.

The scope of the request is limited to devices used at home (water filter jugs and bottles)<sup>12</sup> used with DW supplied at the tap.

## 2. ORGANISATION OF THE EXPERT APPRAISAL

This expert appraisal was carried out in accordance with the French Standard NF X 50-110 "Quality in Expertise – General Requirements of Competence for Expert Appraisals (May 2003)".

It falls within the sphere of competence of the Expert Committee (CES) on Water and the permanent Working Group (WG) on Assessment of substances and processes subject to authorisation in human food (ESPA). ANSES entrusted the expert appraisal to the WG on Water filter jugs, created on 9 April 2015. The methodological and scientific aspects of the work were presented to the members of the CES on Water on 5 April and 10 May 2016, and to the ESPA WG on 27 April 2016. They were approved by the CES on Water in its meeting of 7 June 2016 and by the ESPA WG in its meeting of 16 June 2016.

The WG relied on the following data in particular:

- available scientific articles: the SCOPUS and PUBMED literature databases were queried using the following keywords: "jug filter" or "pitcher filter" or "pour-through device" and "drinking water" or "point-of-use device". Based on English key-words, the search was carried out for the period from January 2000 to October 2015 and only seven articles involved water filter jugs;
- articles in the magazine *60 Millions de Consommateurs* (60Mdc) published by the French National Consumer Institute (INC) and the magazine published by the association UFC-Que Choisir as well as the confidential study reports and data used to write the articles appearing in nos. 408 of October 2003 and 481 of May 2010 of the magazine *Que Choisir*;
- documents submitted by the DGCCRF following the TN 35EA investigation of the fourth quarter of 2012;
- confidential studies provided by the company Brita during the hearings;
- current regulations, recommendations and standards;
- studies and assessments undertaken in other countries;
- documents collected *via* Internet search engines queried with the keywords "carafe filtrante" or "cruche filtrante".

Professional associations specialising in household water treatment, entities responsible for placing water filter jugs on the market, and consumer associations were contacted. The companies Brita and BWT were interviewed by the WG on 13 January 2016 (Annex 1).

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.

The experts' declarations of interests are made public on ANSES's website ([www.anses.fr](http://www.anses.fr)).

The four experts in the CES on Water with risks of conflicts of interest did not take part in the discussions or the approval of this work.

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<sup>12</sup> Sport water bottles that can be raised to the mouth and are intended for only one user are excluded from the scope of the expert appraisal. They are sold primarily on the Internet and are intended for the North American market since they claim NSF/ANSI certification. They are fitted with a screw cap whose design allows the product to be brought to the mouth; this cap contains the filtration device. Filtration occurs when the user drinks, not when the sport bottle is filled, unlike with water filter jugs and disc-based bottles.

### 3. ANALYSIS AND CONCLUSIONS OF THE WG ON WATER FILTER JUGS

#### 3.1. French water filter jugs market

The French Individual Survey on Food Consumption, INCA 2 (2006/2007), showed that 13% of French people (adults and children) belong to a household that treats its water at home. The primary water treatments used are ion-exchange resins (69.7%) and activated carbon filtration (20.3%); other processes (membrane filtration, mechanical filtration, treatment with ultraviolet radiation) are used by less than 10% of these households. In this survey, the use of water filter jugs is not specified; these devices are counted as resin, activated carbon or even mechanical filtration systems. The national representativeness of the INCA 2 survey is not guaranteed for household water treatment since the study population was small (446 households surveyed).

The 2012 opinion poll entitled "*Les Français et l'eau*" (Water in France) undertaken by the Water Information Centre (C.I.EAU) estimated that 16% of all French people use a water filter jug (18% in 2011). The majority of the people surveyed (73%) said they do not use any household water treatment devices (in particular water filter jugs, tap-mounted filters, softeners). Prudhomme (2012) confirmed these values, indicating that approximately 20% of French households are equipped with a water filter jug. It is estimated that 750,000 to one million jugs and 15 million cartridges are sold per year.

In 2013, a survey undertaken by the General Commission for Sustainable Development (CGDD, 2014) estimated that 20% of the population of mainland France over the age of 18 years uses home tap water filtration with water filter jugs or permanent filtration systems installed on taps or under sinks (representative sample of 4000 people).

According to the publication by Zombek (2012), which appeared in a magazine that analyses trends in retail and the mass market, the percentage of equipped households "has reached an optimum penetration rate", on a par with other European markets (20%); of these households, only 13% to 14% are thought to be active (purchasing cartridges on a regular basis). Promotions account for 50% of sales of jugs and 40% of sales of cartridges. The main brands sold in France are as follows: Brita (accounting for 78% of the jug market and 88% of the cartridge market), Terrailon (9.2% of the jug market and almost 6% of the cartridge market), and "own brands" (11.3% of the jug market and 7.8% of the cartridge market). BWT, a new player, offers round and oval cartridges compatible with most existing brands. The SEB group (Tefal and Rowenta) no longer operates on the French market, and Culligan has focused its production on fixed systems (tap-mounted filters). New products such as water filter bottles and sport bottles have recently appeared on the market (Brita Fill&Serve and Fill&Go, and the American products Bobble and Pure). Prudhomme (2012) confirmed that Brita is the market leader with an 80% market share.

Turnover in the water filter jug industry reached almost €70 million in France in 2011 (LSA Commerce & Consommation article: Capitaine 2011). The market of water filter jugs and filtering cartridges is currently declining (LSA Commerce & Consommation articles: Cadoux 2014 and 2015, Le Corre 2015; and DGCCRF information note, 2014). While French people prefer purchasing their jugs at hypermarkets (64.7% in 2012, 66.5% in 2013), sales in these outlets are down (-0.4 points between 2012 and 2013) and only distance and Internet sales are on the rise (+3.8 points between 2012 and 2013). In 2015, Brita was still the leading brand on the market (81.6% market share for jugs and 87.8% for cartridges). Advertising messages on the benefits of water filter jugs now focus on the improvement in the taste of water enjoyed with meals or used for cooking or for the preparation of hot drinks.

The hearings confirmed that Brita is the market leader in France. BWT accounts for 10% of the jug market and 5% of the cartridge market.

### **3.2. Products**

A water filter jug is comprised of a container (jug), a funnel, a cartridge with a filtering active medium, a lid and often a cartridge exchange indicator.

In water filter bottles, the cartridge is replaced with a filtering disc and the lid with a screw cap.

It should be noted that products intended for the French and European markets are generally different from those intended for the North American market, although the latter can be purchased over the Internet. In some cases, they can have similar trade names but be marketed by different companies. Only products intended for the French and European markets are described below.

#### **3.2.1. Materials in water filter jugs and bottles**

According to the documents submitted by the DGCCRF and the information collected during the hearings, water filter jugs are made of styrene-acrylonitrile copolymers (in particular styrene acrylonitrile (SAN), acrylonitrile butadiene styrene (ABS) and/or acrylonitrile styrene acrylate (ASA)).

Since the import and marketing of food packaging products containing bisphenol A have been suspended since 1 January 2015, jugs made of polycarbonate (PC) should no longer be sold in the country (see § 3.3).

Water filter bottles are made of Tritan® copolyester, which is a PC alternative manufactured by Eastman Chemical Company (ANSES, 2013a).

#### **3.2.2. Components of filtering cartridges and discs**

Cylindrical and oval filtering cartridges are comprised of polypropylene (PP) housing, a polyethylene terephthalate (PET) screen located inside the cartridge intended to prevent the release of filter-medium particles, and a filter medium comprised of ion-exchange resin(s) and activated carbon. In the cartridges currently on the market, the entire filter medium or only the activated carbon is generally treated with silver (Ag). The manufacturer's technical leaflet generally indicates if the cartridge contains carbon or a filter medium treated with Ag.

Granulated activated carbon (GAC) is generally used to reduce the chlorine content of water, adsorb organic "taste- and odour-causing" compounds, and remove micropollutants (EPA, 2006; NAC, 1997). Its effectiveness depends on the nature, origin and quality of the product (carbon adsorption capacity), the amount used and its contact time with water.

GAC is also a preferred biological medium, since its roughness promotes the adherence of micro-organisms in the filter, as the organic matter that accumulates on the surface of pores can provide nutrients. The stated aim of treating GAC with Ag is to limit microbial proliferation in the filter of the jug, not to disinfect the water. The bactericidal (reducing the number of micro-organisms)<sup>13</sup> and/or bacteriostatic (inhibiting the development of micro-organisms)<sup>14</sup> effects of Ag against micro-organisms found in water have been studied in various publications (Fewtrell for the WHO, 2014; Bell, 1991). With regards to water filter jugs, no scientific publications specifically studying the effectiveness of treating filter media with Ag in terms of microbial proliferation were identified.

There are various processes for treating GAC with Ag, such as "impregnation" with silver salts, in particular silver nitrate, and the "grafting" of a nanometric layer of silver metal (Ag<sup>0</sup>) atoms onto the

<sup>13</sup> **Bactericidal activity:** ability of a product or active substance to reduce the number of viable bacterial cells belonging to representative test organisms, in defined conditions (NF EN 14885, 2015).

<sup>14</sup> **Bacteriostatic activity:** ability of a product to inhibit the development of viable bacterial cells belonging to representative test organisms, in defined conditions (NF EN 14885, 2015).

surface of the carbon. The GAC currently used in the cartridges of water filter jugs is generally treated with Ag salts.

Ion-exchange resins<sup>15</sup> can be:

- cation-exchange resins used for softening or decarbonation (removal of calcium and magnesium) and the removal of certain metals. Some cation resins are intended to simultaneously enrich filtered water with Mg<sup>2+</sup> and remove Ca<sup>2+</sup>;
- anion-exchange resins used for the removal of nitrates.

Resins can also be treated with Ag.

Some of these cartridges are refillable since their plastic housing can be opened in order to replace the filter medium sold in bags.

The filtering discs of water bottles are comprised of compressed activated carbon not treated with Ag.

### **3.2.3. Conditions of use recommended in instructions for use**

The NF P 41-650 Standard<sup>16</sup> and the CEN draft standard specify the minimum instructions for the use and maintenance of water filter jugs that should be provided to users. The implementation of these two standards is not mandatory under the regulations.

The user manuals of nine different brands collected by the WG during the mandate were examined.

They generally indicate that:

- the jug is designed to be used only with cold tap water whose quality is compliant with the regulatory requirements (nine out of nine manuals),
- the cartridge should be replaced on a regular basis, after 20, 30 or 50 days of use depending on the brand (nine out of nine manuals),
- the filtered water should be consumed promptly, within 24 or 48 hours depending on the brand (seven out of nine manuals),
- if the authorities request that tap water be boiled, the filtered water should also be boiled. The cartridge should then be replaced, once this measure has been lifted. The leaflets also specify that "*for persons with immune deficiencies, it is advisable to always boil tap water*" (six out of nine manuals).

In some cases, the manuals recommend:

- not leaving water in the jug during periods when it is no longer in use (five out of nine manuals),
- keeping the jug and replacement cartridges in a cool place away from sunlight (four out of nine manuals),
- keeping the water filter jug in the refrigerator during its use or in periods of non-use (four out of nine manuals),
- seeking medical advice before use in the event of heart disease, kidney impairment, dialysis, controlled diet (low-potassium diet in particular) (five out of nine manuals).

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<sup>15</sup> Insoluble organic or mineral matter to which ions to be exchanged are attached (AFSSA, 2009).

<sup>16</sup> NF P 41-650 (2013) – Water treatment devices – Specifications for water filter jugs.

Regarding the cleaning of jugs, the entities responsible for placing water filter jugs on the market recommend:

- washing the container (jug), funnel and lid with soapy water prior to use and then on a regular basis (once a week), in particular when replacing the cartridge (eight out of nine manuals). The recipient and funnel can generally be washed in a dishwasher, but this is not always true for the lid (which contains the replacement indicator),
- descaling the lid using a common household descaler containing citric acid (one out of nine manuals),
- not using abrasive products (five out of nine manuals).

Few of the entities responsible for marketing water filter jugs specify that the period of use for the cartridge and its effectiveness vary depending on DW quality or specify filtration capacities based on water hardness (two out of nine manuals).

### **3.3. Current regulations, recommendations and standards, in France and in other countries**

#### **3.3.1. Regulations and recommendations**

##### **3.3.1.1. European Union**

Materials and articles intended to come into contact with food are subject to the requirements of Regulation (EC) No 1935/2004. Article 1 of this regulation excludes fixed public or private water supply equipment. Since water filter jugs are not connected to the drinking water supply system, they are covered by the regulations on Food Contact Materials (FCMs). General requirements applicable to FCMs are described in Article 3 of Regulation (EC) No 1935/2004: *"Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:*

- *endanger human health;*
- *bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof".*

Article 5 of this same regulation stipulates that 17 groups of materials may be subject to specific harmonised measures. Of the materials listed in Annex 1 of this regulation, plastic materials are already covered by requirements described in Regulation (EU) No 10/2011. However, ion-exchange resins and filter media are not subject to any particular requirements in the European Union.

When there are no specific regulations or directives for a group of materials, Article 6 of Regulation (EC) No 1935/2004 authorises EU Member States (MSs) to maintain or adopt national provisions.

For food contact materials and articles subject to specific harmonised measures (such as plastics), written declarations of compliance shall be provided by operators to their clients. These shall include a statement of compliance with the regulatory requirements and information required by subsequent operators in the supply chain to ensure reliable use consistent with the regulatory requirements. Therefore, documentation on the materials used in water filter jugs must be produced by operators.

In the specific case of filtration systems containing activated carbon or another filter medium treated with Ag for the bacteriostatic protection of the cartridge (not having the disinfection of water

as a claim), Ag is classified in biocidal product-type 4<sup>17</sup> (PT4) under Regulation (EU) No 528/2012<sup>18</sup> (EWTA, 2012). Since, from a regulatory standpoint, Ag and silver nitrate are currently being assessed for use under PT4<sup>19</sup>, their use is authorised until the end of the assessment procedure.

