



POSITION PAPER

Organic chemical compounds in toys: Systematic review of EN 71-9, EN 71-10 and EN 71-11

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Contact Person: Tania Vandenberghe

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Summary

A systematic review will be launched by the CEN-CENELEC Management Centre (CCMC) in July 2017 on the following standards:

- EN 71-9:2005+A1:2007, "Safety of toys - Part 9: Organic chemical compounds – Requirements";
- EN 71-10:2005 "Safety of toys - Part 10: Organic chemical compounds – Sample preparation and extraction";
- EN 71 11:2005 "Safety of toys - Part 11: Organic chemical compounds – Methods of analysis".

ANEC has reviewed a document provided by the Chair of CEN TC 52 'Safety of Toys' entitled, "For information and for possible consideration when voting on the forthcoming systematic review on EN 71-9, EN 71-10 AND EN 71-11" (CEN/TC 52 N 2061). The paper identifies several options (revision, withdrawal, combined withdrawal and confirm, confirm, conversion into TS or TR) and proposes some "considerations".

ANEC considers the arguments in the options paper to be highly questionable. Most importantly, they do not reflect the implications for the health of children and we do not consider them appropriate in reaching a decision on the future of the standards.

None of the options "withdrawal", "combined withdrawal and confirm", "confirm", "conversion into TS or TR" is viable.

Consequently, ANEC seeks revision of the three standards, not only to bring them in line with the state-of-the-art but to broaden their scopes and pursue the ambition needed to protect children from the many potentially hazardous organic chemicals in toys.

Background

A systematic review will be launched by the CEN-CENELEC Management Centre (CCMC) in July 2017 on the following standards:

- EN 71-9:2005+A1:2007, "Safety of toys - Part 9: Organic chemical compounds – Requirements";
- EN 71-10:2005 "Safety of toys - Part 10: Organic chemical compounds – Sample preparation and extraction";
- EN 71 11:2005 "Safety of toys - Part 11: Organic chemical compounds – Methods of analysis".

Although mandated by the Commission, the references to these standards have not been published in the EU Official Journal (OJ). The reason for this is that the former scientific committees CSTE (Scientific Committee on Toxicity, Ecotoxicity and the Environment) and SCHER (Scientific Committee on Health and Environmental Risks) provided some critical comments on the CEN report on the risk assessment of organic chemicals in toys which formed the basis of the normative provisions in the above standards. Unfortunately, no efforts have been made to resolve the deadlock, despite the fact that the impasse did not seem unsurmountable.

Whilst compliance with the standards does not give a presumption of conformity, they have been widely used by MS authorities and industry to demonstrate the safety of toys. The fact that the references to the standards have not been published in the OJ does not mean that they are legally irrelevant. For instance, the General Product Directive (GPSD, Directive 2001/95/EC) provides that conformity of a product to the general safety requirement can also be assessed making use of other instruments (such as non-referenced European standards or national standards) in the absence of specific Community provisions governing the safety of the product or where European standards referenced in the OJ are not available.

By Decision 373 taken in Delft on 2016-04-15, CEN TC 52 'Safety of Toys' encouraged "WG 5 at its earliest opportunity to start the process to collect information that can form the basis for informed decisions by NSBs when the systematic review of EN 71-9, -10 and -11 is due in 2017". WG 5 launched an inquiry in June 2016. The results (compiled in document CEN TC 52 N 2004, unfortunately with comments on all 3 parts mixed) showed diverse reactions. Whilst there seems to be an agreement that the standards are outdated, the views regarding the way forward are fundamentally opposed. Whilst some experts supported a fundamental revision with a view to update and broaden the current provisions incorporating additional requirements, some other experts indicated that the standards should be buried.

A main argument by those wishing to abandon the standards was the chemical requirements of the TSD are sufficient, and any new standard should cover only the

relevant requirements in TSD Appendix C (for chemical substances used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth).

In line with this spirit, CEN TC 52 adopted several preliminary work items (PWIs) for new standards on TCEP and alternative flame retardants, isothiazolinones, phenol and bisphenol A in December 2016 (CEN TC 52 N 2010).

