ANEC Position Paper (Monomers - Proposed requirements for Appendix C of the Toy Safety Directive)





Raising standards for consumers



POSITION PAPER

Monomers - Proposed requirements for Appendix C of the Toy Safety Directive

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Summary

In a German opinion (EXP/WG/2017/007) circulated in March 2017 it was proposed "to derive substance-specific limits for the carcinogenic monomers on the basis of risk assessments and to include these limits in Appendix C of the Toys Safety Directive". The opinion was based on a statement by the Federal Institute for Risk Assessment (BfR). It identified 20 monomers with CMR properties listed in Annex I of Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and showed that in several cases the CMR limits in the TSD are insufficient.

In the present position paper, the 20 monomers were screened regarding their probability to be present in toys and some substances were identified which should be restricted as a matter of priority.

It is recommended to include in Appendix C of the TSD:

- a content limit of 1 mg/kg for vinyl chloride in PVC toys;
- a content limit of 1 mg/kg for 1,3 butadiene using the substance as a monomer;
- a content limit of 1 mg/kg for acrylonitrile using the substance as a monomer;
- a content limit of 1 mg/kg for acrylamide using the substance as a monomer;
- a migration limit of 0,077 mg/l simulant for styrene following 3 hours extraction or a third of the value if based on the extraction procedure in accordance with EN 71-10.

Content limits are used for non-threshold CMR substances following the opinion of SCHER (on CMR substances in toys) that the presence of such substances in toys should be excluded using sensitive analytical methods. An additional limitation of migration does not seem necessary for these substances.

For styrene a migration limit is proposed based on a TDI used by WHO (which is a factor of 10 lower than the current limit in EN 71-9).

Some of the 20 CMR monomers not included in the proposal above may need further investigation.



1. Background

In a German opinion (EXP/WG/2017/007) circulated in March 2017 it was proposed "to derive substance-specific limits for the carcinogenic monomers on the basis of risk assessments and to include these limits in Appendix C of the Toys Safety Directive". The opinion was based on a statement by the Federal Institute for Risk Assessment (BfR). It identified 20 monomers with CMR properties listed in Annex I of Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. For 5 of the substances an exemplary comparative risk assessment was carried out based on the general CMR restrictions included in the TSD, an assumed ingestion of 8 mg toy material and a body weight of 7,5 kg. It was found that "the residual content of some genotoxic carcinogens permitted for toys is linked to an additional lifetime risk for cancer that is unacceptable according to the Scientific Committee on Health and Environmental Risks (SCHER) and can therefore pose a considerable health risk". In particular, this was the case for vinyl chloride, acrylamide and acrylonitrile.

For 8 listed CMR substances a content limit of 1 mg/kg is given in the FCM Regulation for plastics materials in addition to specific migration limits (SMLs). The substances are: vinyl chloride, butadiene, ethylene oxide, propylene oxide, 2-methyl-1,3butadiene, epichlorohydrin, 2,4-toluene-diisocyanate and diphenylmethane-2,4[']diisocyanate. By comparison, the TSD allows a concentration of 0,1% (= 1 g/kg) for carcinogens and mutagens cat. 1A and 1B, 1% (= 10 g/kg) for carcinogens and mutagens cat.2. In addition, these substances shall not migrate in detectable quantities (ND). The latter provision applies to further 7 substances: bisphenol A (2,2bis(4-hydroxyphenyl)propane), acrylonitrile, acrylamide, ethylenimine, vinylidene chloride, 1,3-phenylene-diamine and styrene. For 5 substances an SML has been established (phenol, formaldehyde, 1,4-dihydroxybenzene, vinyl acetate (acetic acid, vinyl ester), trioxane). Two of the substances are already covered by Appendix C (bisphenol A and phenol). A restriction for formaldehyde is in preparation. Hence, 17 substances remain which need further investigation.

The harmonized standard EN 71-9 (reference not published in the Official Journal), includes limits for 5 monomers (acrylamide, bisphenol A, formaldehyde, phenol and styrene) in Table 2D. Acrylamide and styrene are also included in the list of 20 CMR substances provided by Germany.