### **3.3.1.2. France**

France has specific regulatory measures applicable to certain materials and articles not covered by harmonised European measures. At the time of this Opinion's publication, no national requirements have yet been published regarding ion-exchange resins or filter media and therefore these materials are, from a legal standpoint, subject only to the general requirements described in Article 3 of Regulation (EC) No 1935/2004 (see beginning of § 3.3.1.1).

To place on the market water filter jugs compliant with the general requirements of the European regulations, manufacturers must, in addition to complying with the criteria applicable to plastics (see Regulation (EU) No 10/2011), demonstrate that the ion-exchange resins and filter media comply with Article 3 of Regulation (EC) No 1935/2004. To do so, operators can rely on the state of the art, in particular benchmarks disseminated by official bodies and guides to good professional practices.

The Council of Europe published Resolution AP(2004)3 on ion-exchange and adsorbent resins used in the processing of foodstuffs, which can serve as a benchmark for market operators even though its implementation is not mandatory.

Since 1 January 2015, under Act no. 2012-1442 of 24 December 2012 suspending the marketing and import into France of food packaging containing bisphenol A, the marketing of polycarbonate (PC) water jugs has been banned in France.

Furthermore, even though this is not mandatory, filter media used in water filter jugs can be authorised under the regulations on DW treatment products and processes (TP&P) (provisions of Article R. 1321-50 of the French Public Health Code (CSP), the Ministerial Order of 29 May 1997 as amended, and Circulars DGS/VS4 of 7 May 1990 and DGS/VS4 no. 2000-166 of 28 March 2000):

- active media used in filtration systems must be authorised and compliant with the purity requirements defined in the standards on products used for the treatment of DW;
- ion-exchange resins must be accredited by the French Ministry of Health for the treatment of DW. Under these regulations, treatments using anion-exchange resins for denitrification are not authorised for home use by private individuals (intermittent operation), since regeneration and disinfection are necessary after a downtime period of over 12 hours. The ministry's accreditation is an indication that the safety of resins has been verified by a third-party organisation (favourable opinions issued by ANSES further to tests undertaken by a laboratory authorised by the Ministry of Health according to the Ministerial Order of 18 August 2009) and is issued for a five-year period.

<sup>17</sup> Product-type 4: Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals. Products used to impregnate materials which may enter into contact with food.

<sup>18</sup> Swedish position paper on allocation of a treated water filter to a PT - CA-July13-Doc.7.2 (revision from May meeting).

<sup>19</sup> [http://echa.europa.eu/information-on-chemicals/biocidal-active-substances?p\\_auth=CUK6NhHu&p\\_p\\_id=echarevbiocides\\_WAR\\_echarevbiocidesportlet&p\\_p\\_lifecycle=1&p\\_p\\_stat e=normal&p\\_p\\_mode=view&p\\_p\\_col\\_id=column-1&p\\_p\\_col\\_pos=1&p\\_p\\_col\\_count=2&echarevbiocides\\_WAR\\_echarevbiocidesportlet\\_javax.portlet.action=searchBiocidesAction](http://echa.europa.eu/information-on-chemicals/biocidal-active-substances?p_auth=CUK6NhHu&p_p_id=echarevbiocides_WAR_echarevbiocidesportlet&p_p_lifecycle=1&p_p_stat e=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&echarevbiocides_WAR_echarevbiocidesportlet_javax.portlet.action=searchBiocidesAction)



Circular DGS/VS4 no. 99-360 of 21 June 1999 on household treatment devices includes water filter jugs. It recommends testing for silver, when filtering materials impregnated with silver are used, and testing for culturable aerobic bacteria at 20°C and 37°C<sup>20</sup>. It should be noted however that given the difficulties in implementing the protocol described in this circular, its implementation is not required by the Directorate General for Health (DGS, 2006).

Lastly, the entity responsible for placing water filter jugs on the market is responsible for providing justification for the claimed properties and consumer safety, in accordance with Articles L.121 and L. 221-1 of the French Consumer Code.

### **3.3.1.3. Other countries**

In the framework of the ENDWARE network<sup>21</sup>, a consultation with European Union MSs was initiated by ANSES in order to collect available studies and data. Three countries responded to France's request: Italy, Hungary and the Czech Republic. On this occasion, it appeared that there are specific provisions in certain MSs but this list is not necessarily exhaustive.

For example:

- In Italy, guidelines for household water treatments were published in accordance with the Italian national decree DM 25/2012 (Ministero de la salute, 2013),
- In Hungary, filtered water must comply with the following criteria: minimum hardness of 50 mg/L (expressed in CaO), and quality limits for Ag of 100 µg/L and 10 µg/L for children (< three years of age).

There are no regulations on water filter jugs in Canada or the United States, but there is a recommendation that they be NSF certified, like other household DW treatment systems.

### **3.3.2. Standards**

There are test standards, whose implementation is not mandatory (a voluntary initiative on the part of the entities responsible for placing products on the market), defining in particular expected performance and safety requirements for water filter jugs and cartridges. These products can be certified by an independent organisation indicating that they comply with these standards.

#### **3.3.2.1. European Union**

A draft European standard on water filter jugs (Draft EN, CEN/TC 426 N 90, 16 August) is currently being prepared by the CEN/PC 426<sup>22</sup> whose French mirror group is coordinated by the AFNOR/P40R committee<sup>23</sup>. This draft will be based on current French (NF P 41-650), German (DIN 10521, 2009) and British (BS 8427, 2004) national standards.

The draft European standard provides for tests in addition to those set out in the French standard (see § 3.3.2.2.), with the aim of measuring<sup>24</sup>:

- the removal of trihalomethanes (THMs) by analysing the reduction in chloroform concentrations,

<sup>20</sup> The NF EN ISO 6222 Standard (July 1999) now stipulates that culturable aerobic bacteria should be counted at a temperature of 36 ± 2°C.

<sup>21</sup> European Network of Drinking Water Regulators - an informal group responsible for drafting regulations on DW for EU Member Countries.

<sup>22</sup> CEN/PC 426: Domestic appliances used for water treatment not connected to water supply.

<sup>23</sup> AFNOR/P40R: Water treatment devices inside buildings.

<sup>24</sup> **Note:** the draft standard under preparation is subject to change.

- the reduction in aluminium concentrations,
- the reduction in scaling using two protocols: measurement of carbonate hardness or the so-called "kettle" test.

**3.3.2.2. France**

The NF P 41-650 (2013) Standard describes specifications, test methods and requirements for water filter jugs governing:

- their design:
  - o materials used in water filter jugs coming into contact with inlet water must comply with the regulations on FCMs,
  - o active media used in filtration systems must comply with the purity requirements defined in the standards on products used for the treatment of DW,
  - o from their placement on the market through to their use, cartridges must be protected against contamination;
- their safety: tests must be undertaken measuring the initial level of microbiological contamination and the potential for colonisation by *Escherichia coli* (*E. coli*) of the jug. The concentration of Ag in the filtered water must not exceed 70 µg/L;
- their effectiveness: a water filter jug complies with the standard if the percentage reductions in concentrations of chemicals in spiked test water, shown in the following table, are reached.

Furthermore, the standard specifies the minimum instructions for the use and maintenance of water filter jugs that should be provided to users.

**Table I: Performance levels for water filter jugs set by the NF P 41-650 Standard**

|                                | Test water*  | Parameter                          | Unit | Reminder of DW quality limits and reference values (Ministerial Order of 11 January 2007) | Initial concentration (test water)** | Expected minimum % reduction |
|--------------------------------|--|------------------------------------|------|---|--------------------------------------|------------------------------|
| <b>Metals</b>                  | Water 1<br>pH = 7.0 ± 0.5<br>Hardness: 150 mg/L CaCO <sub>3</sub><br>Alkalinity: 100 mg/L CaCO <sub>3</sub>    | Copper                             | mg/L | 2   | 3                                    | 80                           |
|                                |  | Lead                               | µg/L | 10  | 100                                  | 90                           |
|                                |  | Nickel                             | µg/L | 20  | 80                                   | 75                           |
| <b>Chemical properties</b>     | Water 2***<br>pH = 7.0 ± 0.5<br>Hardness: 300 mg/L CaCO <sub>3</sub><br>Alkalinity: 200 mg/L CaCO <sub>3</sub> | Total Hardness (TH)                | °f   | Water should be in equilibrium state or slightly scale-forming                            | 30                                   | 30                           |
|                                |  | Total Alkalinity (TA)              | °f   |   | 20                                   | 30                           |
|                                |  | Nitrates                           | mg/L | 50  | 50                                   | 50                           |
|                                |  | Chlorine (free and total)          | mg/L |   | 1                                    | 80                           |
| <b>Organoleptic properties</b> | Water 3<br>pH = 7.0 ± 0.5<br>Hardness: 150 mg/L CaCO <sub>3</sub><br>Alkalinity: 100 mg/L CaCO <sub>3</sub>    | 2,4,6 trichlorophenol (2,4,6 –TCP) | µg/L |   | 5                                    | 50                           |
|                                |  | Geosmin                            | µg/L |   | 0.05                                 | 50                           |

\* Corresponds to basic water of level 2 or higher according to the NF EN ISO 3696 Standard.

\*\* In the standard, initial concentrations are indicated with a precision that varies depending on the parameter.

\*\*\* The release of Ag is measured in conjunction with tests on reductions in levels of chemical parameters.

At least two identical cartridges should be subject to parallel tests undertaken at room temperature (20 to 25°C).

With regards to physico-chemical parameters, under the test protocol, five litres of spiked (except for Ag) test water are filtered per day, per one-litre fraction. Each filtrate is recovered after a 30-minute stagnation period. This process is repeated for five days consecutively, and filtration is stopped for two days. The filtrates corresponding to 5%, 25%, 50%, 75% and 100% of nominal filtration capacity are analysed; nominal capacity is the maximum volume of water that can be filtered by the cartridge, as indicated by the manufacturer. Analyses are then undertaken with a composite sample of the five filtrates recovered during the day.

Regarding microbiological requirements, the French NF P 41 650 Standard recommends tests focused firstly on verifying the initial level of microbiological contamination in the filtration media and secondly on determining the potential for microbial proliferation in the equipment (filter medium and jug).

To assess the initial level of microbiological contamination, the standard provides for the enumeration of *E. coli*, coliforms and enterococci in 100 mL of filtrate obtained after filtering one litre of sterile tap water with a new filtration cartridge.

With regards to tests on the potential for microbial proliferation, the standard relies on the monitoring of *E. coli* growth, in the presence and absence of nutrients, depending on the stage of use of the cartridge. The jug is filled with at least three litres of DW per day. When 25% and 100% of the cartridge's nominal capacity are reached, a total volume of five litres of test water (sterile filtered tap water inoculated with  $10^1$  to  $10^3$  CFU *E. coli*/100 mL) is filtered in the jug (day 0). After this "inoculation" of the active medium, the jug is filled with at least five volumes of tap water and *E. coli* are enumerated in a composite sample of the five filtrates. Then the jug is stored at room temperature (20-25°C). The same protocol is followed for three days (days 1, 2, 3). Throughout the test, *E. coli* densities are compared in the test water (sterile filtered tap water inoculated with *E. coli*), with or without the addition of nutrients. In order to comply with safety criteria, the counts obtained in the jug filtrates on days 1, 2 and 3 must not exceed twice the initial density of *E. coli* in the control water.

When the entities responsible for placing water filter jugs on the market declare their product to be compliant with the standard, all the safety requirements included in the standard must be fulfilled. However, performance requirements need only be fulfilled for parameters for which effectiveness has been claimed by the said entities.

The entities responsible for placing water filter jugs on the market can also have their products certified under the NF406 Standard on "Water treatment devices" by the French Scientific and Technical Centre for Building (CSTB) (see Technical document 5<sup>25</sup>). No requests have been submitted to the CSTB to date.

### **3.3.2.3. North America**

In North America, the standards on Point-of-Entry (POE) and Point-of-Use (POU) water treatment systems can apply to water filter jugs (NSF/ANSI Standards 42, 53 and 401).

To the WG's knowledge, the claim of NSF/ANSI certification for products intended for the French market is only applies to sport water filter bottles (portable systems not included in the scope of the request) and not for water filter jugs or disc-based water filter bottles (none of the nine brands whose user manuals were collected, see § 3.2.3.).

NSF/ANSI certification is a guarantee for users that products with this label comply with general and specific requirements.

<sup>25</sup> <http://evaluation.cstb.fr/doc/certification/certificats/nf406/nf406-dt5-carafes-020708.pdf>.

The NSF/ANSI standards (42, 53 and 401) that can apply to water filter jugs generally guarantee the safety of the materials used, the integrity of their structure, the truthfulness of the claims appearing on the label, and consistency in manufacturing quality. Each of these three standards can be used to verify the effectiveness of water filter jugs in terms of "organoleptic" parameters – reducing concentrations of chlorine and particles, improving appearance, taste and odour, reducing certain ions (sulphates, iron (Fe), manganese (Mn), zinc (Zn)) – (NSF/ANSI Standard 42) and parameters that can affect the health of users – inorganic compounds such as Pb and radon and organic compounds such as volatile organic compounds (VOCs), THMs, pesticides including herbicides (NSF/ANSI Standard 53) and emerging pollutants (NSF/ANSI Standard 401). On the certificate, the parameters for which the performance levels specified in the standard have been achieved must be clearly stated. A water filter jug is not required to meet the reduction targets for all of a standard's "effectiveness" parameters to earn certification.

Furthermore, these three standards recommend verifying the safety of materials in contact with DW (jugs and the body portions of bottles) according to a protocol adapted from NSF/ANSI Standard 61 and the safety of materials in contact with the user's mouth (end pieces of bottles and sport bottles) according to NSF/ANSI Standard 51. The integrity and tightness of devices must be verified. When a bacteriostatic effect is claimed, the geometric mean concentration of heterotrophic bacteria in the filtered water must not exceed that in the initial water.

