



Joint Plastics Industry Position on the 'European Acceptance Scheme' (EAS)

June 1, 2006

This document presents a joint position from EuPC/TEPPFA and Plastics Europe on the draft European Acceptance Scheme (EAS) as drafted by the Regulators (now Expert) Group for the European Commission. The aim of the EAS is to harmonise existing EU member states regulations in the area of drinking water contact applications in a broad sense.

1. Consumer protection

The basic objective of our contributions is to achieve an optimum consumer protection by ensuring a high and consistent level of drinking water quality.

2. Support of European Acceptance Scheme

We basically support the principles of a European Acceptance Scheme with the aim to harmonise test methods and requirements through all EU Member States and to achieve full mutual recognition of test reports between accredited laboratories.

We support the view that the EAS must be based on a sound scientific basis for the protection of public health, and that it must be transparent.

The pass/fail criteria to be set for the different parameters have to be such that materials that are currently authorised in the market are not disqualified for such use.

Note: Plastics in contact with drinking water are severely **overregulated** in comparison with other materials that are used in contact with drinking water. This point has been recognised by various members of the former Regulators Group, but so far it has not shown in subsequent documents. The principle of proportionality must be respected with regard to plastics materials.

3. Reproducibility

In the past many test data have been gathered on the parameters referred to in this paper hereinafter. Comparison of test results among and within laboratories has shown big variations and poor reproducibility for a number of these parameters, and this is unacceptable. This problem must be resolved before the EAS is enforced.

4. Equal opportunity for putting products on the European market

The plastics industry will consistently claim a fair treatment between the different materials insofar as they ensure equal consumer protection, based on realistic health risk considerations. The approaches for metals, cementitious products and plastics must be fully aligned, and simultaneously implemented in full, because in practice water distribution systems consist normally of a combination of products from different materials.

5. Positive List

The plastics industry supports the principle of a positive list of assessed substances used in the manufacture of plastics drinking water materials. The concept of positive listing is of utmost importance as it relates toxicity data on the listed substances with possible

migration of these substances into the water, and hence it is closely related to health risk analysis.

We suggest that the criteria for the positive listing of all substances should be divided into two sets:

a) The first set should cover exclusively the installation period and allow certain higher limits for a restricted period, based on toxicity data and risk analysis. This installation period should be as short as possible, but may be up to one month. For this initial period the food contact regulation limit values would already be a practical solution ensuring adequate safety.

b) The second set should cover the whole life of the product after installation, based also on toxicity data. It could use the limits in the food contact regulation multiplied by a "drinking water factor".

Note: the principles outlined above in a) and b) should apply to all materials.

Positive list of monomers and additives with similar set-up as the plastics food contact positive list as reference (2002/72/EC) should be considered. Comments on Annex 1 of EG-CPDW 188 Rev. 2 are given in Appendix A.

Scientific body to assess the safety of monomers and additives: preferably EFSA/AFCPanel, otherwise SCHER using the data already available as well as the expertise and experience of the Scientific Committee on Food (SCF), and now EFSA/AFC Panel. This is prompted by a meaningful use of resources (avoid duplication of work) and by the adagium: "Don't reinvent the wheel".

6. Lead stabiliser in old plastics pipes and fittings

The European Plastics Pipes and Fittings industry have committed themselves to phase out lead-based stabilisers in PVC pipes and fittings in contact with drinking water. The commitment is expected to take effect from beginning 2006.

7. Pipes and Fittings installed before EAS regulations were in force

Pipes and fittings manufactured in the past could contain heavy metals, e.g. lead as well as other additives which were authorised under the then existing regulations. Because these pipes and fittings will still be in operation for a very long time, minute traces of these additives will nevertheless continue to be found in water samples in the future.

The plastics industry will request a provision to be included in the EAS documents stating that, although the use of such additives in newly produced pipes and fittings is not allowed, piping systems produced before the implementation date of the EAS can be kept in operation without time limit, provided they meet the limits of the former positive list under which the said additives were authorised. A document clarifying this issue is in preparation.

8. Conversion Factor

The conversion factor includes a geometrical factor and a stagnation factor. Regarding the geometrical factor, it is preferred to work with the real figure for the diameter tested and leave it to industry to choose its own worst case for approving a range of products.

Regarding the stagnation factor, a similar approach as used for the other materials must be applied. Further details will be provided in a separate document.