ANEC fundamentally disagreed with the adoption of these PWIs stating: *"It has become apparent that the idea is to eliminate EN 71-9/10/11 and that the proposed PWIs covering substances included in Appendix C of the TSD are designed to become the first documents of a successor standard series. The adoption of the PWIs would clearly anticipate the future of the existing standard series. This is entirely unacceptable.*

First, EN 71-9/10/11 covers currently 72 substances – the new standard series will cover just 6 substances for the time being. Even if further substances will be included in Appendix C (currently about 1 substance per year) it would take many years to fill the gap resulting from a withdrawal of EN 71-9/10/11. Further, Appendix C substances are limited to toys for children up to 36 months and toys intended to be placed in the mouth whilst EN 71-9/10/11 has a broader scope covering in principle all toys. Third, it would make little sense to run EN 71-9/10/11 in parallel to the new standard series as in many cases new standards covering organic chemicals would lead to the need to adapt EN 71-9/10/11 (if already included).

ANEC is deeply concerned that this may result in a significant step backwards in terms of consumer protection acknowledging that EN 71-9/10/11 is outdated and needs desperately a revision. Instead of adapting the standards and complementing them with missing provisions to overcome its deficits (recognised already at the time of publication) their disposal is apparently prepared. ANEC does not accept this and will consider further steps in this regard".

Later, the Chair of CEN TC 52 made available a document entitled: "For information and for possible consideration when voting on the forthcoming systematic review on EN 71-9, EN 71-10 AND EN 71-11" (CEN TC 52 N 2061). The paper identifies several options (revision, withdrawal, combined withdrawal and confirm, confirm, conversion into TS or TR) and proposes to put forward arguments for and against the options presented. ANEC reviewed the document and provides hereinafter some critical comments from a consumer protection perspective.

Option papers (CEN TC 52 N 2061)

The following section provides comments on the referenced options paper. ANEC comments are inserted in the table provided in document CEN TC 52 N 2061.

<p>Option 1 REVISION</p>	<ul style="list-style-type: none"> • The standards are outdated and in that sense need revising <p>ANEC comment: it is true that the standards are not in line with the state-of-the-art (e.g. outdated limits and methods), but more importantly, the standards do not provide an adequate level of safety for children. The introduction of EN 71-9 acknowledges "that not all potentially hazardous organic compounds could be addressed" and points out that "future editions of this standard may address additional organic compounds". Hence, it was acknowledged already by the time the standards were prepared that they are just a starter package which needs to be complemented in many ways. In addition, many requirements focus on toys for small children and ignore toys for older children (e.g. limits for some flame retardants). The report of the former CEN TC 52 WG 9 TG 3 (the group of toxicologists) identified many more substances which shall not be used in toys or which need further investigation. Therefore, the standards need a comprehensive revision broadening its scope not just an update of limits, methods and references.</p> <ul style="list-style-type: none"> • The status of the standards is confusing – they are used but do not provide a presumption of conformity to the TSD <p>ANEC comment: first, it is unclear whether this is a pro or a counter revision argument. The negative connotation suggests that this meant as an argument against revision. ANEC considers the revision as an opportunity to ensure that the standards are referenced in the OJ. Apart from that, it is quite normal in the New Approach system that some standards are not referenced (or certain clauses of standards do not give a presumption of conformity to the essential requirements of a Directive). It is difficult to see how this is "confusing". At best this may be confusing for people not familiar with New Approach legislation. In the field of</p>
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child care articles for instance, there are many standards that are not referenced in the OJ. In practice, the differences between referenced and non-referenced standards are small. In addition, the fact that the references to the standards have not been published in the OJ does not mean that they are legally irrelevant - conformity of a product to the relevant safety requirement can also be assessed making use of other instruments such as non-referenced European standards.

- There are conflicts between new legal requirements and the requirements in EN 71-9

ANEC comment: again it is unclear whether is a pro or a counter argument – ANEC considers the conflict between legal requirements and the provisions in standards an argument in favour of a revision ensuring compatibility between legal and normative requirements.

- The aim of a revision could seem unspecific since TC 52 has decided that substances under Appendix C of the TSD will be covered in a separate set of new standards

ANEC comment: it is unclear what this means, in particular, what an "unspecific" revision is. Any revision of any standard requires to specify the envisaged changes, i.e. identify the specific changes to be made. WG 5 experts have made many valuable proposals in this regard. This is entirely independent of any substances to be covered by separate standards (which ANEC does not support).