The priority table for non-threshold substances prepared by Chemical Subgroup members (EXP-WG-2013-033rev2) includes the following monomers: formaldehyde, 1,4-dihydroxy-benzene, butadiene, acrylamide, ethylene oxide, propylene oxide and ethylenimine (the last 3 substances are in the lowest priority category).

The relevant data including their CLP classifications are included in the table below.

Substances on the list likely to be used or found in toys were investigated more in detail in the sections 2-6. The present paper follows the recommendations given in the opinion by the former Scientific Committee on Health and Environmental Risks (SCHER) on "Risk from organic CMR substances in toys", adopted at its 7th plenary



on 18 May 2010. In particular, non-threshold CMRs (cat. 1A and 1B according to the CLP regulation) should not be present in toys as intentionally added components (i.e. their presence should be excluded using sensitive methods). By contrast, the presence of CMR cat. 2, when characterized by a threshold mechanism, can be accepted based on a risk assessment.

It is assumed that the well-established content limit of 1 mg/kg for some substances given in the FCM Regulation for plastics materials is a suitable limit for exclusion of non-threshold CMR substances. Comparisons are made, where possible, to ensure that exposure to toys using this threshold does not lead to an exposure to exceeding concentrations associated with an additional lifetime cancer risk of 1/1 mio.

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			Reg (EU) No 10/2011		CLP	TSD	EXP-WG-2013-033r2
No.	CAS Number	Name	SML (mg/kg) ¹⁾	Restrictions	Harmonised Classification	Max conc. CMR (%)	Priority table of the Subgroup
1	80-05-7	Bisphenol A ^{3) 5)}	ND ²⁾		Rep1B	0,3	
2	108-95-2	Phenol ^{3) 5)}	60		Mut2	1	
3	50-00-0	Formaldehyde ^{4) 5)}	15		Carc1B, Skin Sens 1	0,1	X (dark green, highest priority)
4	75-01-4	Vinyl chloride	ND ²⁾	1 mg/kg in final product	Carc1A	0,1	
5	106-99-0	Butadiene	ND ²⁾	1 mg/kg in final product	Carc1A, Mut1B	0,1	X (yellow)
6	75-21-8	Ethylene oxide	ND ²⁾	1 mg/kg in final product	Carc1B, Mut1B	0,1	X (red, lowest priority)
7	75-56-9	Propylene oxide	ND ²⁾	1 mg/kg in final product	Carc1B, Mut1B	0,1	X (red, lowest priority)
8	78-79-5	2-Methyl-1,3- butadiene	ND 2)	1 mg/kg in final product	Carc1B, Mut2	0,1	
9	106-89-8	Epichlorohydrin	ND ²⁾	1 mg/kg in final product	Carc1B	0,1	
10	107-13-1	Acrylonitrile	ND ²⁾		Carc1B	0,1	
11	79-06-1	Acrylamide ⁵⁾	ND ²⁾		Carc1B, Mut1B, Rep2	0,1	X (yellow)
12	151-56-4	Ethylenimine	ND ²⁾		Carc1B, Mut1B	0,1	X (red, lowest priority)
13	584-84-9	2,4-Toluene- diisocyanate	ND ²⁾	1 mg/kg in final product	Carc2, Skin Sens 1	1,0	
14	5873-54-1	Diphenylmethane- 2,4'-diisocyanate	ND ²⁾	1 mg/kg in final product	Carc2, Skin Sens 1	1,0	
15	123-31-9	1,4-Dihydroxy- benzene	0,6		Carc2, Mut2, Skin Sens 1	1,0	X (pale green)
16	108-05-4	Vinyl acetate	12		Carc2	1,0	
17	75-35-4	Vinylidene chloride	ND ²⁾		Carc2	1,0	
18	108-45-2	1,3-Phenylene-diamine	ND ²⁾		Mut2	1,0	
19	110-88-3	Trioxane	5		Rep2	3,0	
20	100-42-5	Styrene ⁵⁾	ND ²⁾		Rep2	3,0	



- 1) SML [mg/kg food (simulant)]: Specific Migration Limit
- 2) ND: the substance shall not migrate in detectable quantities
- 3) Specific migration limit in Appendix C of TSD
- 4) Inclusion of specific limit in Appendix C of TSD in discussion
- 5) Specific migration limit in EN 71-9