Industry still opposes the application of the **factor 20** to the arbitrary 50 ppb limit in food, based on the fact that the WHO guidelines relative to using up only 10 % of the TDI, does not apply, because no TDI has been established for these substances. The 50 ppb limit is exposure based, and should be divided by 2 for drinking water to allow for an assumed consumption of 2 liters of drinking water compared with 1 kg of packaged food.

9. Choice of Migration period

The plastics industry considers it to be important that in the EAS a clear and consistent philosophy is applied. Migration testing must be such that it represents real life exposure conditions, i.e. when steady state conditions have been reached.

Although it is known that migration from plastics products into drinking water strongly decreases with time, we do not support the choice of the third migration period as the decisive one, because steady-state conditions will not have been reached at this point. Either the conversion factor applied to the third migration should be multiplied by an additional factor of 0.1 to take into account the real, long-term exposure, or allowance must be made for additional migration periods to be taken into account in the assessment of the safety of a plastic drinking water contact product (maximum 10 migration periods in total).

Our recommendation is the following: take the 3rd migration with the use of an extra factor 0,1 in the conversion, when it has been shown that after the 3rd migration there is still a decrease in migration as function of time. With this approach there is already for a long time experience within a well-known institute, KIWA. The refusal to accept the factor 0.1 was not substantiated (quote M. Fielding: “partly because they [sub group PL&CF] considered other systems offered a higher level of consumer protection and use of a 0.1 factor or similar would compromise their level of consumer protection”, which is totally against the principle of proportionality.

Exposure assessment to allow for the use of reduced assessment products (very low usage levels leading to no (detectable or significant) migration, small surface areas, small contact areas, etc.

10. Taste and Odour

The Taste and Odour parameter is a requirement in the Drinking Water directive and is a key test for the EAS. We stress the importance of the message in paragraph 3 on reproducibility.

11. Colour and Turbidity

Long term experience has shown that this test applied to plastics materials is not relevant for consumer protection. Should this parameter, nevertheless, remain a requirement, then we stress the importance of the message in paragraph 3.

12. TOC

In principle we can accept this test in the EAS. The insufficient reproducibility between laboratories of this test is equally a grave concern and must be improved.

The proposed level of 500 µg/L is not based on any solid data, and needs to be reassessed. We propose three steps in the approval procedure (see our proposed approval scheme in the annex, levels after applying the Conversion Factor):

- If the test results in a value < 500 µg/L (or whatever level is established after reassessment), the product meets the criterion.
- If the test results in a value between 500 µg/L and 1500 µg/L, additional analysis as appropriate should be executed to show conformity to the requirements for individual substances.
- If the test results in a value of > 1500 µg/L, the product will be rejected.

This proposal is only valid for tests at 20°C.

It must be emphasised that requirements for a possible test at 60°C for hot water application have to be fixed separately after carefully analysing today's situation. Above requirements cannot apply to tests carried out at 60°C. New proposals will follow when this issue will indeed come up in the EAS discussion.

13. Cytotoxicity/Genotoxicity

For the time being, cytotoxicity will not be included in the EAS. This test has no quantifiable endpoint, nor any relation to potential hazards for the consumer. Furthermore, the toxicological evaluation of individual substances with their limits in the positive list, combined with GC/MS screening for unsuspected substances, gives a sufficient guarantee for safe products.

14. Chlorine demand

If TOC is an accepted parameter, there is no need for a test on chlorine demand. Both are a measure of inertness. This test does not measure any realistic behaviour of plastic products and is therefore irrelevant; this has been confirmed in the co-normative research Work Package 4. There is a wide agreement among the various parties concerned that this test is not needed in the EAS, and can therefore be removed from the list of tests.

15. Enhancement of Microbial Growth

We accept that a test on enhancement of microbial growth is desired by the regulators, provided that the test corresponds to real life practise. It is imperative that the eventual test method can easily be executed in all laboratories, and is reproducible between laboratories. It is preferred to have a new evaluation and an open discussion with experts to choose the most suitable method in use now. No consideration has been given to the German method (W 270).

16. GC-MS (unsuspected substances)

Eventually a test method on GC-MS may be part of the EAS procedures. Additional research is being conducted, and an EN standard for this analytical method will be developed once the research is finalised. Our estimation is that this method is not yet fully developed and not yet suitable for use in a very critical and determining step in the acceptance scheme. For this reason we propose new investigations (by the European Commission) which have to result in more suitable procedures for this purpose. On top of that, there is very minor experience in European laboratories with this particular method

for drinking water approval, which can lead to extreme confusions and unjustified rejection of products.