For example, Table II gives recommendations regarding effectiveness against three parameters also covered in the French standard:

**Table II: Performance levels set by NSF/ANSI Standard 42 or 53\***

| Parameter                 | Unit | Initial concentration in the test water | Maximum concentration in the filtrate |
|---------------------------|------|---|---------------------------------------|
| Copper                    | mg/L | 3                                       | 1.3                                   |
| Lead (total)**            | µg/L | 150                                     | 10                                    |
| Chlorine (free and total) | mg/L | 2                                       | ≥ 50% reduction                       |

\* the reduction in metals should be analysed with two different water qualities:

- aggressive water with low alkalinity:  $pH = 6.5 \pm 0.25$ ; hardness and alkalinity = 10 – 30 mg/L  $CaCO_3$ ; total dissolved solids (TDS) = < 100 mg/L;
- water with a higher mineral content:  $pH = 8.5 \pm 0.25$ ; hardness = 100 – 200 mg/L  $CaCO_3$ ; alkalinity 100 – 250 mg/L  $CaCO_3$ ; total dissolved solids (TDS) = 200 - 500 mg/L;

\*\* total lead must contain 30% particulate lead including over 20% particles with a size of 0.1 to 1.2 µm.

### 3.4. Claims made by the entities responsible for placing water filter jugs on the market

The following commercial claims can be found in the technical leaflets:

- descriptive claims such as: "purer, clearer water, with a pleasant taste for hot or cold drinks and for the preparation of meals"; "clear, clean and healthy water", "the water filter jug will also protect your household appliances from the formation of limescale".
- specific claims such as:
  - o reducing chlorine ( $Cl_2$ ) concentrations and improving organoleptic properties, odour and flavour;
  - o reducing hardness;
  - o reducing concentrations of metals (such as Pb and copper (Cu)) and more seldom aluminium (Al) or zinc (Zn);
  - o more seldom, reducing concentrations of pesticides and other organic contaminants such as drug residues;
  - o reducing concentrations of nitrates, for certain specific cartridges;
  - o enriching the water with magnesium, for certain specific cartridges.

Compliance with the NF P41-650 or DIN 10521 Standard generally involves reducing concentrations of  $\text{Cl}_2$  and more seldom reducing other parameters (limescale, Pb, Cu).

It appears that these claims are similar to those observed for the sport water filter bottles excluded from the scope of the request:

- compliance with NSF/ANSI Standard 42 primarily involves reducing chlorine and improving odour and flavour,
- compliance with NSF/ANSI Standard 53 involves reducing Cu concentrations.

Certain water filter jugs claim "TÜV food quality" approval issued by the German certification organisation TÜV SÜD<sup>26</sup>.

### **3.5. Quality of filtered water**

The examined data on the quality of filtered water were taken from studies (see § 2) with different test protocols and objectives (see Table IX in Annex 2).

#### **3.5.1. Safety**

##### **3.5.1.1. Change in the pH and aggressiveness/corrosiveness of water**

A decrease in the pH of filtered water can be observed, reaching values below the French quality reference for DW ( $6.5 \leq \text{pH} \leq 9$ )<sup>27</sup>:

- 4 (DWI, 2003);
- 6.1 (Que Choisir, 2010);
- 5.45 (60MdC, 2011);
- 5 (Veschetti, 2013).

The observed change in pH depends on the composition of the filter medium used in the cartridge. While activated carbon tends to increase the pH value, acid cation resins releasing  $\text{H}^+$  ions tend to reduce it.

Although, within a certain limit, no relationship between dietary (food and DW) pH values and direct harmful effects on health has been demonstrated, an indirect effect has been shown due to exposure to metals released by metallic materials in contact with water with a low pH (Health Canada, 2015).

In the United Kingdom (DWI, 2003), a comparison of the corrosiveness of filtered water and non-filtered water to metals showed that contact with jug-filtered water promoted the dissolution of metals, in particular nickel (Ni), found in kettles and saucepans. Ni concentrations of around 1 mg/L were measured when the containers were in contact with filtered water; these values were 50 times higher than the quality limit for DW (20  $\mu\text{g/L}$ ). This increased release of Ni was observed in the first half of the cartridge's lifetime and then fell. At the end of the cartridge's lifetime, there were virtually no differences between the filtered water and non-filtered water. The corrosive nature of filtered water to metals should therefore be taken into account when assessing the safety of water filter jugs. Given the reduction in hardness and alkalinity (TH and TA) claimed on advertisements, packaging and user leaflets for several jugs, the use of water filtered by these jugs to prepare a hot beverage with a kettle is a plausible scenario.

<sup>26</sup> [www.tuv-sud.com/home.com](http://www.tuv-sud.com/home.com)

<sup>27</sup> Ministerial Order of 11 January 2007 on the quality reference values and limits for raw water and DW listed in Articles R. 1321-2, R. 1321-3, R. 1321-7 and R. 1321-38 of the French Public Health Code.

It is stated, in certain technical leaflets, that: "*filtered water should not be used in an appliance to prepare hot beverages*" or "*if the filtered water has to be boiled, stainless steel utensils or kettles with a coated resistance wire should be used*".

Since an increase in the dissolution of metals is observed when certain household utensils are brought into contact with filtered water, special attention should be paid to changes in the values of parameters such as pH, hardness and alkalinity. These changes can cause the calcium carbonate equilibrium to be modified and therefore result in aggressive and corrosive filtered water.

### **3.5.1.2. Release of silver**

#### Released quantities of silver:

The release of Ag<sup>28</sup> is observed in all studies with water filter jugs containing filter media treated with Ag, although it appears to be lower in the most recent studies. The described concentrations corresponding to averages for one or more filtered litres vary depending on the study and can reach:

- mean daily concentrations of 2.6 to 13.1 µg/L for eight cylindrical cartridges and of 2.7 to 14.3 µg/L for six oval cartridges (Świecicka and Garboś, 2010, Garboś and Świecicka, 2012 and 2013) (Table III). These studies concluded that all these cartridges comply with the migration limit for Ag proposed by the authors, i.e. 25 µg/L, which is below the limits set in the French NF P 41-650 Standard (70 µg/L) and in the draft European standard<sup>29</sup> (80 µg/L). However, it should be noted that normative values have no regulatory value;
- up to 30 µg/L (CRECEP, 1997);
- around 20 µg/L for tests undertaken with two jugs in homes, and between 6.5 and 14 µg/L for laboratory tests undertaken with three jugs (Que Choisir, 2003);
- values ranging from 6 to 18 µg/L (average of 10.6 µg/L) were observed in water filtered by five jugs using a filter medium treated with Ag, during laboratory tests (Que Choisir, 2010);
- values of 3 to 43 µg/L with an average value of 21.6 µg/L for all of the tests undertaken in 31 households (Que Choisir, 2010), thus demonstrating a wide range of observed concentrations of Ag. In 3 out of 31 cases, the concentration of Ag in filtered water could not be measured;
- values ranging from 17 to 39 µg/L (<1 µg/L in the initial water) (Veschetti, 2013);
- up to 50 µg/L in the first few filtered litres with a decrease in release over time (DWI, 2003). Tests undertaken on Monday morning following stagnation over the weekend at various points in the cartridge's lifetime showed concentrations in the third litre of filtered water that were almost always lower than in the first litre.
- values of 12 to 30 µg/L released in the first few filtered litres (5% of the cartridge's nominal capacity) and of 4 to 7 µg/L in the last filtered litres (100% of the cartridge's nominal capacity) for tests undertaken according to the NF P 41-650 Standard (documents provided by the DGCCRF following the TN 35EA investigation of the fourth quarter of 2012);
- values ranging from 11 to 43 µg/L in filtered water (Deshommes, 2012), i.e. concentrations two to ten times lower than the limit value set by the US EPA (MCL = 0.1 mg/L).

These observations are summarised in Table IV, taking into account the influence of the cartridge's age.

<sup>28</sup> The Ag analysis method used in most studies is the NF EN ISO 17294-2 Standard (ICP/MS analysis). Since it recommends acidifying samples to a pH of 2 with nitric acid before analysis, the quantity of total Ag released is measured. The analysis of dissolved Ag requires filtration prior to analysis, which is not indicated in any of the appraised studies. The WG therefore considered that the concentrations of released Ag observed corresponded to total Ag.

<sup>29</sup> (Draft EN, CEN/TC 426 N 60, 15 August).

According to Jarvis *et al.* (2014), the quantities of released Ag are higher when the water to be filtered has a lower mineral content. Although this difference is not observed at the start of filtration (5% of the cartridge's nominal capacity), it appears from 25% of the cartridge's nominal capacity. Deblonde *et al.* (2014) indicate that the quantities of released Ag are higher in the water of jugs kept at room temperature than in the water of jugs kept in the refrigerator. The results observed in the DWI study (2003) showed differences in Ag release profiles between tests undertaken with groundwater with a low concentration of assimilable organic carbon (AOC) and those undertaken with surface water with a high concentration of AOC. The release of Ag was higher with groundwater with a low concentration of AOC and decreased less quickly with the cartridge's nominal capacity.

Some technical leaflets state that for hygiene reasons, the filter medium in the cartridge has been treated with Ag and that there may be a small amount of Ag in the filtered water.

**Table III: Mean daily concentrations of Ag released in water throughout the life cycle of the cartridge (Garboś and Świecicka, 2012 and 2013)**

| Garboś and Świecicka (2012)<br>Round cartridges<br>(Non-chlorinated synthetic test water: Hardness =<br>135-180 mg/L CaCO <sub>3</sub> and pH = 6.5 – 7.5) |   | Garboś and Świecicka (2013)<br>Oval cartridges<br>(Test water compliant with the BS 8427 (2004)<br>Standard) |   |
|--|---|--|---|
| Jug  | Mean daily<br>concentration of Ag<br>(µg/L) | Jug  | Mean daily<br>concentration of Ag<br>(µg/L) |
| A  | 4.9 ± 1.8                                   | A  | 8.2 ± 5.2                                   |
| B  | 2.6 ± 2.6                                   | B  | 9.6 ± 6.5                                   |
| C  | 3.4 ± 2.8                                   | C  | 2.7 ± 3.1                                   |
| D  | 10.4 ± 2.7                                  | D  | 8.4 ± 1.4                                   |
| E  | 3.0 ± 3.1                                   | E  | 7.1 ± 5.4                                   |
| F  | 10.5 ± 2.0                                  | F  | 14.3 ± 3.7                                  |
| G  | 13.1 ± 1.8                                  |  |   |
| H  | 3.7 ± 4.9                                   |  |   |

**Table IV: Silver concentrations observed in various laboratory tests, at the beginning and end of the cartridge's lifetime (jugs having a filter medium treated with Ag)**

| Study   | Number of<br>jugs tested<br>(number of<br>different<br>brands) | Beginning of the cartridge's lifetime<br>(5 to 7.5 litres filtered) |                   |                | End of the cartridge's lifetime<br>(90 to 114 litres filtered) |                   |                |
|---|--|---|-------------------|----------------|--|-------------------|----------------|
|   |  | Minimum<br>(µg/L)   | Maximum<br>(µg/L) | Mean<br>(µg/L) | Minimum<br>(µg/L)  | Maximum<br>(µg/L) | Mean<br>(µg/L) |
| DWI<br>(2003)   | 6(3)   | 25.2  | 48.7              | 36.7           | 13.5   | 32.3              | 21.6           |
| Que Choisir<br>(2011)                                       | 5(5)   | 12.4  | 18                | 14             | 11.3   | 16                | 13.5           |
| NF P 41-650<br>Standard or<br>similar<br>protocol<br>(2012) | 6(3)   | 7   | 30                | 17             | 4  | 11                | 7              |
| Garboś and<br>Świecicka<br>(2013)<br>Oval<br>cartridges     | 12(6)  | 3.3   | 17                | 11             | 0.3  | 10.5              | 5              |
| Garboś and<br>Świecicka<br>(2012)<br>Round<br>cartridges    | 16(8)  | 7.2   | 15.3              | 10.2           | 0.8  | 11.4              | 4.8            |

Toxicity and reference values:

The European DW Directive of 1980<sup>30</sup> required testing for Ag with a quality limit of 0.01 mg/L. This parameter was not included in Council Directive 98/83/EC currently in force. No French texts dealing with DW quality take this parameter into account and/or set a quality limit for Ag. According to the results of DW health inspections available in the Ministry of Health's SISE-Eaux database for the 1984 to 2014 period, only four in 7,577 Ag screening analyses show a concentration above 10 µg/L in tap water supplied in France.

While the contribution of DW to dietary exposure to Ag in the population is limited, according to the data of the second Total Diet Study (TDS2), the average daily dietary intake of Ag in the population in France ranges from 1.29 to 2.65 µg/kg bw/day according to the best-case and worst-case scenarios for adults and from 1.60 to 3.47 µg/kg bw/day for children.

This illustrates the need to attribute only a fraction of the oral Toxicity Reference Value (TRV) to water. And yet most of the guidelines proposed by various international organisations attribute the majority of oral exposure to drinking water.

Current TRVs and guidelines for Ag are given in Tables V and VI:

**Table V: TRVs (oral route) and guidelines for Ag proposed by various organisations**

| Source                                    | Type of study | Critical effect  | TRV   | Guideline in water or FCMs   | Study reference  | Comments  |
|---|---------------|--|---|--|--|---|
| <b>WHO (2003a)</b>                        | Epidemiology  | To protect from argyria (black staining of the hair and teeth) | Lifetime NOAEL of 10 g (0.39 mg/person/day)   | 100 µg/L (Unusual construction since 100% of the TRV is attributed to water)                 | Studies dating from 1935   | Value of 100 µg/L used by some American states, EFSA for FCMs and Australia in particular.  |
| <b>US EPA In the IRIS database (1991)</b> |               | To protect from argyria  | LOAEL of $1.4 \cdot 10^{-2}$ mg/kg/day or 25 g/lifetime (by ingestion) converted into an RfD of 5 µg/kg/day (by oral route) | 150 µg/L (100% of the TRV attributed to water)   | Value set in 1996 based on studies from 1935 that appear different from those of the WHO |   |
| <b>EFSA (2004, 2011)</b>                  |               |  | Lifetime NOAEL of 10 g (0.39 mg/person/day)   | Specific migration limit (SML) of 0.05 mg Ag/kg food/day for substances used in organic FCMs |  | Opinion of 2011 on silver zeolite containing 2 - 5% Ag (Ref.: 86437)<br><br>Opinion of 2004 on glass containing Ag (Ref.: 86432) and on zirconium hydrogen phosphate, sodium and silver (Ref.: 86434) |

<sup>30</sup> Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption.