2. Vinyl chloride (chloroethylene)

2.1 Basic data

H₂C)Cl

EC / List no.: 200-831-0

CAS no.: 75-01-4



Harmonised classification and labelling (health related only):

Carc. 1A H350 – May cause cancer

NOTE: In CLP notifications this substance has been also self-classified:

Muta. 2 H341 Suspected of causing genetic defects

It should be further noted that several reviews of the toxicity of vinyl chloride arrived at the conclusion that vinyl chloride is a genotoxic carcinogen (e.g. IARC¹ or WHO²). Hence, vinyl chloride is considered to be a non-threshold compound.

2.2 Possible exposure

Toys made from PVC are widespread. The "Environmental Health Criteria 215: Vinyl Chloride"³ published in 1999 contains a reference to data from a German investigation from 1978 where the vinyl chloride content of PVC toys (and other products) was < 0,05 ppm. Later data generated in the eighties and early nineties showed residues below 1 ppm in various PVC products (bottles, packaging films). However, recent data on vinyl chloride residues in PVC articles including toys do not seem to be available (in particular, from PVC products manufactured outside of the EU) and, therefore, exposure to vinyl chloride from toys is unknown. Hence, a concentration exceeding 1mg/kg (the threshold used in the EU FCM regulation for plastic materials) is not excluded.

¹ <u>http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-31.pdf</u>

² <u>http://www.who.int/ipcs/publications/ehc/ehc_215/en</u>

³ http://www.who.int/ipcs/publications/ehc/ehc 215/en/



As pointed out in the German position paper this limit can be regarded as sufficiently protective. The additional lifetime cancer risk resulting from an ingestion of 8 mg toy per day containing 1 mg/kg vinyl chloride would be below 10⁻⁶. A joint position paper of SCCS, SCHER and SCENIHR adopted in June 2012⁴ indicated that the vinyl chloride dose after oral administration resulting in a lifetime cancer risk of 10⁻⁶ was 1,4 ng/kg bw/d. By comparison, ingestion of 8 mg toy containing 1 mg/kg vinyl chloride (or any other substance) would give a dose of 8 ng, or about 1,07 ng/kg bw/day for a child of 7,5 kg assuming 100% resorption. Hence, the application of a content limit of 1 mg/kg for vinyl chloride will - even under worst case assumptions - lead to a dose somewhat below the one associated with the additional lifetime cancer risk of 1/1 Mio. Therefore, the 1 mg/kg threshold seems appropriate.

2.3 Existing relevant limits (other than shown in the table)

In Germany a limit of 1 mg/kg applies to certain products including toys according to the consumer goods ordinance ("Bedarfsgegenständeverordnung").

2.4 Proposal for inclusion in Appendix C

It is recommended to set a limit of 1mg/kg vinyl chloride in Appendix C for PVC toys (in accordance with the content limit in the EU FCM regulation for plastic materials).

Test method: EN ISO 6401 "Plastics - Poly(vinyl chloride) - Determination of residual vinyl chloride monomer - Gas-chromatographic method (ISO 6401:2008)". The indicated LOQ is 0,1mg/kg.

3. 1,3-butadiene (buta-1,3-diene)

3.1 Basic data

CH

EC / List no.: 203-450-8 CAS no.: 106-99-0



Harmonised classification and labelling (health related only):

Hence, 1,3-butadiene is considered to be a non-threshold compound.

⁴ <u>http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_092.pdf</u>



3.2 Possible exposure

1,3-butadiene is mainly used for the production of acrylonitrile butadiene styrene (ABS), thermoplastic elastomers as well as rubbers such as styrene-butadiene (SBR) rubber. Such materials can be found in toys. A European Risk Assessment Report⁵ was published in 2002 which looked among other at the release of free monomer from polymeric consumer products. It concluded that the "*level of risk to human health under current levels of consumer exposure in the EU is uncertain, but in view of the very low estimated exposure levels, it is predicted that there would be negligible residual risk*". But it was also stated: "*Risks cannot be excluded for all other exposure scenarios, as the substance is identified as a non-threshold carcinogen*". The release from toys was not part of the assessment. As regards the oral exposure route only the migration of the free monomer from a few food contact materials (which were already regulated at the time) was looked at.