Where possible, our experts should participate in the development of this standard and support or contribute to subsequent investigations.

In any case, GC/MS can be applied in a practical and meaningful way only if a "threshold of regulatory concern" for unsuspected substances, based on realistic consumer exposure assessments, is established.

17. Requirements for reaction products

Although GC-MS detects reaction products as well, it seems possible that this issue will be taken on board separately. (This is not yet the case). We do not support the position on separate treatment of reaction products, because this will be covered within the context of GC/MS investigation of unsuspected substances. In our view, any attempt to set up a positive listing of reaction products will prove unworkable whilst achieving no significant enhancement of customer protection.

Relevant information on known reaction products should be delivered to the assessment body as part of the petition dossier (as for food contact).

18. Modelling

The migration behaviour by use of mathematical modelling is accepted in the EAS proposals, and is supported by industry. This concept is already accepted in the plastics food contact area to everybody's satisfaction. In the drinking water sector it should be even easier to apply migration modelling due to the fact that water is the only contact medium. Migration modelling has been proven to be a very valuable and powerful tool to reduce the need for migration testing considerably. The first reaction to migration modelling from the regulators was positive. A plan for further formal acceptance is being worked out.

Note: The paragraph on migration modelling that was included in the Proposals for positive list (RG-CPDW 188) no longer appears in the latest draft (EG-CPDW 188 Rev. 2)

19. Approval Scheme and AoC

The plastics industry has developed a draft approval scheme and an Attestation of Conformity (AoC), and these will be promoted. The basic aim is to avoid unnecessary duplication or repetition of test work. A copy of this approval scheme and Attestation of Conformity is enclosed in Appendix B and C.

20. Listing of approved compounds/formulations

A key aspect in the above mentioned approval system is the acceptance of EU-wide officially approved and registered compounds to avoid that the same aspects are evaluated repeatedly in the different countries and that at the expense of all producers. This implies the setting up of a system of listing. We are prepared to work together with the relevant European and national authorities and institutes in order to further develop and implement this concept.

21. Piling up of safety factors

We have the impression that the former subgroup PL&CF was adding too many times safety factors to safety factors and was combining it with worst case situations:

- it was chosen to propose the 3rd migration, knowing they are too high without justification
- stagnation times of 12hrs and 24hrs was chosen instead of 4hrs, as also proposed by metals
- the choice of one single conversion factor $F_{go}=20$ has not been justified clearly
- all those considerations are added to the fact that migration values, derived from food contact evaluations, already establish safety consideration when dividing original (food contact) migration limits by 20.

Pass/fail criteria should be set in relation to protection of the consumer, not to the analytical feasibility.



General

EuPC is the professional representative body of plastics converters within Europe whose activity embraces all sectors of the plastics converting industry. EuPC represents over 37.000 predominantly medium-sized plastics processing enterprises within Europe employing over 1.5 million persons. The combined processing capacity of EuPC's members amounts to more than 35 million tons of plastics per year, representing a turnover of approximately € 130 billion.

TEPPFA represents the European Plastic Pipes and Fittings Industry that supplies products for the water supply chain. This sector has a yearly production of 3.000.000 tons of plastics pipes and fittings products with a significant part for the supply of drinking water. At European level, plastic pipes and fittings have the biggest market share. (~52%)

PlasticsEurope, with around 50 member companies, is the voice of the plastics manufacturing industry (virgin material manufacturing), representing over 90 per cent of Western Europe's polymer production capacity – with a turnover of more than € 29 billion.

EuPC and PlasticsEurope support the aim of the EAS in terms of potential benefits and costs. With this approach more transparency in the future procedures will be given than the existing situation in the different Member States. The system should also be practical and favour harmonisation.

Appendix A

- **Comments on Annex 1 (Draft Positive lists of monomers and additives, etc.) to Document EG-CPDW 188 Rev. 2.**

- The PL now includes substances for cementitious products. This may lead to confusion.

- The PL now also includes all monomers and additives mentioned in the draft EU Super Regulation (version July 2004).

The draft EU Super Regulation is a non-document, it has no legal power, and it is subject to considerable change. Moreover, the whole concept of the Super Regulation seems to be on hold. It would be much better to refer to the existing and respected plastics food contact directive (2002/72/EC as amended). In any case, the inclusion of the monomers and additives authorised in the EU for use in plastics food contact applications into the positive list of monomers and additives for use in drinking water contact applications is a positive response to one of our points of critique.

