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Position paper

EU Subgroup on chemicals in toys fails its mission

Critical review

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1. Executive summary

During the revision of Directive 88/378/EEC on the Safety of Toys, ANEC and BEUC expressed strong concerns about inadequate chemical requirements. The new Toy Safety Directive (2009/48/EC) was adopted in 2009 after 8 years of discussion.

Despite the concerns from ANEC and BEUC, the revised Directive will still permit the use of many dangerous chemicals, such as carcinogenic, allergenic and hormone disrupting substances, despite the potential risks to children’s health.

Since the second half of 2010, there has been growing criticism of the chemical requirements in the new Toy Safety Directive. The shortcomings are also acknowledged by several Member States. Following a presentation by ANEC at the Commission’s Expert Group meeting on the Safety of Toys in September 2010, and a proposal made by the Dutch delegation, a WG on chemicals in toys was created as a Subgroup of the Expert Group with the aim of gathering information on the chemical requirements in the Toy Safety Directive, and to make proposals within the legal framework for improving the chemical requirements of the Directive. The group first met in November 2010.

On the occasion of the second anniversary of the European Commission Subgroup on chemicals in toys, this ANEC-BEUC position paper presents a critical review of two years of discussions.

ANEC and BEUC have to conclude that very little progress has been made and that as a result, the Subgroup has failed its mission to protect children from dangerous chemical substances in toys, as most problems remain unsolved.

It has become clear that the significant shortcomings of the Directive, like the lack of a generic ban of CMR substances in toys intended for use by children under 36 months or in mouth-actuated toys, can be solved only by a fundamental revision of the chemical requirements of Directive 2009/48/EC. Such revision is unavoidable as it is unacceptable that the health of children should be ‘played’ with further.

2. Introduction

Both ANEC and BEUC expressed strong concerns about inadequate chemical requirements during the revision of the Toy Safety Directive (TSD, 2009/48/EC) which was adopted in 2009 after 8 years of discussion. The main points of criticism were and remain:

- The Directive lacks a Comitology procedure which would allow the adoption or modification of limits for all kinds of toys and all kinds of substances in a fast and flexible way (without having to change the whole piece of legislation in the European Parliament and the Council). This is currently possible only for allergenic fragrances and elements (points 11 and 13 of Part III of Annex II), and for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth (according to article 46).
- Requirements for CMR substances are not strict enough to protect children’s health because of the inadequate thresholds which are based on the classification of mixtures according to Regulation 1272/2008/EC on classification, labelling and packaging of substances and mixtures.
- Requirements for allergenic fragrances are deficient as in some cases only labelling is required. However, all listed fragrances should have been banned.
- Sensitizers other than allergenic fragrances are not covered.
- Some of the limits for elements have been increased and are questionable (e.g. lead, barium)
- Endocrine disrupting chemicals are not addressed.
- Persistent, bio-accumulative and toxic chemicals (PBT), as well as very toxic and very bio-accumulative (vPvB) chemicals, are substances of very high concern and should have been prohibited.
- Chemicals falling in other classes of dangerous substances such as “very toxic”, “toxic”, “harmful”, “corrosive”, “irritant” or non-classified (or not yet classified) substances which pose health hazards are not covered (or only in broad terms in Annex III point 1 of the TSD).
- Materials used in toys for children under 3 years should follow the principles of the plastic materials in contact with food legislation (No 10/2011), i.e. only approved substances should be allowed to be used.

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In fact, the Toy Safety Directive is not fit for purpose as it does not protect children from exposure to dangerous chemicals sufficiently. These shortcomings have also been acknowledged by several Member States.

Following a presentation by Dr Franz Fiala, on behalf of ANEC, at the European Commission’s Expert Group meeting on the Safety of Toys in September 2010 and a proposal from the Dutch delegation, a WG on chemicals in toys was created as a sub group of the Expert Group with the aim to advise the latter on chemical issues.