- If revised, a prioritization of the substance groups covered by the standards is needed; some may have low priority as they are treated elsewhere and could thus be removed

ANEC comment: again it is completely unclear what this means. Which substances are covered elsewhere and have a low priority? Appendix C substances again? ANEC does not support this statement and stresses that the standards EN 71-9/10/11 cover currently 72 substances, whilst the new standard series on Appendix C substances will cover only 6 substances for the time being. In addition, Appendix C substances cover only chemical substances used in toys intended for use by children

under 36 months or in other toys intended to be placed in the mouth. Even if Appendix C substances will be covered by a new standards series, this does not mean that these substances are to be considered as low priority. On the contrary, it would be more than desirable to establish requirements for TCEP and alternative flame retardants or isothiazolinones for toys for older children.

- There are limited resources in the relevant WG in CEN TC 52 and a revision of these standards is a large task and the work already undertaken with elaboration of standards supporting Appendix C needs to be considered

ANEC comment: resources are always limited but the question is, which resources can be made available by the Commission for this purpose (and any other standardisation work e.g. on Appendix C substances). However, this is subject to debate and negotiation. So resources are not fixed in size but are variable. In addition, CEN TC 52 could ask the Commission to make sufficient resources available. Further, it must be debated whether the working methods of TC 52 are efficient enough, e.g. whether it is really necessary to develop specific analytical methods for toys. For instance, existing standards for the measurement of VOC emissions could be used instead of the rather strange method currently included in Annex A of EN 71-11. Lastly, there may be means of conformity assessment other than testing (e.g. using Safety Data Sheets of substances used in the production).

- A future publication of a reference to the revised standards in the OJEU would require a specified standardization request from the European Commission (COM) but presently no such request seems to be planned

ANEC comment: first, it is pure speculation to declare that there is no intention on the part of the Commission to issue a standardisation request dealing with parts 9, 10 and 11 without having any confirmation for this. Secondly, it is overlooked that also CEN TC 52 could take the initiative and propose to the Commission to incorporate the revision of the standards in the

	<p>standardisation request in preparation.</p> <ul style="list-style-type: none"> • A standardization request would also be needed to clarify the scope and aim of a revision and to clarify the link between TSD Appendix C restrictions and the EN71-10 and -11 standards <p>ANEC comment: ANEC agrees that a standardisation request is needed but primarily for securing funding, not necessarily for the reasons given. WG 5 experts provided many ideas on the scope of the revision. We believe that "the link between TSD Appendix C restrictions and the EN71-10 and -11 standards" does not need a clarification in a standardisation request.</p>
<p>Option 2 WITHDRAWAL</p>	<ul style="list-style-type: none"> • The TSD Appendix C restrictions presently refer to EN 71-10 and -11 and withdrawal could cause uncertainty <p>ANEC comment: correct, but a rather minor issue. It is significant that the main issue – the significantly reduced protection for children - is not subject of consideration in any of the arguments brought forward. Once again ANEC would like to stress that the health of children must have highest priority. It must be borne in mind that the TSD covers only few organic chemicals – CMRs (with rather high generic thresholds that are not necessarily protective), nitrosamines and nitrosatable substances and fragrances and a limited number of substances in Appendix C. A withdrawal of the standards would leave a vacuum and constitute a movement in the wrong direction, i.e. to abolish a very minimum of protection instead of updating and broadening the standards and providing the protection children deserve.</p> <ul style="list-style-type: none"> • The requirements in EN 71-9 are no longer in line with all TSD requirements <p>ANEC comment: correct, but this is no argument for a withdrawal.</p> <ul style="list-style-type: none"> • The methods in EN 71-10 and -11 have not been checked scientifically against the limits of the new TSD Appendix C restrictions <p>ANEC comment: The methods including those for substances in Appendix C need improvement (i.e. lower LOQs), but do not need to be "checked scientifically".</p>