- The PL on monomers and additives should also include the paragraph on salts of authorised acids, phenols or alcohols as it is included in the plastics food contact directive 2002/72/EC. It reads as follows:

"The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorised acids, phenols or alcohols which are also authorised. However, names containing "... acid(s), salts" appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases the meaning of the term "salts" is salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc".

- The initial monomers list has been split into a list A and a list B which is also a positive response to one of our points of critique.

- There are various monomers in list B that should be in list A (e.g. BADGE, diphenyl carbonate, alpha-methylstyrene, trimellitic acid, trimellitic anhydride, and probably more). In this respect, all substances positively evaluated by EFSA for food contact applications should be automatically included in the DW PL (with appropriately adjusted migration limits), as soon as these evaluations are published by EFSA. It should not be necessary to wait for these substances to be incorporated into an amended directive (or regulation) on food contact.

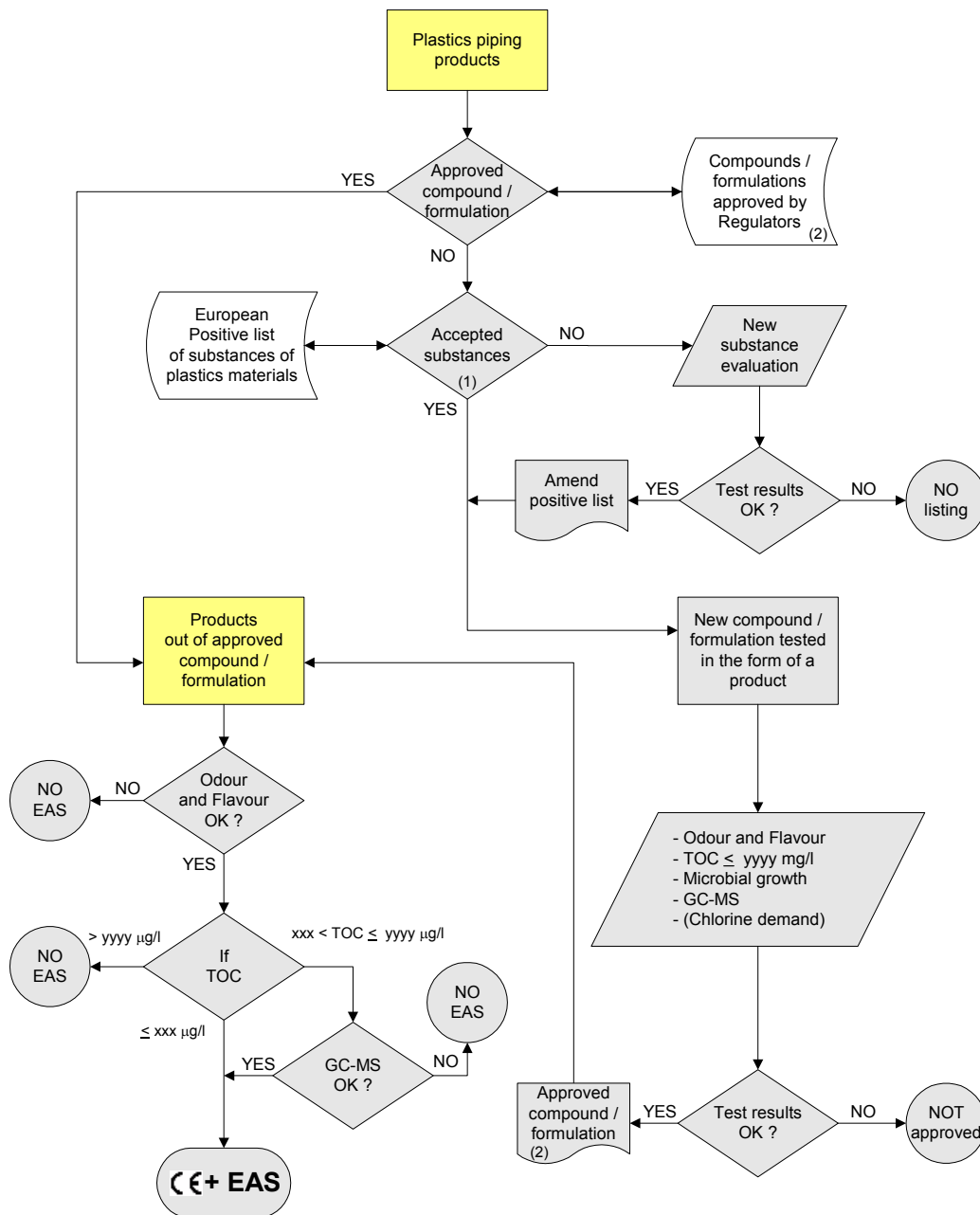
- There are various substances in the additives list that are truly monomers. These substances are also included in the monomers list. Their appearance in the additives list is unclear.