**Table VI: Other guidelines appearing in various reference bases**

| Source   | Guideline  | Comments   |
|--|--|--|
| <b>P-SC-EMB (2014)</b>                             | Specific release limit (SRL) of 80 µg/kg food/day for metals and alloys used in FCMs | This value will be revised by the Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB) in light of the publication by Hadrup <i>et al.</i> (2012) |
| <b>NF P41-650 Standard – Water filter jugs</b>     | The concentration of Ag must not exceed the value of 70 µg/L in filtered water       |  |
| <b>Draft European standard – Water filter jugs</b> | The concentration of Ag must not exceed the value of 80 µg/L in filtered water       |  |

Furthermore, in its opinion on the re-evaluation of silver (E174) as a food additive, EFSA considered that the available information was insufficient to assess the safety of Ag, primarily due to doubts about the form of Ag in this additive, and requested additional information (EFSA, 2016).

The guidelines proposed by the WHO and the US EPA cannot be used as is because:

- the original publications are old and are not available,
- they are based on the same effect, argyria, which occurs at relatively high doses and is not necessarily the most relevant effect considering the now-known properties of Ag. The consequences of prolonged exposure to low concentrations of Ag still remain unknown. Moreover, tests should be undertaken to determine whether Ag causes, like other trace metals (titanium (Ti), Pb), potential renal dysfunction following chronic exposure to low concentrations (ANSES, 2013c),
- according to the literature, the health effects of exposure to Ag differ depending on its form (nanoparticles versus ions). Therefore, the corresponding TRVs may not be the same (Hadrup, 2012),
- to establish these TRVs, the amount to be attributed to other routes of exposure (diet, consumer goods, cosmetics, etc.) should be determined.

Effects other than argyria are observed at low doses, such as the disruption of liver enzymes and blood parameters, and immunotoxicity with a change in thymus weight. According to Hadrup *et al.* (2012), for the same molarity, Ag nanoparticles ( $14 \pm 4$  nm in diameter) and ions do not have the same toxicity; the ionised form is thought to be more toxic by ingestion than the nanoparticulate form. Hadrup and Lam (2014) propose a Tolerable Daily Intake (TDI)<sup>31</sup> of 2.5 µg/kg bw/day. It should be noted that the upper exposure limit in the French population according to the TDS2 study is 2.65 µg/kg bw/day (ANSES, 2011).

It now appears that it is analytically possible to distinguish between the ionised and nanoparticulate forms in water (Hadioui *et al.*, 2013). However, although the information collected during the hearings indicates that Ag is used in salt form to treat the filter medium, the WG does not have any data on the form of Ag found in filtered water.

In the absence of data, the WHO attributes 10% or 20% of the TRV to water for consumption of 2 L/day, resulting in a management limit of around 7 or 15 µg/L, considering the toxicity benchmark of 2.5 µg/kg bw/day indicated above.

<sup>31</sup> TDI = NOAEL (No Observed Adverse Effect Level)/100.

Furthermore, for organic materials used for products in contact with drinking water (PDW), the Agency recommends that the quantities of a compound supplied by the materials should not exceed 10% of the quality requirements for DW, which is more stringent than the current regulations (20%) (ANSES, 2013b). For metallic materials used for PDW, the 4MS recommend a contribution of 90% or 50% for metallic elements (Ag is not specified), depending on whether or not the material is the only source of DW contamination (4MS, 2011).

Silver salts can be used to treat filter media in order to avoid the proliferation of micro-organisms in the cartridge.

The released concentrations of Ag vary from one study to the next, depending on the period of use of the cartridge and the quality of the water to be filtered. It appears, according to the limited data available, that the release of Ag is inversely proportional to the mineral content of the water to be filtered.

Concentrations of (total) Ag range from 3 µg/L to 50 µg/L in filtered water. In the studies by Garboś and Świecicka (2012, 2013), the mean daily concentrations observed throughout the lifetime of the cartridge range from 3 to 15 µg/L with water with controlled alkalinity. Approximately 20 µg/L Ag are released on average in tests undertaken in users of water filter jugs living in various regions of mainland France (Que Choisir, 2003, 2010).

The WG considers that the guideline value for Ag in water of 100 µg/L, established by the WHO based on a study from 1935, should be revised in light of the new toxicity data available. The toxicological benchmark of 2.5 µg/kg bw/day proposed by Hadrup and Lam (2014) would result in a new value in water of 7 or 15 µg/L depending on the percentage of the toxicological benchmark attributed to water. Therefore, the WG considers that the establishment of a new TRV and a new guideline for the "silver" parameter in DW by *ad hoc* groups of experts is necessary.

### **3.5.1.3. Release of ammonium**

A significant increase in ammonium ions was observed, with concentrations in filtered water ranging from 0.1 to 7.1 mg/L (four out of nine jugs), for an initial concentration below 0.1 mg/L (Veschetti, 2013). Jarvis *et al.* (2014) showed the release of up to 1 mg/L ammonium in filtered water at the beginning of the cartridge's lifetime.

Further to a request from the European Commission regarding potential health risks related to exposure to ammonium released by water filter jugs, EFSA concluded, in an opinion published in 2012, that ammonium ions are not, at the concentrations reported by Brita GmbH, a particular source of toxicity, including for susceptible populations. According to the information provided to EFSA by Brita GmbH, the released concentrations are below 10 mg/L in the first litre of filtered water (not meant to be consumed) and below 5 mg/L in the fifth litre, and then decrease to 0.5 mg/L in the fifteenth litre. The mean concentration is below 0.5 mg/L for a total volume of filtered water of 100 L. According to Brita GmbH, the released ammonium is formed during the steam sterilisation of the cartridges as part of the manufacturing process.

For information, ammonium is considered as an indicator of possible microbiological contamination in water, since it is the main compound produced during the decomposition of organic matter. Directive 98/83/EC thus provides a quality reference value of 0.5 mg/L. In France, the regulatory quality reference value for DW is set at 0.1 mg/L and 0.50 mg/L for groundwater if it is demonstrated that the ammonium has a natural origin. These values are not based on health effects (WHO, 2011).

The concentrations of ammonium released by water filter jugs can exceed the French regulatory quality reference value for DW set at 0.1 mg/L. However, EFSA has concluded that the observed concentrations, ranging from 0.5 to 5 mg/L, do not pose any health risks, including for susceptible populations (EFSA, 2012).

#### **3.5.1.4. Release of sodium and potassium**

Some cation resins used for the softening of water can be supplied in sodium (Na<sup>+</sup>) or potassium (K<sup>+</sup>) form.

An increase in the concentration of Na<sup>+</sup>, from 63 mg/L (initial concentration) to 173 mg/L maximum was observed by Veschetti (2013).

Although the TDS2 study of 2011 (ANSES, 2011) stated that daily intakes of Na<sup>+</sup> are too high in relation to the French and international guidelines, ANSES no longer recommends any guidelines due to a lack of data confirming that reducing sodium intakes has a relevant clinical effect on cardiovascular mortality in normotensive or hypertensive subjects. That said, in particular given the prevalence of hypertension and data on the consumption of salt in France, the Agency, like other international institutions, describes a need to monitor sodium intakes (ANSES, 2011; IOM, 2013; Adler *et al.*, 2014).

According to the TDS2 study, the average daily intake of Na<sup>+</sup> in the French population is estimated at 2.65 g/day for adults and 2.00 g/day for children. Although water has not been identified as a major contributor to total dietary exposure (1% for adults and 0% for children), the contribution of filtered water to average daily intake should be determined, in particular in the framework of a low-sodium diet.

The quality limit in DW, set at 200 mg/L Na<sup>+</sup>, is not based on health effects but on the fact that the taste of water can be modified above this value (WHO, 2011).

Some leaflets for water filter jugs state that the concentration of K<sup>+</sup> may increase "*slightly*" during filtration. Jarvis *et al.* (2014) showed that around 70 mg/L K<sup>+</sup> are released at 5% of the cartridge's nominal capacity. The quantity released then rapidly decreases, for a concentration below 0.3 mg/L at 100% of nominal capacity. Veschetti (2013) indicated that the concentration of K<sup>+</sup> in filtered water increased from 31 mg/L (initial concentration) to 50 and 83 mg/L for two out of nine tested water filter jugs.

Since ANSES, like other international institutions, recommends an equimolar ratio between intakes of Na<sup>+</sup> and K<sup>+</sup> (WHO, 2012), the nutritional reference value for K<sup>+</sup> depends on that set for Na<sup>+</sup>. Furthermore, EFSA submitted for public consultation proposed Dietary Reference Values (DRVs) of 3500 mg/day for the adult population, 800 mg/day for children between the ages of one and three years, and 750 mg/day for children between the ages of seven and eleven months.

According to the TDS2 study, the average daily intake of K<sup>+</sup> in the French population is estimated at 2854 mg/day for adults and 2186 mg/day for children. Although water has not been identified as a major contributor to total dietary exposure (0% for adults and for children), the contribution of filtered water to average daily intake would be worth determining, in particular in the framework of a low-potassium diet.

The WHO did not consider it necessary to set a quality limit in DW for potassium (WHO, 2011).

The WG finds it unfortunate that measurements of sodium and potassium in filtered water were not taken in most of the available studies and have not been included in the NF P 41-650 Standard or the draft European standard, considering the need to monitor sodium intakes and the molar ratio between daily intakes of Na<sup>+</sup> and K<sup>+</sup>, which should not be greater than one. Moreover, the quantities of Na<sup>+</sup> and K<sup>+</sup> likely to be released in filtered water should be indicated in user manuals for water filter jugs in order to inform people on a controlled diet. No conclusions can be drawn from the few available data as to the risk related to the release of potassium and/or sodium in filtered water.

#### **3.5.1.5. Release of other contaminants**

In a CRECEP study dating from 1997, a large number of parameters were taken into account: physico-chemical and microbiological parameters included in health inspections of DW, volatile organohalogen compounds, volatile and semi-volatile non-halogenated compounds, a semi-quantitative GC-MS spectrum, and cytotoxicity. In addition to the release of Ag, the occurrence of Mn, for one brand of water filter jug (up to 65 µg/L), and Pb (up to 16 µg/L) was observed in filtered water. The CRECEP indicates that the occurrence of Mn could be due to its release by the activated carbon or materials comprising the jug, or else by the accumulation and reduction of the Mn found in water. The report does not specify the initial quality of the test water. No release of organic compounds was observed. However, it should be noted that this is an old study and that the analytical performance of the methods used was limited.

The WG does not have adequate data ensuring that there is no release of metals (or other compounds) initially retained in the filter when the cartridge's nominal capacity is exceeded (saturation of the cartridge).

#### **3.5.1.6. Potential for the colonisation of water filter jugs by micro-organisms and microbiological quality of filtered water**

##### Initial level of contamination of water filter jugs

The initial level of microbiological contamination in filter media was studied in a laboratory (documents provided by the DGCCRF following the TN 35EA investigation of the fourth quarter of 2012); Pietsch 2012; Jarvis *et al.*, 2014). In these studies, levels of microbiological contamination in filtration media were assessed by analysing the filtrate from a new filtration cartridge. The results showed no detection of the standard indicators of faecal contamination (*E. coli* and enterococci) and/or a very limited number of culturable aerobic flora, which did not call into question the microbiological quality of the products when they were brought into use.

##### Level of contamination of filtered water

In strict compliance with the conditions of use recommended by the supplier, the bacteriological quality of filtered water was monitored in a laboratory based on the volume of filtered water (Eurofins, 2012; Deblonde *et al.*, 2014). The tests undertaken by Eurofins (2012) on the basis of the water being periodically renewed three times a week and the filtered water being stored at 4°C indicate a maximum contamination level of 22 CFU/mL for culturable micro-organisms at 22°C and 12 CFU/mL for that enumerated at 36°C. In the study by Deblonde *et al.* (2014), covering three separate trials, the concentration of bacterial flora measured at the end of the recommended period of use (four weeks) did not exceed 55 CFU/mL. The findings concur and show the maintenance of the microbiological quality of filtered water, in particular when there is refrigeration during stagnation (storage at 4°C). The study by UFC-Que Choisir (2010) also confirmed the control of microbiological contamination in the water filtered by the device if the supplier's recommendations are observed and the jug containing the filtered water is kept in the refrigerator.

Potential for the colonisation of water filter jugs

A first series of studies relied on initial artificial contamination of the filtering surface using a bacterial suspension with a known titre: Veschetti (2013) provided periodic supplies of *Enterococcus aerogenes* while Jarvis *et al.* (2014) added a strain of *E. coli* at 25% and 100% of the cartridge's nominal capacity. In both cases, the conclusions indicate a lack of proliferation over time.

A second series of studies assessed the colonisation of water filter jugs in a laboratory when they were used in intentionally degraded conditions (CRECEP, 1997; Eurofins, 2012; Pietsch, 2012; Deblonde *et al.*, 2014). Significantly extending the maximum period of use, exceeding the nominal filtration volume and/or maintaining the device at room temperature for stagnation periods ranging from several hours to several days were the parameters taken into account by these various studies for promoting microbial development. It should be noted that these test conditions had the advantage of being close to the actual conditions of use of some users. The test data are consistent and show no detection of standard indicator micro-organisms such as *E. coli* and enterococci. However, they show significant proliferation of culturable aerobic flora. For example, concentrations of around  $10^2$  to  $10^6$  CFU/mL are described in several independent studies of suppliers of water filter jugs (CRECEP, 1997; Que Choisir, 2010; Veschetti, 2013).