	<ul style="list-style-type: none"> • Withdrawal does not prevent the future use of the standard(s) (e.g. pending the availability of new standards supporting TSD Appendix C restrictions). The use of the standards, especially for the method parts 10 and 11 might continue despite a withdrawal and any legal references to the standards will remain in place unless legislation is changed <p>ANEC comment: formally correct, but it is not an elegant solution. Apart from that, we do not consider it really relevant.</p> <ul style="list-style-type: none"> • The status of the standards is confusing – they are used but do not provide a presumption of conformity to the TSD <p>ANEC comment: as stated above, this is not confusing, nor an argument for or against revision or withdrawal.</p>
<p>Option 3 Combined WITHDRAWAL and CONFIRM (they are individual standards and will be voted on separately. The withdrawal of one is an option)</p>	<ul style="list-style-type: none"> • Withdrawal of EN 71-9 and confirming EN 71-10 and EN 71-11 would remove the problem of conflicting requirements (TSD vs EN 71-9) is avoided, but would ensure that the TSD legal references to test methods remain valid <p>ANEC comment: this is illogical. Apart from the fact that it is undesirable from a consumer protection perspective to abandon EN 71-9, also parts 10 and 11 need urgently updating. Finally, EN 71-9 is mentioned 15 times in part 10, and 13 times in part 11.</p> <ul style="list-style-type: none"> • Confirming EN 71-10 and -11 would leave the opportunity open to gradually amending the method parts <p>ANEC comment: methods without corresponding requirements are of little value.</p>
<p>Option 4 CONFIRM</p>	<ul style="list-style-type: none"> • Limit values for substances and /or limits of quantification for methods are in some cases obsolete <p>ANEC comment: agreed, but it is also true that the standards do not provide an adequate level of safety for children given its limited coverage of relevant substances of concern (as stated above). Confirmation is not a serious option – at least when protection of children is in the focus.</p> <ul style="list-style-type: none"> • According to standardization rules, there should be no

	<p>contradicting requirements between EN 71-9/-10/-11 and other standards (e.g. foreseen standards addressing Appendix C requirements). Therefore, also if the standards were confirmed, they would soon need to be revised</p> <p>ANEC comment: Confirmation is not a serious option as pointed out above. In fact, the standards should be more frequently updated.</p> <ul style="list-style-type: none"> • It could be investigated if it is a possible option that standards can be confirmed e.g. "until new standards supporting App C restrictions have been made available" <p>ANEC comment: this is illogical as the new standards will cover only 6 substances and cannot be seen as a replacement of a standard covering 72 substances.</p> <ul style="list-style-type: none"> • Confirming the standards would also mean that the confusion of the status of the standards versus the TSD would remain among economic operators <p>ANEC comment: the confirmation is not a serious option as pointed out above. Apart from this, we cannot see a "confusion".</p>
<p>Sub-option to 2 CONVERSION into a CEN TS or TR</p>	<ul style="list-style-type: none"> • If the standards are withdrawn, it could be considered to transfer useful information from the three standards into a technical specification or a technical report. The information would then be available but the confusion around its status might be reduced <p>ANEC comment: This makes no sense. It would be absurd to publish outdated specifications as other deliverables and would also be against consumer protection.</p>

Irrespective of the arguments above, ANEC believes that it would be detrimental for the reputation of CEN if EN 71-9/10/11 were to be withdrawn. We are confident that many actors share the assessment that a withdrawal of the standards would mean the sacrifice consumer protection.

Conclusions

ANEC considers the arguments in the options paper to be highly questionable. Most importantly, they do not reflect the implications for the health of children and we do not consider them appropriate in reaching a decision on the future of the standards.

None of the options "withdrawal", "combined withdrawal and confirm", "confirm", "conversion into TS or TR" is viable. **Consequently, ANEC demands a revision of the three standards, not only to bring them in line with the state-of-the-art but to broaden their scopes and pursue the ambition needed to protect children from the many potentially hazardous organic chemicals in toys.**

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.

ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.



Raising standards for consumers

**European association for the coordination
of consumer representation in standardisation aisbl**

Avenue de Tervuren 32, box 27, B-1040 Brussels, Belgium

Tel.: +32 2 743 24 70 / Fax: +32 2 706 54 30

E-mail: anec@anec.eu

EC Register of Interest Representatives:

Identification number 507800799-30

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