Supplemental material on migration - release potential of BPA during service life

Disclaimer: The presented information reflects the current knowledge of the authorities but during the project new data might become available. It is not guaranteed that the information presented here will be used in the Annex XV restriction report or in the presented way. The information provided is largely of a general nature and is not intended to address the specific circumstances of any particular individual or entity. Further, the information is not professional or legal advice.

1. Introduction

Data on emissions are available on a use-specific or sector-specific basis. There are large data gaps at the level of individual uses by sector and thus downstream uses. Bisphenols are used in various applications that are wide dispersive.

To reduce the environmental concentrations the restriction aims on restricting either the residual content or the release potential by limiting the migration. Either the product complies with a residual bisphenol content of 10 ppm or, if the permissible residual content is exceeded, it must be shown in a use specific test setting that the migration limit of 0.04 mg/L is complied with over the entire service life.

Since products made from polymers are exposed to different stressors indoors and outdoors, they are equipped or treated differently. This must be considered when deriving material test methods with regard to the migration limit. The (differently equipped) material must be stressed accordingly, for example in laboratory tests adapted to the intended uses.

The migration limit of 0.04 mg/L BPA in the eluate, as single analyte or as sum with other bisphenols of concern (BosC) must be observed for all materials containing or made from BPA and BosC. The migration limit is proposed in accordance with the existing migration limit for BPA in the EU Toy Safety Directive, which was derived for toys to guarantee their safety. The concentration limits for drinking water and food contact materials are in a very similar order of magnitude. For this reason, no new value was derived for the time being.

This value is considered as proportionate because it is

- practically and economically feasible for most uses
- effective in minimizing releases
- implementable from an analytical point of view.

Using a migration limit is considered to be the best available method to limit the marketability of articles that release a larger amount of BPA/BosC, to lower the BPA/BosC content in mixtures and to encourage conditions of processing that prevent or minimize the release of BPA/BosC. The value serves the goal of minimizing environmental concentrations. It is expected that this low migration value will result in decreasing concentrations of BPA/BosC in environmental matrices.

BPA and BosC possess endocrine disrupting properties. For endocrine disruptors in the environment, no safe exposure concentrations can be derived (please refer to the introduction of the call for evidence document). Therefore, environmental emissions need to be minimized as much as possible.

2. Release potential based on BPA/BosC content and use

The concentration of bisphenols in the final product and the amounts that can be released, depend on the type of use, the concentration originally used and on how well the material consisting of the bisphenolic monomer and/or containing bisphenols as an additive is protected. The likelihood of a release is influenced by whether it is a direct, environmentally open outdoor application or an indirect emission due to indoor use or the release of BPA/BosC from articles during service life regardless of whether it is embedded in a matrix or applied as an additive. The sole concentration on its own does not provide a direct indication of the release potential. The concentration must be regarded in the context of the quantitative distribution of the use of the article. The potential for distribution and release of BPA/BosC is greatly increased for daily uses that permeate all areas of life. For additive uses, for example, concentrations are basically low, but because the substances are not applied in a matrix-bound manner (e.g. in a mixture), their release is more likely. From a chemical point of view, release is possible from all areas of application of BPA/BosC.

2.1. Release from uses for the production of other chemicals

Bisphenols are a starting material for the production of other chemicals. The residual content of BPA in the produced chemical can be up to 35 percent depending on the chemical manufactured from/with BPA. In this case, the release is to be expected in the manufacturing process itself, and possibly from residues during service life and waste stage.

2.2. Release from uses as an additive in mixtures

There are some applications where BPA is directly used as an additive (e.g. as stabilizer of mixtures) and can therefore be easily released to the environment during processing. Typical contents in the mixture are 0.04-1%. Other than the use in polymers, in these applications BPA is not chemically bound or held back in a matrix and may therefore be much more accessible for leaching for example by water[1]. The likelihood of release is higher for mixtures containing BPs as additives. Additionally, these mixtures are often used in open applications which also increases the likelihood of release. Release occurs due to the absence of strictly controlled conditions (i.e. closed production sites in a plant). As a proxy it is assumed that strictly controlled conditions do not occur during professional or consumer use.