3. European Commission Subgroup on chemicals in toys: results of 2 years of work

The Subgroup had its first meeting in November 2010. Initially, expectations were high. But, following two years of work and discussion, the main results are:

- The only tangible outcome reached, resulting in a legal act, is an insignificant reduction of the cadmium values following an EFSA opinion suggesting a lower TDI value (Commission Directive 2012/7/EU). The old limits were: 23 mg/kg for scraped-off material, 1.9 mg/kg for dry material and 0.5 mg/kg for liquid material. The new limits are: 17 mg/kg for scraped-off material, 1.3 mg/kg for dry material and 0.3 mg/kg for liquid material. The limits correspond to 5% of the TDI value. The reduction is appreciated but does not make a big difference in practice.
- The current limits for lead in the TSD are the following: 13, 5 mg/kg in dry, brittle, powder-like or pliable toy material, 3, 4 mg/kg in liquid or sticky toy material and 160 mg/kg in scraped-off toy material. Based on a Commission proposal, Member States agreed to reduce the limits for lead (again following an EFSA opinion). However, in this case not a 5% allocation was used as in case of cadmium but a 10% allocation resulting in the following values: 4 mg/kg in dry, brittle, powder-like or pliable toy material, 1 mg/kg in liquid or sticky toy material and 47 mg/kg in scraped-off toy material. ANEC and BEUC consider these values are twice the appropriate levels. We recall point 22 of the preamble to the TSD which requests limits for arsenic, cadmium, chromium VI, lead, mercury and organic tin at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee. This has so far been ignored by the Commission. Even worse, industry objected to the lowering, claiming certain products such as writing instruments are not able to fulfil the requirements. Hence, the Commission was obliged to carry out an impact assessment. As a result, the adoption of the new limits will be much delayed, and possibly the requirements will be diluted, e.g. by introducing exceptions for certain toys. ANEC and BEUC object to this and call for a further reduction of the limits by a factor of 2.
- In addition, the Commission plans to ban the flame retardant TCEP (and possibly some similar substances) in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth following an opinion of the scientific committee SCHER. However, ANEC and BEUC believe that the ban of TCEP should be extended to all toys which, however, cannot be done using the Comitology procedure without a change of the Directive, and should include its halogenated alternatives TCPP and TDCP which are

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also subjects of the SCHER opinion. It remains to be seen whether the Commission will follow this suggestion.

- The Commission plans setting limits for the release of the reprotoxic substance formamide (found in puzzle mats) in line with French regulatory measures, i.e. $40\mu\text{g}/\text{m}^3$ for 7 days or $20\mu\text{g}/\text{m}^3$ for 28 days to cover inhalation exposure. This intention is certainly positive.
- We welcome that kathone, a preservative used in finger paints and a strong sensitizer, will also be banned. This is in particular a positive change bearing in mind that the substance is permitted in the European Standard for finger paints.
- The current barium limit in the new TSD is not only 30 times higher than the one stipulated by WHO, but significantly higher than the previous limit in EN 71-3, itself based on the bioavailability limits of the old TSD. Following a call from ANEC for a significant reduction in the limit, the Commission asked SCHER for an opinion. Unfortunately SCHER did not follow the position of the WHO and called for a reduction by only a factor of 3. ANEC believes the lower level should be used when two scientific committees disagree on the appropriate safety level. However, the Commission will follow SCHER rather than WHO.