The study undertaken in the United Kingdom (DWI, 2003) showed that the increase in culturable aerobic bacteria in the filtrate depended on the initial concentration of organic matter in the water before filtration, the water filter jug's storage time and temperature (more significant growth at 20°C than at 4°C), and rinsing. The highest bacterial count was observed in the first few litres of filtered water, after stagnation, which are theoretically intended to be discarded. Tests undertaken with water supplemented with *E. coli* and *Salmonella* showed the same phenomenon. These were not detected in the filtrate or filter.

Eurofins (2012) and Deblonde *et al.* (2014) showed that refrigeration of the jug containing the filtered water helped significantly delay over time the development of bacterial flora in all the assessed types of water. Conversely, the highest growth rates for culturable aerobic bacteria were found when the jug containing the filtered water was kept at room temperature and when the water was not renewed.

The available studies cannot be used to demonstrate the effectiveness of treating the filter medium with Ag in terms of microbial proliferation, since the WG does not have comparative studies undertaken with an untreated filter medium and a treated filter medium.

Comparison with other types of water (non-filtered tap water and bottled water)

Eurofins (2012) compared microbial development in DW filtered with a water filter jug, DW kept in a glass container without filtration, and bottled water. It appeared that the microbiological quality of tap water kept in a glass container deteriorated more quickly than for the same water filtered and stored in the same conditions in a water filter jug. Bacterial counts, which were initially low in both types of water (< 6 CFU/mL), exceeded 300 CFU/mL from the seventh day in the tap water kept in a glass pitcher, despite storage at 4°C. Under the same refrigeration conditions, the contamination of the tap water filtered with a water filter jug remained low and stable (< 5 CFU/mL). At 20°C, the concentration of 300 CFU/mL was exceeded from the fourth day for the tap water kept in a glass container and at the end of the ninth day for the tap water filtered by a water filter jug. The aerobic flora counts observed for bottled water were also high:

- from opening, they exceeded 100 CFU/mL in two out of three assessed natural mineral waters;
- the threshold of 300 CFU/mL was exceeded from three days of storage at room temperature (after opening), for two out of three spring waters.

It should be noted that these results have been taken from an isolated study, whose test conditions are not all known (state of cleanliness and age of the jugs and cartridges, concentration of chlorine in the water, occurrence of silver in the filtered water, initial water quality, etc.).

Similarly, Deblonde *et al.* (2014) compared concentrations of bacterial flora for tap water always kept in a water filter jug but either subject to prior filtration or not. After three days of stagnation, counts of culturable aerobic flora were the same as or better than those observed in the non-filtered tap water stored under the same conditions. The results indicated low levels of heterotrophic flora in the water maintained at 4°C (below 55 CFU/mL in all cases).

However, when the water was stored at 20°C, the measured densities of culturable aerobic flora varied greatly. Bacterial counts varied depending on the test performed, with concentrations above 300 CFU/mL observed in the filtered water and non-filtered water. Veschetti (2013) states that the increase in total culturable flora in water filtered by nine water filter jugs of different brands was equivalent to that observed in bottles of natural mineral water.

Armas and Sutherland (1999) showed that culturable aerobic flora in bottled water analysed on the same day the bottles were purchased varied from  $5.10^2$  to  $5.8.10^4$  CFU/mL, depending on the brand as well as the incubation medium and temperature.

#### Microbiological quality of home-filtered water

Studies undertaken in the homes of private individuals showed an increase in culturable aerobic bacteria at 22°C and 36°C in water filtered by water filter jugs, above the regulatory limits set for bottled water (100 CFU/mL and 20 CFU/mL respectively for culturable micro-organisms at 22°C and 36°C)<sup>32</sup>, in 25 out of 31 cases (Que Choisir, 2010). Analyses in filtered water showed the presence of coliforms in one sample and of enterococci in another sample (different places); however, analyses of water before filtration had showed no contamination. Regarding the coliform analyses, it should be noted that in 14 out of 31 cases, the results could not be interpreted. Considering the conclusions of previous studies, these results could be due to non-compliance with the instructions for use recommended by the entities responsible for placing water filter jugs on the market.

#### Methodology for determining colonisation potential in water filter jugs

The confidential studies submitted during the hearings as well as independent studies show significant methodological diversity in the approaches used for assessing changes in the microbiological quality of water filtered by water filter jugs. Of the parameters that vary from one study to another, the nature of the tested micro-organisms can be underlined.

The French NF P 41 650 Standard and the draft European standard recommend assessing the potential for the microbiological colonisation of filtration devices using a reference strain of *E. coli*. The suitability of the choice of this micro-organism is questionable in that *E. coli* is enumerated as an indicator of faecal contamination (WHO, 2001), not as a bacterium typical of DW colonisation phenomena.

Therefore, several studies have used other micro-organisms to assess proliferation on the surface of the filter medium or in the filtered water. For example, culturable aerobic flora at 22°C and 36°C has been most commonly used (Que Choisir, 2010a; Pietsch, 2012; Eurofins, 2012; Veschetti, 2013; Deblonde *et al.*, 2014). This parameter, "chemo-organotrophic and heterotrophic flora", whose development is facilitated in the presence of organic matter, is suitable for assessing microbial proliferation at 22°C and 36°C as a function of time. The proliferation of culturable aerobic flora is not systematically indicative of an increase in exposure to pathogenic micro-

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<sup>32</sup> Ministerial Order of 14 March 2007 on the quality criteria for bottled water, on specific treatments and labelling statements for bottled natural mineral and spring water, and natural mineral water distributed in public refreshment bars.

organisms but does reflect favourable conditions for the multiplication and survival of micro-organisms (WHO, 2003b)<sup>33</sup>.

In the framework of health inspections of DW in France, a maximum variation in culturable aerobic flora must not exceed a factor of ten in relation to the usual value. For bottled water, concentrations of culturable aerobic flora should be measured within less than 12 hours of bottling and must not exceed 100 CFU/mL for flora at 22°C and 20 CFU/mL for flora at 36°C. It should be noted that the criteria applicable to drinking water and bottled water are exceeded by the concentrations reported in studies on filtered water kept at room temperature (Eurofins, 2012; Deblonde et al., 2014).

The *Pseudomonas aeruginosa* bacterium, an opportunistic pathogen likely to be found in water, has also been investigated in certain studies (CRECEP, 1997; Pietsch, 2012). This bacterial species is capable of multiplying in water and on moist surfaces with minimal nutritional requirements (ANSES, 2010). Thus, *P. aeruginosa* could be a more suitable bacterial indicator than *E. coli* for assessing colonisation phenomena affecting filtering surfaces or containers. However, the data from the studies currently available do not demonstrate whether the occurrence of this bacterial species in filtered water is occasional or recurrent. On the other hand, there are data for the period from 1996 to 2009 on tap water (ANSES, 2010): further to the analysis of over 2000 samples, the prevalence of *P. aeruginosa* was estimated at 3.2% with a median value of 8 CFU/100 mL and a 90<sup>th</sup> percentile of 200 CFU/100 mL.

In the framework of the European Committee for Standardisation CEN/TC 426, some countries are in favour of including testing for *P. aeruginosa* in the draft European standard.

While the inoculation of filtering media with suspensions of bacterial strains does not result in these micro-organisms being maintained in water filter jugs over time, several studies show, in the absence of refrigeration, the gradual development of culturable aerobic flora in filtered water; this can reach high concentrations of around 10<sup>2</sup> to 10<sup>6</sup> CFU/mL. However, this phenomenon is not specific to water filtered by a jug and can be observed for non-filtered water kept in a container at room temperature. Moreover, the described concentrations remain similar to those observed in bottled waters that have been stored for several days.

This gradual development of culturable aerobic flora is observed despite the Ag treatment of the filter media. The WG does not have any studies demonstrating the effectiveness of Ag against microbial proliferation in the filter medium and/or filtered water.

Furthermore, the action of chlorine residual, intended to maintain the microbiological quality of water when it is supplied, is no longer ensured if this chlorine residual is retained by the filtering cartridge (see § 3.5.2.1).

The degree of this proliferation can depend on:

- the amount of organic matter in the water to be filtered,
- the temperature,
- the stagnation time,
- hygiene conditions during the use and storage of the water filter jug,
- the age of the jug and the duration of use of the cartridge.

Therefore, given the differences observed between the results of laboratory tests undertaken according to the manufacturer recommendations and those of tests undertaken with users or in laboratories under degraded conditions, the WG would like to stress the importance of considering

<sup>33</sup> WHO (2003): "There is no evidence, either from epidemiological studies or from correlation with occurrence of waterborne pathogens, that HPC values alone directly relate to health risk. They are therefore unsuitable for public health target setting or as sole justification for issuing 'boil water' advisories. Abrupt increases in HPC levels might sometimes concurrently be associated with faecal contamination; tests for *E. coli* or other faecal-specific indicators and other information are essential for determining whether a health risk exists".

real uses by consumers at home when assessing risks of microbiological contamination.

Compared to the very low level of culturable aerobic flora observed mainly in tap water from the supply system as part of health inspections, the filtration of water with jugs can lead users to consume water with degraded microbiological quality, in particular if there is a stagnation phase at room temperature prior to consumption.

Although this degradation is characterised only by an increase in culturable aerobic flora for which there are no data demonstrating a direct risk to the health of consumers, it can reflect a favourable medium for the proliferation and survival of micro-organisms, including potentially pathogenic bacteria.

The WG has questions about the levels of culturable aerobic flora that can be found immediately after water has been filtered, since the available values were generally obtained after the filtered water had undergone a stagnation phase.

The WG considers that *P. aeruginosa*, an opportunistic pathogenic micro-organism, is a more suitable indicator than *E. coli* when it comes to assessing colonisation phenomena affecting filtering surfaces or containers. *P. aeruginosa* is capable of colonising moist surfaces even when there are very few nutrients. Moreover, *P. aeruginosa* can occasionally be found in the native flora of tap water. It is also the only *Pseudomonas* species for which there is a standard for its enumeration in water (NF EN ISO 16266).

### **3.5.2. Effectiveness**

Tests were undertaken in laboratories with tap water and/or spiked water as well as in the homes of consumers. Tables X and XI given in Annex 3 respectively summarise the effectiveness results of the study published by UFC-Que Choisir in 2010 and the results of tests undertaken according to the protocol in the NF P 41-650 Standard or a similar protocol.

#### **3.5.2.1. Reduction of chlorine concentrations and improvement of organoleptic properties**

In the study undertaken by UFC-Que Choisir (2003), all the models were assessed with water spiked with 0.1 mg/L free chlorine. The generated water contained less than 0.03 mg/L, i.e. a reduction of at least 70%; this value was underestimated since 0.03 mg/L corresponds to the limit of quantification (LQ) for the analytical method.

In 2010, the same association carried out laboratory tests with seven jugs of different brands, with tap water not spiked with chlorine (concentration of free chlorine ranging from 0.1 to 0.18 mg/L), and 70% to 100% reductions in free chlorine were observed. The reduction in chlorine did not significantly change depending on the volume of water filtered (nominal capacity of the cartridge) for the various water jugs that were tested.

Tests in the homes of consumers (31 households) confirmed these results. In the homes of consumers where the average chlorine concentration was 0.2 mg/L, water filter jugs showed an average reduction of 80%, with reductions ranging from 0% to 98% depending on the initial concentrations, which were sometimes low (around the LQ of 0.03 mg/L).

In 2011, a study undertaken by the INC and published in the magazine *60 Millions de Consommateurs* considered that the organoleptic tests were "satisfactory" overall but did not specify the parameters measured or the results.



Reports on tests undertaken according to the NF P 41-650 Standard or a similar protocol show reduction rates for chlorine (free and total) always above 80% and reduction rates for sapid and odorous compounds (geosmin and 2,4,6 trichlorophenol) generally above 50% (documents provided by the DGCCRF following the TN 35EA investigation of the fourth quarter of 2012). The percentage reductions in chlorine, geosmin, and 2,4,6-TCP did not significantly change depending on the volume of water filtered (nominal capacity of the cartridge) for the water jugs tested. The percentage reductions were consistent with those recommended in the standard.

The WG would like to point out that geosmin and trichlorophenol are not representative of all of the flavour-generating compounds in DW.

### **3.5.2.2. Reduction of metal concentrations**

Effectiveness varies depending on the jug, the metal tested and the concentration in water prior to filtration.

The study undertaken by UFC-Que Choisir (2003) showed that the three models of jugs and four cartridges tested helped reduce the concentration of Pb from 100 µg/L (spike value) to less than 20 µg/L.

In 2010, UFC-Que Choisir published the results of laboratory tests undertaken with seven jugs of different brands with water spiked with 20 to 22 µg/L Pb. In six out of seven cases, Pb could no longer be detected ( $< LD = 10 \mu\text{g/L}$ ), even after 174 litres were filtered, i.e. a reduction of at least 50% (% reduction underestimated). For one of the jugs, Pb was again measurable (between 10 and 11 µg/L) after 114 litres had been filtered. In tests undertaken in real-life situations, this effectiveness could not be verified, since Pb was not detected in the test water before or after filtration (31 households).

In 2011, the INC published the results of laboratory tests undertaken with tap water (the quality of this water was not specified) and with water spiked with Pb (+100 µg/L); Cu (+3 mg/L); Ni (+80 µg/L); Al (+200 µg/L); Fe (+200 µg/L); Zn (+5 mg/L); and arsenic (As) (+10 µg/L).

Regarding Pb, the report states that two out of eight jugs were "*poorly effective*" and three out of eight "*fully*" retained this element. Nothing is described for the other three jugs.

The study gives reduction rates from 55% to 90% for Cu, from  $> 37\%$  to 80% for Ni, from 28% to 95% for Zn, and from 30% to over 80% for As.