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[1] Fischer B., Milunov M., Floredo Y., Hofbauer P., Joas A. (2014): Identification of relevant emission pathways to the environment and quantification of environmental exposure for bisphenol A: Research Project on behalf of the German environment agency - https://www.umweltbundesamt.de/publikationen/identification-of-relevant-emission-pathways-to-the

2.3. Release from uses in plastics

If BPA is used in polymers it is incorporated and covalently bound to the polymer matrix. Releases from polymers can occur due to leaching of residual monomers in the polymer matrix or due to break down of chemical bonds and thus destruction of the polymeric structure, initiated for example by weathering effects in case of outdoor uses. If BPA is used as an additive for the production of plastics it is similarly incorporated into the matrix. Contents may vary between 15-89% with varying qualities and resulting unknown residual content.

3. Stressors and release mechanisms from uses in polymers

Stressors can affect products. As BPA/BosC are used as a monomer for polymers or as an additive in a ready-to-use mixture such as a top coat or paint that can protect an article or as an additive in a polymer or plastic, the question is which stressors these products are exposed to during their life cycle, primarily service life.

Stressors affect the material containing BPs as a monomer or additive. There are three main types of application for articles e.g. plastics that can release BPs: Indoor use without stressors, indoor use with stressors and outdoor use. These stressors cause ageing of all types of plastics. The articles containing aged plastics can release fragments from the matrix, such as oligomers or even monomers. The attacked structure can also release additives. The ageing of plastics[2] is influenced by external factors like temperature, oxygen concentration, atmospheric stresses, global and solar radiation, mechanical stress, biological stresses (macro- and microbiological) and internal factors like chemical structure, physical structure, impurities. In outdoor uses the likelihood of decomposition processes is high, as stressors like weathering effects, water contact or abrasion are permanently present. The materials a might be stressed to if used indoor, e.g. by cleaning processes (varying pH of cleaning agents), the normal wearing and tearing (mechanical stress during normal use of tableware) or the laundering and disposal of e.g. clothes. In some uses the stressors are negligible, e.g. in optical media.

Water is of particular relevance when considering atmospheric ageing. This can be e.g. precipitation water or also dew formation. In addition to outdoor weathering, many BPA/BosC-based or BPA/BosC-containing articles are also in constant contact with water (e.g. coating systems for buildings, geotextiles). Moisture changes the volume of e.g. moulded units or surface coatings depending on porosity. If the temperature also changes, this leads to stresses that can damage the article, the material, the plastic. The interface climate at surface boundaries to open air, the so-called microclimate, is of utmost importance. For example, the thermal stress on surfaces of e.g. moulded parts or general surfaces is greater than in the ambient air. The property changes due to weathering usually take place on the surface of the samples and in a thin, underlying layer. Each weather effect contributes individually to a damage pattern. It is therefore important to note that the environmental influences are not additive, but reinforce each other (synergetic effect). Besides this the combination of different polymers and the various additives they contain also harbour the risk of interactions with unwanted effects

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[2] Ehrenstein, G. W.; Pongratz, S. (2007): Beständigkeit von Kunststoffen. München: Hanser Verlag (1).

e.g. chemical interaction[3] (this concerns plastic composite systems, paint systems, products consisting of several sub-products).

4. Testing

4.1. Tests developed for stability assessment of plastics

To predict the service life of plastics, they are either aged in time-lapse tests or examined directly in the open air. As a rule, these tests are necessary to check the respective stability requirements depending on the application and to better equip the materials against stressors in the respective areas of application. Testing the stability of a plastic is considered an ageing criterion in practice. From these tests, the eluates can also be examined.

There are several stability, leaching and analytical standards for determining stability and material equipment requirements. Therefore, if levels of BP(A) in articles need to be analyzed to ensure marketability during service life, some standards are available.