In a study by Y. Abbe et al. entitled "Volatile Substances in Polymer Toys Made from Butadiene and Styrene"⁶ published in 2013 seventy-three toy samples comprising fifty-nine ABS toys, twelve thermoplastic elastomer toys and two styrene-butadiene rubber toys purchased in Japan were investigated. 1,3-butadiene was detected in 88% of the ABS samples with a minimum of 0,04 mg/kg, a maximum of 5,3 mg/kg and a mean value of 0,78 mg/kg. The maximum value is above the limit of 1 mg/kg included in the FCM regulation. No 1,3-butadiene was detected in the other materials.

In its health assessment of 1,3-butadiene⁷ the US EPA indicated an Inhalation Unit Risk (of carcinogenicity) of 3×10^{-5} per μ g/m³ (a value for oral exposure is not available). By comparison, the corresponding value by the US EPA for vinyl chloride⁸ is 8.8 x 10⁻⁶ per μ g/m³. There does not seem to be a significant difference bearing in mind the uncertainties in the calculations.

Hence, the application of a content limit of 1 mg/kg for 1,3-butadiene seems appropriate.

3.3 Existing relevant limits (other than shown in the table)

None identified.

3.4 Proposal for inclusion in Appendix C

It is recommended to set a limit of 1 mg/kg for 1,3-butadiene in Appendix C for materials using this substance as a monomer (in accordance with the content limit in the EU FCM regulation for plastic materials).

⁵ <u>http://www.echa.europa.eu/documents/10162/1f512549-5bf8-49a8-ba51-1cf67dc07b72</u>

⁶ http://dx.doi.org/10.4236/ajac.2013.45029

⁷ https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=54499

⁸ <u>https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1001</u>



Test method: EN 13130-4 "Materials and articles in contact with foodstuffs – Plastics substances subject to limitation - Part 4: Determination of 1,3-butadiene in plastics". The indicated LOQ is 0,1mg/kg.

4. Acrylonitrile

4.1 Basic data

N =CH

EC / List no.: 203-466-5

CAS no.: 107-13-1



Harmonised classification and labelling (health related only):

Carc. 1B	H350 – May cause cancer
Acute Tox. 3	H301 – Toxic if swallowed
Acute Tox. 3	H311 – Toxic in contact with skin
Acute Tox. 3	H331 – Toxic if inhaled
STOT SE 3	H335 – May cause respiratory irritation
Skin Irrit. 2	H315 – Causes skin irritation
Skin Sens. 1	H317 – May cause an allergic skin reaction

It should be noted that the European Risk Assessment report quoted below considered acrylonitrile a non-threshold carcinogen.

4.2 Possible exposure

Acrylonitrile is mainly used as a monomer to prepare polyacrylonitrile and several copolymers, such as styrene-acrylonitrile (SAN), acrylonitrile butadiene styrene (ABS), acrylonitrile styrene acrylate (ASA), and other synthetic rubbers such as acrylonitrile butadiene (NBR). Some of these materials can be found in toys. A European Risk Assessment Report⁹ was published in 2004 which concluded that "*there is potential for indirect exposure of consumers as a consequence of use of products manufactured from acrylonitrile, due to the presence of residual monomer*". Although "*the predicted exposures are very low*" the report pointed to the fact that acrylonitrile is a non-threshold carcinogen and concluded: "*There is a need for limiting the risks;*

⁹ http://echa.europa.eu/documents/10162/22bf49d3-e951-44b8-a45a-6973d3dc62f6



risk reduction measures which are already being applied shall be taken into account". Exposure from toys was not part of the assessment.

In a study by Y. Abbe et al. entitled "Volatile Substances in Polymer Toys Made from Butadiene and Styrene"¹⁰ (mentioned in section 3. on 1,3-butadiene) acrylonitrile was detected in 95% of the ABS samples with a minimum of 0,42 mg/kg, a maximum of 55 mg/kg and a mean value of 14 mg/kg. Acrylonitrile was detected in one thermoplastic elastomer toy (0,2 mg/kg).