The reports on laboratory tests undertaken in accordance with the NF P 41-650 Standard or using a similar protocol confirm the values from the studies published by UFC-Que Choisir in 2003 and 2010 in relation to Pb. The observed reduction rates were greater than 80% and 90%, at 100% of the nominal capacity of the cartridges, for initial concentrations of 50 and 100 µg/L respectively (the standard recommends a minimum percentage reduction of 90% for an initial concentration of 100 µg/L). The reductions observed for Cu were always above 80% (minimum % reduction recommended in the standard), even at 100% of nominal capacity. Regarding Ni, even though the minimum reduction rate of 75% recommended in the standard was sometimes achieved at the beginning of filtration, it was never maintained throughout the lifetime of the cartridge.

In Canada, Deshommes *et al.* (2010) studied the metal-removing effectiveness of four NSF/ANSI 53-certified water filter jugs of different brands, fitted with cartridges containing GAC and a cation resin, under various conditions. Removal percentages from 68% to 99% were observed for total Pb, whereas the performance levels stated by the manufacturers were above 95%. The authors specify that the initial concentrations of Pb in the tests undertaken (1-36 µg/L) were below those indicated in the NSF standard (150 µg/L Pb). They cite the study by Gulson *et al.* (1997) which showed that the Pb reduction rate depended on its initial concentration, the species of Pb and the quality of water before filtration.

Deshommes *et al.* (2010) also indicate that water filter jugs were able to remove slightly more dissolved Pb than the other devices tested (tap-mounted and under-the-sink devices) due to the presence of resin in the filter. However, the other devices were more effective against particulate Pb.

Concentrations of Cu, chromium (Cr), cobalt (Co), Ni and Ag were also measured in various test conditions (in the laboratory and in a home, with and without spiking). After filtration, levels of Cu, Ni and Cr in water were below the North American guidelines for water (1.3 mg/L, 0.1 mg/L, 0.1 mg/L respectively).

In the study by Carrière *et al.* (2011), the performance of two water filter jugs (filter made of GAC + cation resin) as well as two tap-mounted filters and two under-the-sink filters (made of activated carbon "blocks") was tested in terms of the removal of Mn (Table VII). These devices were all NSF-53 certified for the removal of Pb. Four non-certified devices were also tested. The tests were undertaken with potable water produced by the city of Montreal, for which certain parameters were adjusted to have "synthetic" groundwater (pH adjusted to 8.5, hardness of 125 mg/L CaCO<sub>3</sub>, initial Mn concentrations of 100 and 1000 µg/L).

**Table VII: Removal of manganese (Mn) by two water filter jugs (values taken from the graphs appearing in the article by Carrière *et al.*, 2011)**

| % of nominal capacity | Total filtered volume (L) | % Mn reduction<br>[Mn] <sub>initial</sub> = 100 µg/L | % Mn reduction<br>[Mn] <sub>initial</sub> = 1000 µg/L | % hardness reduction<br>[Mn] <sub>initial</sub> = 100 µg/L | % hardness reduction<br>[Mn] <sub>initial</sub> = 1000 µg/L |
|-----------------------|---------------------------|--|---|--|---|
| 50                    | 75                        | 60-75  | 70-85   | 38-45  | 55  |
| 100                   | 150                       | 60-70  | 65-75   | 25   | 30  |
| 150                   | 225                       | 60   | 65-70   | 18-20  | 18-25   |
| 180                   | 270                       | 60   | 55-70   | 10-15  | 10  |
| 200                   | 300                       | 55   | 60  | 10   | 12-15   |

### 3.5.2.3. Reduction of hardness and alkalinity

In 2010, UFC-Que Choisir published the results of laboratory tests undertaken with seven jugs of different brands with water containing between 74 and 117 mg/L calcium (Ca<sup>2+</sup>). After the filtration of six litres, the reduction rates ranged from 27% to 93% depending on the brand. They then decreased fairly rapidly as the filtered volume increased, ranging from 0% to 28% after 84 litres. In the homes of consumers (31 households), this reduction ranged from 6% to 98%.

In 2011, the INC published the results of tests undertaken with tap water ([Ca<sup>2+</sup>] = 120 mg/L on average) and with spiked water ([Ca<sup>2+</sup>] = 89.5 mg/L; [hydrogen carbonates] = 244 mg/L; [Mg<sup>2+</sup>] = 18.5 mg/L). The report indicates:

- for calcium: removal rates between 11% and 93% at the beginning of filtration, which rapidly fell and were all below 10% at the end of the cartridges' lifetime,
- for hydrogen carbonates: removal rates from 100% at the beginning of filtration to less than 20% at the end of the cartridges' lifetime,
- for magnesium: the same reduction rates as for calcium.

Reports on laboratory tests undertaken in accordance with the NF P 41-650 Standard, or using a similar protocol provided by the DGCCRF (see Annex 3), show that the reduction capacities of water filter jugs for the hardness (TH) and alkalinity (TA) parameters decreased significantly as the volume of filtered water increased. These average reductions were below 15% at the end of the cartridge's lifetime (100% of nominal capacity), although some jugs achieved the minimum 30% reduction required by the standard.

It should be noted that some cartridges release magnesium at the same time as they remove calcium (see § 3.2.2 and 3.4).

**3.5.2.4. Reduction of nitrate concentrations**

The study published in Que Choisir in 2003 showed, with laboratory tests, for the only cartridge claiming nitrate removal, a reduction from 99% to 44% within ten days, for water spiked with 50 mg/L nitrates.

In the study published by UFC-Que Choisir, none of the seven tested cartridges claimed nitrate removal. While the average nitrate removal rate was 30% at the beginning of the test (six litres of filtered water), it was only 2% after 36 litres had been filtered. It is difficult to generalise the results in homes of consumers (31 households), since the types of cartridges used were not specified (traditional cartridge or cartridge specifically claiming nitrate removal).

The report submitted by the INC (2011) indicated that nitrate reductions ranged from 8% to 17% for cartridges not specifically claiming nitrate removal.

**3.5.2.5. Removal of other contaminants**

The study published in the magazine Que Choisir (2010) also dealt with laboratory tests undertaken with water spiked with glyphosate. Since the spike levels were fairly close to the LQ (0.1 µg/L), it is not possible to clearly rule as to the potential effectiveness of these devices against this herbicide. In the tests undertaken in the homes of consumers whose tap water was contaminated with 0.2 to 0.32 µg/L glyphosate, reductions ranging from 26% to 50% were observed, but this assessment relied on only three measurements.

Anumol *et al.* (2015) studied the effectiveness of three water filter jugs (filter medium comprised of activated carbon and resin) and three refrigerator filters against nine organic contaminants including drugs and pesticides (tap water and surface water spiked at concentrations ranging from 140 to 1300 ng/L). The tests were undertaken in accordance with NSF/ANSI Standard 53. The authors indicate that the refrigerator filters were more effective than the water filter jugs. Regarding the latter, the average removal rates for organic contaminants throughout the lifetime stated by the manufacturer were 70.7%, 90.6% and 94.9% for the three jugs.

Carrasco-Turrigas *et al.* (2013) compared the performance of a water filter jug (filter medium comprised of activated carbon and resin) and a reverse osmosis device in removing disinfection by-products in drinking water: trihalomethanes (THMs), bromate and 3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone (MX). The results obtained with the water filter jug are given in Table VIII.

**Table VIII: Removal of disinfection by-products (Carrasco-Turrigas *et al.*, 2013)**

| Parameter      | Number of samples | Initial mean value | % reduction after 1L | % reduction after 75L | % reduction after 150L |
|----------------|-------------------|--------------------|----------------------|-----------------------|------------------------|
| THM*           | 4                 | 104.23 µg/L        | 89                   | 76                    | 74                     |
| Bromate        | 2                 | 2.90 µg/L          | 12                   | +7 (increase)         | 12                     |
| MX             | 2                 | 0.6 ng/L           | [MX] < LQ            | [MX] < LQ             | [MX] < LQ              |
| pH             | 1                 | 8.21               | 34                   | 22                    | 17                     |
| Total chlorine | 1                 | 0.24 mg/L          | 58                   | 50                    | 8                      |

\* Sum of chloroform, bromodichloromethane, dibromochloromethane and bromoform.

Regarding the assessment of the effectiveness of water filter jugs, it should be noted that the test conditions described in the various studies examined by the WG are not all the same, making it difficult to compare and summarise the results.

In light of the data available in France, the WG observes that reduction levels vary depending on the tested water filter jug, the volume of filtered water (% of the cartridge's nominal capacity reached), the measured parameter and its initial concentration, and the quality of the water to be filtered.

However, the following findings are worth noting:

- A reduction in chlorine of at least 70% throughout the lifetime of the cartridge and often above the minimum reduction rate of 80% recommended by the NF P 41-650 Standard;
- Reductions in metals often above those recommended by the aforementioned standard, i.e. 80% for Cu and 90% for Pb, throughout the lifetime of the cartridge recommended by the manufacturer. For nickel, effectiveness quickly decreases during the use of the cartridge and even though the minimum reduction rate of 75% recommended in the standard is sometimes achieved at the beginning of filtration, it is never maintained throughout the lifetime of the cartridge;
- Highly variable results in terms of the reduction in hardness and alkalinity depending on the jug. Even though the minimum reduction rate of 30% recommended in the standard is sometimes achieved at the beginning of filtration, it is never maintained throughout the lifetime of the cartridge;
- Nitrate removal effectiveness is difficult to determine, since the cartridges tested in the available studies were generally not those specifically claiming nitrate removal (ion-exchange resin different from so-called "traditional" cartridges);
- Effectiveness in the removal of organic compounds (e.g. pesticides) cannot be assessed due to the insufficient number of results;
- Reduction rates are higher if the initial concentration is high, for a given parameter, irrespective of the underestimations sometimes observed for low concentrations due to the LQ of the analytical method used;
- For tests undertaken in accordance with the NF P41-650 Standard, the initial spike concentrations in test water are above the quality limits in DW set for Cu, Pb and Ni, and above the maximum value recommended at the tap in France for Cl<sub>2</sub> (Vigipirate plan no. 10200/SGDSN/PSE/PSN/CD of 17 January 2014).

Given that the TDS2 study specifies that *"for calcium, iron, magnesium and copper, high percentages of the population have intakes below their estimated nutritional requirements"* (ANSES, 2011), the WG considers that users should be informed of the reduction in calcium concentrations in filtered water.

### **3.6. Limitations and uncertainties**

#### **3.6.1. Limitations relating to the available data**

The WG notes the lack of alerts involving water filter jugs reported *via* alert systems (RASFF, RAPEX, INFOSAN and OECD). However, some products are monitored more than others depending on the regulations in force, the analytical capacities of testing laboratories, and their country of origin. Therefore, alerts are not necessarily representative of the actual situation relating to product anomalies on the market. These alert systems are used to gather qualitative information about the types of anomalies encountered.

A small number of scientific articles dealing with the safety and effectiveness of water filter jugs were identified, as stated in Section 2 (Organisation of the expert appraisal).

The WG was unable to obtain all of the reports for the visits carried out as part of the DGCCRF's TN 35EA (2012) investigation or the documents collected during these visits. The data submitted did not specifically indicate the composition of the cartridges or the materials used in the water filter jugs.

The WG did not always have access to all of the raw data used to write the articles published by the magazines of consumer associations.

The expert appraisal also took into account unpublished, non-independent studies submitted by manufacturers of water filter jugs.

The WG would like to emphasise that:

- the available studies are often old (dating from before 2013) and involve only jugs with cylindrical or oval cartridges. Thus, some of the tested jugs are no longer on the market and no studies have been published on new products, in particular water filter bottles using discs of compressed activated carbon as the filter medium,
- the studies often describe laboratory tests, which are not representative of actual conditions of use in the homes of consumers where hygiene and environmental conditions are not always controlled and where a faster and more severe degradation of filtered water can be observed according to the few available studies.

Furthermore, the WG considers it unfortunate that there are no studies:

- comparing the microbiological quality of filtered water, simultaneously with a filter treated with silver and an untreated filter,
- undertaken in a laboratory reproducing the actual conditions of use of water filter jugs in households. That said, the WG notes it is difficult to define conditions making it possible to undertake a rigorous "user" study.

### **3.6.2. Limitations relating to the study protocols**

The results given in this Opinion rely on raw data in some cases and on reports in other cases, in which the test protocols are not always described in detail. For example, the WG did not always have information on the properties of the test water before filtration, the volume of filtered water, the analytical methods used and/or their performance levels.

The laboratory tests undertaken with spiked water to assess reductions in contaminants were not all carried out with the same quality of test water or the same spike concentrations. The test water was not always representative of the quality of tap water, which can contain contaminants in trace form (concentrations below the analytical limits of detection). Sometimes the water was spiked at concentrations above the regulatory quality limits and/or reference values for DW, whereas water filter jugs are intended to be used with DW only. Moreover, physico-chemical parameters were not analysed simultaneously in filtered water, in particular in the tests undertaken in accordance with the French standard.

In the studies published in the magazines *Que Choisir* and *60 Millions de Consommateurs*, the tests were undertaken in a laboratory and also in a panel of consumers, unlike in the other available studies. The criteria used for recruiting and selecting households (socioprofessional categories, etc.) were not specified in these latter studies.

It is therefore difficult to compare the results from the various available studies on account of the wide variety of protocols used in laboratories or in homes.

## **3.7. Conclusions and recommendations of the WG on Water filter jugs**

### *Regarding the safety and effectiveness of water filter jugs, in light of the available data*

In light of the wide variety of materials and filtration systems used and the lack of precise knowledge of the composition of water filter jugs and cartridges, it is not possible to undertake an exhaustive assessment of the risks related to the use of water filter jugs. As a reminder, all plastic materials used must comply with the European regulations on food contact materials (Regulation

(EC) No 1935/2004 and Regulation (EU) No 10/2011, including their amendments), although these do not require that manufacturers provide a third party with the formulation of materials.