- *The draft positive lists of monomers and additives should be carefully checked for individual interests.*



- An appropriate transition period for list B monomers and list B additives will have to be established.
- There is a considerable number of substances that are part of plastics drinking water compositions that have been submitted for authorisation to national Drinking Water authorities. These substances should also eventually be included in the PL. So far, they are included in confidential lists. (See also the specific paragraph in the APME letter to Mr Fielding of December 10, 2003.

**European Acceptance Scheme (EAS)
for Plastics Piping Products
(Position Paper)**



Definition of compound / formulation:
Clearly defined homogenous mixture of base polymer with additives, i.e. anti-oxidants, pigments, stabilisers and others, at a dosage level necessary for the processing and the intended use of the final product.

- (1) Conformity with Positive list (or existing additional lists)
- (2) Rules to be established by Regulators

Assessment of conformity (AoC) for plastics piping products related to EAS characteristics

Compound/formulation for plastics piping products

New compound/formulation that require type testing (TT)

Table 1 — Characteristics for new compound/formulation

Characteristics	Requirements ^c	Test method and parameters ^c	Sampling procedure
Conformity to positive list			Once/compound resp. formulation
Odour and Flavour ^a		EN 1420-1	Once/compound resp. formulation
TOC ^{a b}	I ≤ xxxx µg/l II ≤ xxxx µg/l III ≤ xxxx µg/l	EN 1484 I II III	Once/compound resp. formulation
Microbial growth ^a		WI of CEN/TC164/WG3/AHG3	Once/compound resp. formulation
GC-MS ^{a b}	I II III	WI of CEN/TC164/WG3/AHG7	Once/compound resp. formulation
Chlorine demand ^{a b}		EN 14718	Once/compound resp. formulation
^a Tested in the form of pipe or fitting ^b To be tested on migration water prepared according to EN 12873-1 ^c Test parameters and requirements depending on the end use category (see clause 3)			

Approved compound/formulation that require audit testing (AT)

Table 2 — Characteristics for approved compound/formulation

Characteristics	Requirements ^c	Test method and parameters ^c	Sampling procedure
Odour and Flavour ^a		EN 1420-1	Once/compound resp. formulation/year
TOC ^{a b}	I ≤ xxxx µg/l II ≤ xxxx µg/l III ≤ xxxx µg/l	EN 1484 I II III	Once/compound resp. formulation/5 years
Microbial growth ^a		WI of CEN/TC164/WG3/AHG3	Once/compound resp. formulation/5 years
GC-MS ^{a b}	I II III	WI of CEN/TC164/WG3/AHG7	Once/compound resp. formulation/10 years
Chlorine demand ^{a b}		EN 14718	Once/compound resp. formulation/10 years
^a Tested in the form of pipe or fitting ^b To be tested on migration water prepared according to EN 12873-1 ^c Test parameters and requirements depending on the end use category (see clause 3)			

Products out of approved compound/formulation

Products that require type testing (TT)

Table 3 — Characteristics for pipes out of approved compound/formulation

Characteristics	Requirements ^d	Test method and parameters ^d	Sampling procedure
Odour and Flavour ^c		EN 1420-1	One diameter/compound resp. formulation
TOC ^{a c}	I ≤ xxxx µg/l II ≤ xxxx µg/l III ≤ xxxx µg/l	EN 1484 I II III	One diameter/compound resp. formulation
GC-MS ^{a b c}	I II III	WI of CEN/TC164/WG3/AHG7	One diameter/compound resp. formulation
^a To be tested on migration water prepared according to EN 12873-1 ^b This test has only to be performed if the TOC value exceeds the given limit ^c Characteristics already tested by the raw material manufacturer in the form of a pipe from the same manufacturer out of the same compound/formulation shall be taken into account ^d Test parameters and requirements depending on the end use category (see clause 3)			