As pointed out in the German position paper a daily dose of 1,9 ng/kg is associated with an additional lifetime cancer risk of 10^{-6} for the substance as calculated in the joint position paper of SCCS, SCHER and SCENIHR mentioned in section 2.2. By comparison, ingestion of 8 mg toy containing 1 mg/kg acrylonitrile (or any other substance) would give a dose of 8 ng, or about 1,07 ng/kg bw/day for a child of 7,5 kg assuming 100% resorption. Hence, the application of a content limit of 1 mg/kg for acrylonitrile will - even under worst case assumptions - lead to a dose somewhat below the one associated with the additional lifetime cancer risk of 1/1 Mio. Therefore, a 1 mg/kg threshold seems appropriate.

4.3 Existing relevant limits (other than shown in the table)

None identified.

4.4 Proposal for inclusion in Appendix C

It is recommended to set a limit of 1 mg/kg in Appendix C for materials using acrylonitrile as a monomer.

Test method: ISO 4581 "Plastics -- Styrene/acrylonitrile copolymers -- Determination of residual acrylonitrile monomer content -- Gas chromatography method". The indicated LOQ is 0,3 mg/kg (for the method in Annex A).

NOTE 1: There is no content limit for acrylonitrile in the EU FCM regulation for plastic materials. However, a content-based limit seems better in line with the position of SCHER on CMR substances in toys from 2010 that "*non-threshold carcinogens should not be present in toys as intentionally added components*" and should "*be determined directly in the toy using appropriate extraction procedures and sensitive chemical-analytical procedures*". Apart from that it would be extremely difficult to set a suitable migration limit using the EN 71-10 extraction method ensuring exposure below the level associated with an additional lifetime cancer risk of 10⁻⁶ as the required method would need a very low LOQ (i.e. 8 ng/100ml or 80 ng/l simulant).

NOTE 2: A material complying with the ND migration requirement in accordance with the FCM regulation for plastic materials would not necessarily be sufficiently protective if used as a toy. An acceptable migration of 10 ppb (=10 μ g/kg food = ND) would correspond to a migration of about 170 ng from 10 cm² (instead of 600 cm²)

¹⁰ <u>http://dx.doi.org/10.4236/ajac.2013.45029</u>



from the FCM). This is higher compared to the 8 ng which would be allowed in 8 mg toy using the 1 mg/kg content limit.

5. Acrylamide

5.1 Basic data

H₂C HO

EC / List no.: 201-173-7 CAS no.: 79-06-1, 122775-19-3



Harmonised classification and labelling (health related only):

Carc. 1B	H350 – May cause cancer
Muta. 1B	H340 – May cause genetic defects
Repr. 2	H361f – Suspected of damaging fertility
Acute Tox. 3	H301 – Toxic if swallowed
Acute Tox. 4	H312 – Harmful in contact with skin
Acute Tox. 4	H332 – Toxic if inhaled
STOT RE 1 exposure	H372 –Causes damage to organs through prolonged or repeated
Skin Irrit. 2	H315 – Causes skin irritation
Skin Sens. 1	H317 – May cause an allergic skin reaction
Eye Irrit. 2	H319 – Causes serious eye irritation

Hence, acrylamide is considered to be a non-threshold compound.

5.2 Possible exposure

Most of acrylamide is used to manufacture polyacrylamides which are used for a great number of products including toys (e.g. water growing toys). A European Risk Assessment Report¹¹ was published in 2002 which concluded that the risks for consumers are already low. However, it also stated: "*Risks cannot be excluded for all other exposure scenarios, as the substance is identified as a non-threshold*

¹¹ <u>https://echa.europa.eu/documents/10162/50218bf9-ba0f-4254-a0d9-d577a5504ca7</u>



carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered". Exposure from toys was not part of the assessment.