Moreover, the WG stresses that depending on the origin of the water filter jugs and bottles sold on websites, the materials in water filter jugs do not necessarily comply with the aforementioned European regulations, and the monitoring of food contact materials in water filter jugs should be maintained (DGCCRF, 2014). It will also be necessary to closely monitor European discussions and decisions relating to the European regulations on the marketing of biocidal products regarding Ag and Ag salts used for the treatment of filter media (PT4 products).

In addition, since effectiveness depends on the composition and properties of the cartridge (nature and origin of the filter medium, grain size, adsorption surface) as well as on the quality of the water to be filtered and the user's practices, it is not possible to generalise the effectiveness assessment to all systems on the market.

However, in light of the available data and in spite of the corresponding limitations (see § 3.6), some trends can be observed:

- in some cases, the pH of filtered water decreases below the limits required for DW, and the aggressiveness and/or corrosiveness of filtered water increases;
- when the filter medium is treated with Ag, Ag is released at concentrations that are generally around 20 µg/L but can reach values of around 50 µg/L in filtered drinking water. It also appears that the concentration of Ag in filtered water varies depending on the quality of the initial water;
- in some cases, sodium, potassium and/or ammonium are released in filtered water;
- compared to the very low level of culturable micro-organisms usually observed in tap water, the filtration of water with jugs can lead users to consume water with diminished microbiological quality, in particular if there is a storage phase at room temperature after filtration and before consumption. The control for this change is an increase in the concentration of culturable aerobic flora, for which the WG has no data demonstrating a direct risk to consumer health. However, this increase can reflect a favourable medium for the survival and proliferation of micro-organisms, and potentially of pathogenic micro-organisms (micro-organisms accidentally added to the jug, or opportunistic pathogens found in the heterotrophic flora). This phenomenon, which can also be observed for non-filtered DW stored in a container at room temperature, is observed despite the Ag treatment of the filter medium. The WG does not have comparative data demonstrating the bacteriostatic effect of the Ag contained in the filter medium;
- the minimum reduction rates recommended in the NF P 41-650 Standard are generally met throughout the lifetime of the cartridge for the organoleptic properties of water (chlorine in particular), lead and copper. The effectiveness of water filter jugs throughout the lifetime of the cartridge in relation to other parameters (TH and TA, nitrates<sup>34</sup> and softening in particular) is more questionable. Furthermore, the initial spike concentrations in test water set in the aforementioned standard are above the DW quality limits established for certain parameters (see Box in § 3.5.2.).

The WG notes a change in the claims made by manufacturers in user leaflets and advertising messages. They are now focused on the improved "taste" of water associated with the use of water filter jugs.

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<sup>34</sup> The removal of nitrates requires the use of specific cartridges containing anion resins.

Regarding the standardised test protocols (NF P 41-650 Standard and/or draft European standard)

The WG questions the choice of criteria used to set the minimum reduction rates in the NF P 41-650 Standard, which differ from one parameter to the next.

The WG recommends the implementation of standardised safety and effectiveness tests with several waters of differing quality reflecting the diversity of DW, as practised in the NSF/ANSI standards:

- for safety tests other than microbiological tests and for effectiveness tests, two test waters having the DW upper and lower quality limits for pH and conductivity and the extreme TH and TA values observed in France:
  - o water 1 (soft water with a low mineral content), "synthetic" or bottled, with properties close to the following values: pH =  $6.5 \pm 0.2$ ; TH and TA from 5 to 7° f and conductivity =  $200 \pm 20$   $\mu\text{S/cm}$  at 25°C;
  - o water 2 (hard water), "synthetic" or bottled, with properties close to the following values: pH =  $9 \pm 0.2$ ; TH and TA from 30 to 35° f and conductivity =  $1100 \pm 100$   $\mu\text{S/cm}$  at 25°C;
- for microbiological safety tests:
  - o water 3: DW whose TOC value is between 1.5 and 2 mg/L.

Regarding test waters 1 and 2, if the option of using bottled water providing more comparable results is selected, then each country should select a pair of bottled waters with stable properties that are easy to obtain. If the "synthetic" water option is selected, the standards should clearly state how this water is manufactured.

With regards to physico-chemical aspects, the WG recommends:

- in addition to measuring (total) Ag, systematically measuring sodium, potassium and ammonium, and measuring the pH, TA and TH of filtered water, throughout the lifetime of the cartridge, in order to assess the aggressiveness and corrosiveness of the filtered water;
- that filtered water should comply with the quality limits and reference values set in the regulations on DW quality (pH between 6.5 and 9, quality limit for sodium: 200 mg/L, quality reference value for ammonium: 0.1 mg/L) and should be in calco-carbonic equilibrium. Otherwise (aggressive and corrosive water), a clear statement by the manufacturer should be necessary advising against its use in contact with metallic utensils (with the exception of stainless steel utensils and metallic utensils with an organic coating which are *a priori* less vulnerable) or ceramic utensils for preparing hot beverages or foods. Regarding the presence of ammonium, the WG notes that EFSA concluded that the concentrations released in filtered water did not pose any health risks, including for vulnerable populations (EFSA, 2012) (see § 3.5.1.3).

With regards to microbiological safety tests, the WG recommends:

- monitoring, as a function of the filtered volume, culturable aerobic bacteria at 22°C and 36°C (according to the NF EN ISO 6222 Standard). The WG recommends that the flora in water immediately after filtering should not exceed the thresholds set for bottled water, i.e. 100 CFU/mL for culturable bacteria at 22°C and 20 CFU/mL for culturable bacteria at 36°C, throughout the lifetime of the cartridge;
- after inoculation, monitoring *P. aeruginosa* (according to the NF EN ISO 16266 Standard), a bacterium with potential pathogenicity to humans likely to be found in the native flora of water. The WG considers that the analysis of bacteria indicative of a pathogen of faecal origin such as *E. coli* is not suitable in the framework of a standard for water filter jugs that are filled with DW and used in accordance with the manufacturer's recommendations. The WG suggests using DW with various spike concentrations: 1, 10 and 100 CFU/inoculum. It appears important to the WG to examine the capacity of *P. aeruginosa* to colonise the

- filtration system based on concentrations consistent with those typically encountered for a minority of samples of tap water;
- and at the same time, monitoring TOC since the quantity of organic matter in filtered water can influence microbial proliferation.

With regards to effectiveness tests, the WG recommends undertaking them with spiked water before filtration:

- with concentrations corresponding to the quality limits or reference values for DW,
- for chlorine, with a concentration of residual free chlorine of 0.3 mg/L, corresponding to the recommended maximum value at the tap in France<sup>35</sup>.

Preliminary laboratory tests will need to be undertaken in order to verify the feasibility of these recommendations.

Furthermore, the WG would like to draw attention to the fact that the data from standardised laboratory tests are not necessarily representative of actual conditions of use (different hygiene and environmental conditions) by consumers.

#### Regarding the implementation of new studies

The WG recommends that a new Toxicity Reference Value (TRV) be established and a new maximum concentration in filtered water be set for Ag by the *ad hoc* group(s) of experts responsible for these themes, in light of the most recent toxicological data.

Moreover, a study making it possible to identify the form(s) of Ag potentially released in filtered water (ionic or nanoparticulate) could be useful for establishing a new guideline in filtered water.

The WG deems it necessary to consider the benefits/risks of using Ag in the filter medium since it does not have any comparative studies demonstrating the impact of Ag treatment on the potential formation of a biofilm on the filter medium and/or the microbiological quality of filtered water.

However, the WG does not consider it useful to draft specifications for a new study dealing with the safety and effectiveness of water filter jugs, given the market's rapid pace of change. Such a study would cover only the devices on the market at the time of the study and the results would be processed when the devices were no longer necessarily available for sale.

#### Regarding the use of water filter jugs

The WG recommends:

- keeping the water filter jug in the refrigerator and consuming the filtered water promptly, ideally within 24 hours of filtration;
- paying special attention to effectiveness claims for water filter jugs displayed by manufacturers (showing that parameters are compliant with the standard);
- complying with the instructions for use and any precautions for use (e.g. cleaning the jug, replacing the cartridge, contact between filtered water and certain metallic or ceramic utensils particularly when the water is heated);
- complying with the restrictions and precautions for use indicated in the leaflets for certain users (e.g. feeding infants, seeking medical advice for people on a controlled diet, in particular a low-sodium or low-potassium diet).

The Agency's report on hygiene recommendations for the preparation and storage of baby bottles (AFSSA, 2005) specifies that it is not advisable to use water that has been filtered or softened (with a water filter jug for example or any other type of home filtration treatment).

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<sup>35</sup> Vigipirate plan no. 10200/SGDSN/PSE/PSN/CD of 17 January 2014.



Lastly, the WG reiterates that water filter jugs are intended to be used only with tap water complying with the quality limits and reference values set by the regulations on DW quality.

#### **4. AGENCY CONCLUSIONS AND RECOMMENDATIONS**

The French Agency for Food, Environmental and Occupational Health & Safety adopts the conclusions of the WG on Water filter jugs, which were approved by the ESPA WG and the CES on Water.

The expert appraisal was undertaken following an internal request issued with the aim of assessing the safety and effectiveness of water filter jugs in a context of reports submitted to the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF), of questions put to Members of Parliament, and of articles published in the media.

It was carried out based on a review of the literature and of test and study reports provided by the DGCCRF, consumer associations and manufacturers. Hearings were also held with the entities responsible for placing water filter jugs on the market.

The available data are not representative of the devices currently on the market or of actual conditions of use. In addition, they do not cover the wide range of materials and filter media used or the various properties of drinking water (DW) likely to fill water filter jugs supplied at the taps of users. They also do not reflect variability in the practices of users.

Regarding the safety of water filter jugs, although the available data are unable to demonstrate a risk to consumer health, the Agency notes that filtration can result in a decrease in pH, the release of silver, sodium, potassium and/or ammonium, and a deterioration in the microbiological quality of water for all or part of the cartridge's lifetime.

The Agency recommends that filtered water should comply with the quality limits and reference values defined in the regulations on DW. It insists on the need to inform users of restrictions or precautions for use in light of observed effects on the quality of filtered water. The Agency reiterates that materials used in water filter jugs, bottles and cartridges must comply with the regulations on food contact materials (FCMs), and that manufacturers have a *de facto* obligation to ensure that FCMs do not transfer to filtered water quantities of components likely to be harmful to human health, cause an unacceptable change in the composition of filtered water, or alter its organoleptic properties. It also draws the attention of consumers to products available for sale online, which may not be compliant with the European regulations, and underlines the need for the public authorities to monitor the compliance of these products.

Based on the available data, it is not possible to assess the actual effectiveness of all the water filter jugs on the market, as this effectiveness depends on the composition and properties of the filtering cartridge, the quality of the water to be filtered, and the user's practices. Furthermore, effectiveness should be evaluated in relation to the claims made by the entities responsible for placing products on the market.

The Agency considers that effectiveness claims should be verified by standardised tests. Moreover, reduction rates for the tested parameters should appear on the packaging and/or user leaflets of water filter jugs.

In light of the information set out above and the conclusions of the WG, the Agency stresses the importance of improving the current standardised test protocols on the safety and effectiveness of water filter jugs.

Lastly, the Agency insists on the fact that water filter jugs and bottles are not designed to make non-potable water potable. They are intended to be used only with DW supplied at the tap of users.

Roger GENET

## **KEYWORDS**

*Carafe filtrante, pichet filtrant, cruche filtrante, bouteille filtrante, gourde filtrante, système de filtration à domicile, système de filtration au point d'usage, eau destinée à la consommation humaine.*

*Jug filter, pitcher filter, pour-through device, point-of-use device, drinking water.*

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DIN 10521 (2009) – Food hygiene – Household water filters which are not connected to water supply – Household water filters using cation exchange resin and activated carbon.

Draft EN (CEN/TC 426 N 60, 15 August) – Domestic appliances used for drinking water treatment not connected to water supply – Jug water filter systems – Safety and performance requirements, labelling and information to be supplied.

NF EN ISO 3696 (1995) – Water for analytical laboratory use – Specification and test methods.

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NF EN 14885 (2015) – Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics.

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NSF/ANSI Standard 42 (2014) – Drinking Water Treatment Units – Aesthetic Effects.



NSF/ANSI Standard 51 (2014) – Food Equipment Materials.

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## **ANNEX 1: PRESENTATION OF THE PARTICIPANTS**

**INTRODUCTION:** Experts, Expert Committee and WG members, or designated rapporteurs are all appointed in their personal capacity, *intuitu personae*, and do not represent their parent organisation.

The four experts in the CES on Water with risks of conflicts of interest did not attend the presentations or the approval of this work.

### **WORKING GROUP ON WATER FILTER JUGS**

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#### **Chairwoman**

Ms Sophie AYRAULT - Team leader / Doctor authorised to supervise research - CEA, Gif-sur-Yvette - Geochemistry, chemistry of water including mineral chemistry.

#### **Members**

Mr Fabien BOLLE - Head of the FCM Department - Belgian Scientific Institute of Public Health - Chemical risks, public health, FCMs.

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Ms Catherine CHUBILLEAU - Hospital practitioner / Doctor of Pharmacy, Doctor of Science - Niort Hospital Centre - Epidemiology, microbiology of water.

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Ms Fabienne PETIT - Teacher-researcher / Professor - Rouen University / CNRS UMR M2C - Microbial ecology.

Mr Patrick SAUVEGRAIN - Engineer, technical coordinator for food packaging - National Metrology and Testing Laboratory (LNE) - Analytical chemistry, processes, FCM regulations.

### **"ESPA" WORKING GROUP AND CES ON WATER**

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The work covered in this Opinion was monitored and adopted by the following expert groups:

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Mr Yves LÉVI - Professor of public health and the environment - Paris Sud University - Public health, emerging pollutants, health risk assessment, microbial ecology.

## **Members**

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Mr Jean-Luc BOUDENNE - Professor - Aix-Marseille University - Water metrology, chemistry and water quality. Laboratory for Environmental Chemistry.

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■ **"ESPA" WG**

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**Members**

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Mr Jalloul BOUAJILA - Lecturer at Paul Sabatier University (Toulouse) - Pharmacology, analytical methodology.