Table 4 — Characteristics for fittings out of approved compound/formulation

Characteristics	Requirements ^d	Test method and parameters ^d	Sampling procedure
Odour and Flavour ^c		EN 1420-1	One diameter/one product type/compound resp. formulation
TOC ^{a c}	I ≤ xxxx µg/l II ≤ xxxx µg/l III ≤ xxxx µg/l	EN 1484 I II III	One diameter/one product type/compound resp. formulation
GC-MS ^{a b c}	I II III	WI of CEN/TC164/WG3/AHG7	One diameter/one product type/compound resp. formulation
^a To be tested on migration water prepared according to EN 12873-1 ^b This test has only to be performed if the TOC value exceeds the given limit ^c Characteristics already tested by the raw material manufacturer in the form of a fitting from the same manufacturer out of the same compound/formulation shall be taken into account ^d Test parameters and requirements depending on the end use category (see clause 3)			

Table 5 — Characteristics for valves/assemblies out of approved compound/formulation

Characteristics	Requirements ^d	Test method and parameters ^d	Sampling procedure
Odour and Flavour ^c		EN 1420-1	Once/one product component/compound resp. formulation
TOC ^{a c}	I ≤ xxxx µg/l II ≤ xxxx µg/l III ≤ xxxx µg/l	EN 1484 I II III	Once/one product component/compound resp. formulation
GC-MS ^{a b c}	I II III	WI of CEN/TC164/WG3/AHG7	Once/one product component/compound resp. formulation
^a To be tested on migration water prepared according to EN 12873-1 ^b This test has only to be performed if the TOC value exceeds the given limit ^c Characteristics already tested by the raw material manufacturer in the form of a valve component from the same manufacturer out of the same compound/formulation shall be taken into account ^d Test parameters and requirements depending on the end use category (see clause 3)			

Products that require audit testing (AT)

Table 6 — Characteristics for pipes out of approved compound/formulation

Characteristics	Requirements ^c	Test method and parameters ^c	Sampling procedure
Odour and Flavour		EN 1420-1	Once/one diameter/compound resp. formulation/year
TOC ^a	I ≤ xxxx µg/l II ≤ xxxx µg/l III ≤ xxxx µg/l	EN 1484 I II III	Once/one diameter/compound resp. formulation/5 years
GC-MS ^{a b}	I II III	WI of CEN/TC164/WG3/AHG7	See TOC if necessary
^a To be tested on migration water prepared according to EN 12873-1 ^b This test has only to be performed if the TOC value exceeds the given limit ^c Test parameters and requirements depending on the end use category (see clause 3)			

Table 7 — Characteristics for fittings out of approved compound/formulation

Characteristics	Requirements ^c	Test method and parameters ^c	Sampling procedure
Odour and Flavour		EN 1420-1	Once/one diameter/ one product type/ compound resp. formulation/year
TOC ^a	I ≤ xxxx µg/l II ≤ xxxx µg/l III ≤ xxxx µg/l	EN 1484 I II III	Once/one diameter/ one product type/ compound resp. formulation/5 years
GC-MS ^{a b}	I II III	WI of CEN/TC164/WG3/ AHG7	See TOC if necessary
^a To be tested on migration water prepared according to EN 12873-1 ^b This test has only to be performed if the TOC value exceeds the given limit ^c Test parameters and requirements depending on the end use category (see clause 3)			

Table 8 — Characteristics for valves/assemblies out of approved compound/formulation

Characteristics	Requirements ^c	Test method and parameters ^c	Sampling procedure
Odour and Flavour		EN 1420-1	Once/one product component/compound resp. formulation/year
TOC ^a	I ≤ xxxx µg/l II ≤ xxxx µg/l III ≤ xxxx µg/l	EN 1484 I II III	Once/one product component/compound resp. formulation/5 years
GC-MS ^{a b}	I II III	WI of CEN/TC164/WG3/ AHG7	See TOC if necessary
^a To be tested on migration water prepared according to EN 12873-1 ^b This test has only to be performed if the TOC value exceeds the given limit ^c Test parameters and requirements depending on the end use category (see clause 3)			

End use category of the product

Table 9 — End use category of the product

Category	Description	Fg	Fo	Fgo	
I	Domestic & Service lines dn ≤ 90 mm	40	0,5	20	
II	Distribution lines dn 110 – 315 mm	5	2	10	
III	Trunk mains ≥ 355 mm	1,33	4	5 ^a	
^a Fgo rounded down to the next entire figure Note: Fg is a geometric factor relating S/V (dm-1) Fo is a factor relating to contact (residence) time (day) Fgo = Fg x Fo					