4.2. Available standardized tests - for the release potential of BPA from weathering of plastics and coatings (examples)

A number of standardized methods are available to simulate weathering conditions and thus release potential of substances such as BPA:

In Germany, a test for outdoor weathering may be carried out according to DIN EN ISO 877. ISO/DIS 15314 is available for testing under maritime conditions. With artificial weathering, a time reduction of approx. 8.5 times can be achieved. For example, DIN 75220 is available for artificial weathering simulation. Specific test methods have been derived for the various areas of application, such as DIN 75220 for vehicle parts in Germany. In addition, the following methods are available:

- DIN EN ISO 877-1:2011-03 Plastics - Methods of exposure to solar radiation - Part 1: General guidance (ISO 877-1:2009)
- DIN EN ISO 2810:2019-12 Paints and varnishes - Natural weathering of coatings - Exposure and assessment (ISO/DIS 2810:2019)
- DIN EN ISO 4892-1:2016-10 Plastics - Methods of exposure to laboratory light sources - Part 1: General guidance (ISO 4892-1:2016)
- DIN EN ISO 11341:2004-12 Paints and varnishes - Artificial weathering and exposure to artificial radiation - Exposure to filtered xenon-arc radiation (ISO 11341:2004)
- DIN EN ISO 11507:2007-05 Paints and varnishes - Exposure of coatings to artificial weathering - Exposure to fluorescent UV lamps and water (ISO 11507:2007)
- SAE J 1976:2012-04-16 Outdoor Weathering of Exterior Materials

[3] SKZ.Weiterbildungs-und Technologie-Forum. Fachtagung-Bewitterung von Kunststoffen in der Automobilindustrie. - Dr. Kruse. Presentation.10./11.03.1999.Würzburg.Weathering of plastics in the automotive industry

- DIN EN 12224:2000-11 Geotextiles and geotextile-related products - Determination of the resistance to weathering
- DIN EN ISO 29664:2017-05 Plastics - Artificial weathering including acidic deposition (ISO 29664:2010)
- ISO/IEC 17025: 2005 to do migration testing and chemical analysis of food contact materials (FCM).

4.3. Available analytics for Bisphenol A

A method to determine free bisphenols for coated articles can be found in EN71. The analytic of BPA, in e.g. water matrix may be conducted with a (ESI) LC MS/MS System. Different methods of instrumental analytics must be developed, standardized and well documented according to European standards for the derivation of chemical analysis - decision limit, detection limit and determination limit under repeatability conditions and validation of analytical methods.

5. Socio-economic aspects

The authorities assume that manufacturers of polymers and mixtures analyze their products in order to ensure marketability further down the supply chain. It is the understanding of the authorities that the residual limit is already met by most articles manufactured in the EEA. For certain articles this is not true. However, it is the authorities understanding that those articles can meet the migration limit: EEA producers already protect articles against stressors sufficiently in order to guarantee functionality and extend the service life.

The authorities assume that manufacturers of polymers and mixtures could test and certify their products for downstream users in regard to the concentration limit. From the first call for evidence, it is known that the cost of residual content analysis is about of 200€. The authorities ask for additional information on how to estimate the number of necessary tests for the proposed restriction. The authorities also would like to better understand whether it is necessary to differentiate between an initial testing of products after entry into force of the restriction and later more limited (e.g. yearly) testing.

If the product complies with a residual content of 10 ppm no further testing would be required. However, if the permissible residual content is exceeded, it must be shown that the migration limit of 0.04 mg/L is complied with over the entire service life. From the first call for evidence, it is known that the cost of the life cycle simulation analysis to determine migration from the article is around 1000€ per substance and use.

The authorities expect no significant cost resulting from the establishment of a concentration limit of 10 ppm. Testing and certification can be done by upstream manufacturers. The situation is not as clear for the proposed migration limit. The authorities expect that for a majority of uses testing for migration limit/certain standard stressors (like UV, heat, water) can be done by upstream manufacturers who then pass through information in the supply chain on which stressors have been considered for migration limit testing.

However, with regard to the large variety of uses it is unclear whether all/most existing uses can be considered through standard testing/certification. Therefore, the authorities currently search for information on limits of such standard testing in regard to the migration and plausible estimates on how many 'standard' tests could reasonably be expected and how many additional tests would be necessary for 'non-standard' applications.

Again, the authorities also would like to better understand whether it is necessary to differentiate between the initial testing requirements after entry into force of the restriction and later more limited (e.g. yearly) testing.

Additionally, the authorities do not have sufficient data to assess the impact on imports. They assume that certification for concentration limits should be implementable for imported articles, too. However, ensuring suitable testing on the migration limit – especially in articles with several different components that contain BPA/BosC might be demanding for importers. More information on this topic is needed to better understand monetary impacts and practicability in regard to imports.