Mr Nicolas CABATON - Researcher at INRA (Toulouse) - Toxicology, food contact materials.

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Mr Dany CHEVALIER - Lecturer at Lille 2 University - Toxicology, xenobiotics, contaminants.

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Mr Angel GIL-IZQUIERDO - Researcher for the National Research Council (Spain) - Metabolism, plant extracts.

Ms Florence LACOSTE - Head of the analysis & expert appraisal department at ITERG (Pessac) - Chemistry, analytical methods.

Mr Claude LAMBRE - Retired - Toxicology, immunotoxicity.

Mr Michel LAURENTIE - Research Director, Department Head at ANSES in Fougères - Toxicokinetics, toxicodynamics, statistics.

Mr Jean-Michel MAIXENT - Professor at Poitiers University - Pharmacological trials, toxicology.

Ms Anne PLATEL - Lecturer at Institut Pasteur in Lille - Toxicology, genotoxicity, QSAR.

Mr Philippe SAILLARD - CTCPA (Bourg-En-Bresse) - Food packaging, toxicology, impact of processes, food contact materials.

Mr Patrick SAUVEGRAIN - Engineer at the LNE (Trappes) - Methodological trials, chemistry, food contact materials.

Mr François ZUBER - Scientific Director at the CTCPA (Avignon) - Industrial processes, industrial systems.

## **ANSES PARTICIPANTS**

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### **Coordination and scientific contribution**

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Ms Anne NOVELLI - Water Risk Assessment Unit - ANSES.

Mr Bruno TESTE - Food Risk Assessment Unit - ANSES.

### **Scientific contribution**

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Mr Gilles RIVIÈRE - Deputy Head of the Food Risk Assessment Unit - ANSES.

### **Administrative secretariat**

Ms Virginie SADÉ - ANSES.

## **HEARINGS WITH EXTERNAL PARTIES**

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### **Company BRITA**

Mr Sébastien ZOTT, Managing Director of BRITA France.

Mr Knut SAUERBIER, Intellectual Property and Product Compliance Director, BRITA GmbH.

Mr Mickaël TALARMAIN, Legal and Public Affairs Manager, BRITA France.

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Mr Thomas TAITL, Product Manager, BWT.

Ms Michela QUARANTA, Certification Manager, BWT.

Ms Véronique THARREAU, Scientific Manager, BWT France.

**ANNEX 2: PROTOCOLS USED IN THE APPRAISED STUDIES**

**Table IX: Summary of laboratory test protocols**

|  | Water filter jugs tested                       | Type of water  | Test duration  | Filtered volumes  | Analyses   | Comments   |
|--|--|--|--|---|--|--|
| <b>NF P41-650 Standard</b>                         |  | Spiked test water:<br>Pb (100 µg/L)<br>Cu (3 mg/L)<br>Ni (80 µg/L)<br>Nitrates (50 mg/L)<br>TH 30 °F<br>TA 20 °F<br>Total Cl 1 mg/L<br>Cl <sub>2</sub>   | 26 calendar days<br>(20 working days) for a cartridge with a nominal capacity of 100 L | 5 L/day per fraction of 1 L, for 5 days followed by 2 days of downtime. Each filtrate is collected after a rest period of 30 minutes    | Analysis of the test water and filtrate at 5%, 25%, 50%, 75% and 100% of the nominal filtration capacity   | During the downtime periods (weekends), the jug is stored according to the manufacturer's recommendations, or else at room temperature, in a non-confined atmosphere |
| <b>Que Choisir 2003</b><br>(Laboratory tests only) | 3 models of water filter jugs and 4 cartridges | -Tap water (control)<br>-Water spiked with Cl <sub>2</sub> (0.1 mg/L) and Pb (50 µg/L)<br>-Water spiked with Cl <sub>2</sub> (0.1 mg/L) and Pb (100 µg/L)<br>-Water spiked with NO <sub>3</sub> (50 mg/L)<br>-Water spiked with NO <sub>3</sub> (100 mg/L) | 4-5 weeks  | Tap water 6 L/day except on weekends (WE), per fraction of 1 L. On Fridays, 1 L of water is kept in the jug for stagnation over the WE. | Every Monday, an aliquot of each 1 L fraction is taken in order to have an average sample of the day's fractions, which is then split to undertake physico-chemical and microbiological analyses (enumeration of culturable micro-organisms at 22°C). The volume that stagnated over the WE is analysed on Monday.<br>Each Monday of the first 2 weeks, analysis of Ag in the volume of control water (not spiked) that stagnated for 1 WE and the average fraction from the 6 litres filtered during the day. | During downtime periods, the jug is stored in the refrigerator.  |
| <b>Que Choisir 2010</b><br>(Laboratory tests only) | 7 water filter jugs                            | Tap water<br>Spiked water:<br>Pb 25 µg/L,<br>NO <sub>3</sub> 50 mg/L,<br>glyphosate and AMPA 0.1 µg/L  | 6 weeks  | Same as in 2003   | Same as in 2003.<br>Physico-chemical analyses; chlorine, nitrates, silver, lead, glyphosate and AMPA.<br>Microbiological analyses (culturable aerobic bacteria at 22°C and 36°C, <i>Escherichia coli</i> , coliforms at 37°C, sulphate-reducing bacteria and intestinal enterococci) in the water that stagnated over the WE.  | The jug is stored in the refrigerator over the WE.   |

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|                                    |   |   |  |   |   |   |
|------------------------------------|---|---|--|---|---|---|
| <b>INC 60 MDC</b>                  | 8 water filter jugs   | Tap water<br>Spiked water:<br>Pb, Cu, Ni, NO <sub>3</sub> ,<br>Ca, Mg, HCO <sub>3</sub> :<br>at the<br>concentrations in<br>the NF P40-650<br>Standard<br>Al, Fe, NO <sub>2</sub> , As:<br>at the<br>concentrations in<br>the Ministerial<br>Order of 11<br>January 2007<br>Zn: 5mg/L | 28 calendar<br>days (20<br>working days) | Tap water<br>On day 0<br>(Monday): 8L,<br>then 7L except on<br>WEs<br>Spiked water:<br>1L/day for the<br>first 4 days, then<br>1L on days 7, 14,<br>21 and 28   | On days 0, 1, 2, 3,<br>7, 14, 21 and 28   |   |
| <b>Garboś and Świecicka (2012)</b> | 9 water filter jugs with cylindrical cartridges including one not treated with Ag (2 cartridges of each type analysed simultaneously) | Non-chlorinated synthetic water:<br>Hardness = 135-180 mg/L CaCO <sub>3</sub><br>and pH = 6.5 – 7.5   | 26 calendar<br>days (20<br>working days) | 5 L/day per fraction of 1 L, for 5 days followed by 2 days of downtime. Each filtrate is collected after a rest period of 30 minutes  | Analysis of the test water and filtrate at 5%, 15%, 25%, 50%, 75% and 100% of the nominal filtration capacity set randomly at 100 L   | Before the test, the cartridges are prepared according to the manufacturer's instructions |
| <b>Garboś and Świecicka (2013)</b> | 6 water filter jugs with oval cartridges (2 cartridges of each type analysed simultaneously)  | Water compliant with the BS 8427 (2004) Standard  | 26 calendar<br>days (20<br>working days) | 5 L/day per fraction of 1 L, for 5 days followed by 2 days of downtime. Each filtrate is collected after a rest period of 30 minutes  | Analysis of the test water and filtrate at 5%, 15%, 25%, 50%, 75% and 100% of the nominal filtration capacity set randomly at 100 L   | Before the test, the cartridges are prepared according to the manufacturer's instructions |
| <b>DWI (2003)</b>                  | 4 brands of cartridges (3 gravity-fed cartridges for 100 L (A, B and C) and 1 pump cartridge for 750 L) + 9 brands of kettles         | 3 types:<br>"X" = low-nutrient groundwater,<br>"Y" = high-nutrient surface water,<br>"Z" = softened water for tests on metal leaching   | 8 weeks                                  | 1 - With waters X and Y and for cartridges A, B and C: 5 L/day per fraction of 1 L separated by 30 minutes.<br>For cartridge D, similar protocol in terms of the % use of the cartridge with adjusted volumes<br>2 - Separate analysis, using the same protocol, of a cartridge with a lifetime of 20 weeks<br>3 - Test with the cartridges "spiked" with <i>Salmonella</i> and <i>E. coli</i> (A to C)<br>4 - Test with waters X and Z for cartridges A, B, C. Boiled filtered water brought into contact with metallic utensils (saucepan and kettle)<br>5 - Test on the influence of the storage temperature for | 1 - Analysis of the test water and filtrate after: 5, 10, 15, 25, 50, 75, 100, 150 and 200 L + 2 times 1 L Monday morning after stagnation over the WE and prior discarding of 2 L.<br>2 - Analysis of the test water and filtrate after 20 weeks.<br>3 - Analysis of the test water and filtrate after 10%, 50% and 100% of the cartridges' lifetime | Cartridges prepared according to supplier recommendations, first litres discarded.        |



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|                      |   |           |         |  |  |   |
|----------------------|---|-----------|---------|--|--|---|
|                      |   |           |         | filtered water (4 and 20°C)<br>6 - Real-life test in homes equipped with kettles for metal leaching  |  |   |
| <b>CRECEP (1997)</b> | 2 water filter jugs of different brands (1 tested with 1 cartridge and the other with 3 cartridges) | Tap water | 1 month | 3 operating periods (2 L flow with each filtration) separated by 4 hours + overnight stagnation for 16 hours.<br>Extended stagnation periods were also added: 60 hours = WE; 8 days = short holidays; 30 days = long holidays. | Analysis of the test water and filtrate:<br>- on start-up after preparation<br>- after each stagnation period: 16 hours, 60 hours, 8 days and 30 days. | Before the test, the cartridges are prepared according to the manufacturer's instructions |

**ANNEX 3: SUMMARY OF EFFECTIVENESS RESULTS**

**Table X: Summary of observed reduction percentages (documents submitted by the DGCCRF following the TN 35EA investigation of the fourth quarter of 2012)**

The tests were undertaken according to the protocol in the NF P 41-650 Standard but sometimes with spike concentrations different from those in the standard and with filtered volumes and parameters other than those recommended in the standard.

| Parameter                 | C <sub>initial</sub> | Total number of jugs tested (Number of jugs of different brands) | Beginning of the cartridge's lifetime (5 to 7.5 litres filtered) |                     |                     | End of the cartridge's lifetime (90 to 100 litres filtered) |                     |                     |
|---------------------------|----------------------|--|--|---------------------|---------------------|---|---------------------|---------------------|
|                           |                      |  | Minimum reduction %  | Maximum reduction % | Average reduction % | Minimum reduction %   | Maximum reduction % | Average reduction % |
| Copper                    | 3 mg/L               | 2 (1)  | 94   | 97                  | 95.5                | 90  | 91                  | 90.5                |
|                           | 200 µg/L             | 2 (2)  | 86   | 91                  | 88.5                | 86  | 94                  | 90                  |
| Lead                      | 100 µg/L             | 2 (1)  | 95   | 97                  | 96                  | 95  | 97                  | 96                  |
|                           | 50 µg/L              | 2(2)   | 87   | 91                  | 89                  | 83  | 89                  | 86                  |
| Nickel                    | 80 µg/L              | 2 (1)  | 91   | 92                  | 91.5                | 51  | 60                  | 55.5                |
|                           | 30 µg/L              | 2 (2)  | 41   | 56                  | 49                  | 29  | 35                  | 32                  |
| Cadmium                   | 5 µg/L               | 2 (2)  | 80   | 80                  | 80                  | 83  | 83                  | 83                  |
| Zinc                      | 500 µg/L             | 2 (2)  | 50   | 65                  | 58                  | 59  | 71                  | 65                  |
| TH                        | 30°F                 | 4 (2)  | 15   | 85                  | 50                  | 4   | 26                  | 15                  |
| TA                        | 20°F                 | 4 (2)  | 30   | 81                  | 54                  | 5   | 42                  | 13                  |
| Nitrates                  | 50 mg/L              |  |  |                     |                     |   |                     |                     |
| Chlorine (free and total) | 1 mg/L               | 4 (2)  | >99  | >99                 | >99                 | 79  | 89                  | 82                  |
|                           | 0.5 mg/L             | 2 (2)  | 81   | 88                  | 84                  | 85  | 87                  | 86                  |
| 2,4,6 -TCP                | 5 µg/L               | 2 (1)  | 95   | 95                  | 95                  | 95  | 95                  | 95                  |
| Geosmin                   | 0.05 µg/L            | 4 (2)  | >99  | >99                 | >99                 | 46  | >99                 | 75                  |

**Table XI: Summary of observed reduction percentages (Que Choisir, 2010)**

| Parameter     | C <sub>initial</sub> | Total number of jugs tested (Number of jugs of different brands) | Beginning of the cartridge's lifetime (6 litres filtered) |                     |                     | End of the cartridge's lifetime (114 litres filtered) |                     |                     |
|---------------|----------------------|--|---|---------------------|---------------------|---|---------------------|---------------------|
|               |                      |  | Minimum reduction %                                       | Maximum reduction % | Average reduction % | Minimum reduction %                                   | Maximum reduction % | Average reduction % |
| Calcium       | 74-117 mg/L          | 14 (7)   | 27  | 94                  | 70                  | 2   | 23                  | 14                  |
| Lead          | 20-23 µg/L           | 7 (7)  | > 50*   | > 50*               | > 50*               | > 50*   | > 50*               | > 50*               |
| TH            | 20-33 °F             | 14 (7)   | 25  | 93                  | 69                  | 0   | 25                  | 14                  |
| TA            | 15-20 °F             | 14 (7)   | 4   | 20                  | 8                   | 11  | 18                  | 14                  |
| Free chlorine | 0.10-0.18 mg/L       | 14 (7)   | 86  | 100                 | 92.5                | 71  | 94                  | 79                  |

\* the reduction % is underestimated, since the LQ for the method is 10 µg/L.