The German position paper reports that a daily dose of 2 ng/kg is associated with an additional lifetime cancer risk of 10^{-6} for the substance as calculated in the joint position paper of SCCS, SCHER and SCENIHR mentioned above. By comparison, ingestion of 8 mg toy containing 1 mg/kg acrylamide (or any other substance) would give a dose of 8 ng, or about 1,07 ng/kg bw/day for a child of 7,5 kg assuming 100% resorption. Hence, the application of a content limit of 1 mg/kg for acrylamide will - even under worst case assumptions - lead to a dose somewhat below the one associated with the additional lifetime cancer risk of 1/1 Mio. Therefore, a 1 mg/kg threshold seems appropriate.

5.3 Existing relevant limits (other than shown in the table)

EN 71-9 sets an "action limit" in the aqueous migrate for acrylamide of 0,02 mg/l corresponding to a release of 2 μ g from 10 cm² per hour = 200 ng/kg for a child of 10 kg. This is a factor of 100 above the dose associated with lifetime cancer risk of 10⁻⁶ (or even a factor 300 if 3 hours of exposure are calculated). So, the limit in EN 71-9 is entirely inappropriate.

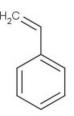
5.4 Proposal for inclusion in Appendix C

It is recommended to set a limit of 1 mg/kg in Appendix C for materials using acrylamide as a monomer (see NOTEs in 4.4).

Test method: to be determined.

6. Styrene

6.1 Basic data



EC / List no.: 202-851-5 CAS no.: 100-42-5



Harmonised classification and labelling (health related only):

Repr. 2	H361f – Suspected of damaging fertility
Acute Tox. 4	H332 – Toxic if inhaled



STOT RE 1 exposure	H372 –Causes damage to organs through prolonged or repeated
Skin Irrit. 2	H315 – Causes skin irritation
Eye Irrit. 2	H319 – Causes serious eye irritation

6.2 Possible exposure

Styrene is a monomer used for the production of polymeric materials such as polystyrene (PS), acrylonitrile butadiene styrene (ABS), styrene-butadiene rubber (SBR), styrene-acrylonitrile resin (SAN) and unsaturated polyesters.

A draft European Risk Assessment Report¹² was published in 2008 which concluded that there is generally no need for risk reduction measures for consumers beyond those which are being applied (with the exception of some very specific applications). Exposure from toys was not part of the assessment.

In a study by Y. Abbe et al. entitled "Volatile Substances in Polymer Toys Made from Butadiene and Styrene"¹³ (mentioned in section 3. on 1,3-butadiene) styrene was detected in 100% of the ABS samples with a minimum of 71 mg/kg, a maximum of 2600 mg/kg and a mean value of 928 mg/kg. Styrene was also detected in five thermoplastic elastomer toys (up to 0,5 mg/kg).

6.3 Existing relevant limits (other than shown in the table)

EN 71-9 sets an "action limit" in the aqueous migrate for styrene of 0,75 mg/l corresponding to a release of 75 µg from 10 cm² per hour = 7,5 µg/kg for a child of 10 kg. This limit (TDI/10) is based on a TDI of 77 µg/kg. However, the WHO Guidelines for drinking-water quality, fourth edition including addendum (2017)¹⁴ use a TDI of 7,7 µg/kg. It is based on the same NOAEL for decreased body weight observed in a 2-year drinking-water study in rats, but using an uncertainty factor of 1000 (100 for inter- and intraspecies variation and 10 for the carcinogenicity and genotoxicity of the reactive intermediate styrene-7,8-oxide).

6.4 Proposal for inclusion in Appendix C

It is recommended to set a migration limit of 0,077 mg/l simulant (in accordance with EN 71-10, clause 6) in Appendix C for materials using styrene as a monomer.

Test method: extraction in accordance with EN 71-10, determination to be determined (e.g. EPA Analytical Methods for Drinking Water - 815-B-16-016) NOTE: The extraction time in EN 71-10 is 60 minutes. In fact, the time should be 3 hours in line with current risk assessment practices. Else the limit should be reduced by a factor of 3.

¹² <u>http://echa.europa.eu/documents/10162/13630/trd rar uk styrene en.pdf</u>

¹³ <u>http://dx.doi.org/10.4236/ajac.2013.45029</u>

¹⁴ <u>http://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en/</u>



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About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 34 countries.

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Raising standards for consumers

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