4. Most problems remain unsolved

Although some of the steps described above can be seen as moves in the right direction, the overall outcome is wholly inadequate. The main problems are still unsolved. This includes:

- The Commission rejected ANEC's call for a generic ban on CMR substances in toys intended for use by children under 36 months, or in other toys intended to be placed in the mouth, using a low level of detection of 0,01 mg/kg (10 ppb) based on a dynamic migration test (head-over-heels), such as the one contained in EN 71-10 (to be modified). It was further suggested by ANEC that equivalent approaches be used for volatile CMR substances and the dermal contact route. The argument of the Commission is that article 46, point 2 of the TSD allows only the setting of limits for specific substances and not generic ones. It reads: "*The Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth....*". However, this is not the only possible interpretation, as one could also interpret "specific" as related to the user group or toy category complementing generic chemical requirements for all kinds of toys. This is a severe limitation which prevents practical and comprehensive solutions and would be extremely time consuming. Instead of adopting a generic ban, the Commission suggests to ban (a few) individual CMR substances. This is not acceptable and falls behind provisions of other pieces of legislation (e.g. the general ban of CMR substances in the Cosmetics Regulation). Following the interpretation of the Commission, a revision of the TSD is necessary.
- Further, the general limits for CMR substances included in the TSD for all kinds of toys which are based on thresholds for the classification of chemical mixtures according to the CLP Regulation () allowing e.g. up to 1% of a category 2 carcinogen or up to 3% of a category 2 substance toxic for reproduction are entirely inadequate. In fact, such substances should be completely eliminated from toys. It should not be forgotten that children under three years also play with toys intended for older children. At a minimum the generic content based CMR limits should be reduced to 0,01% with stricter limits for certain CMR substances where required. Again this would need a change of the TSD.
- The above mentioned article 46, point 2 of the TSD also asks to take into account legislation in the field of food contact materials: "*... taking into account the packaging requirements for food as laid down in Regulation (EC) No 1935/2004 and the related specific measures for particular materials, as*

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well as the differences between toys and materials which come into contact with food". It should be noted that the most important of these specific measures – the Commission Regulation on plastic materials and articles intended to come into contact with food (No 10/2011) - includes an approval system (positive list) as requested by ANEC for toys for children under 36 months, or in other toys intended to be placed in the mouth. However, the Commission judged that the adoption of the positive-list approach is not in compliance with article 46. However, this is a pillar of the protection philosophy in the food contact area. It is difficult to envisage how the latter can be taken into account (as the TSD requires) when the most essential concept behind it is ignored. In ANEC's opinion it would not be very difficult to convert the limits contained in the regulation on plastic materials in contact with food into toy limits (ANEC had even provided suggestions how this could be accomplished). Clearly this approach would cover only plastics materials for the time being (and even here gaps would be left) and would have to be complemented step by step with rules for other materials. But it would have been a good start.

- Migration limits in the TSD for nitrosamines and nitrosatable substances in toys intended for use by children under 36 months, or in other toys intended to be placed in the mouth (0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosatable substances), are inadequate as the Commission itself has admitted in its response to the German request to maintain the more stringent national values of 0,01 mg/kg and, respectively, 0,1 mg/kg). The changes, however, cannot be made by Comitology and requires a revision of the Directive.
- The opinion by SCCS concerning "Fragrance allergens in cosmetic products", adopted in June 2012¹, stated that many more fragrance substances than those identified in the SCCNFP opinion of 1999 (on which some provisions of the Cosmetics Regulation are based, and which formed the basis of the TSD requirements) have been shown to be sensitizers in humans. The substances which are listed in this SCCS opinion need to be evaluated with respect to toys. Changes could accordingly be made through Comitology.
- Sensitizers other than allergenic fragrances must be banned as a group.
- Limits for lead and barium should be set as described above.
- Probably as a result of industry lobbying, biocides used in toys were exempted from the authorization requirement for biocides when the

¹ Scientific Committee on Consumer Safety: Opinion on fragrance allergens in cosmetic products, June 2012, SCCS/1459/11.

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Regulation "concerning the making available on the market and use of biocidal products" (No 528/2012) was approved (the exemption was introduced in the final deliberations). This means that biocides used in toys do not need to be authorized. This is a serious omission. We call for either an approval system for biocides to be introduced in the TSD, or to remove the exemption for toys in the biocidal products regulation.

- Endocrine disrupting chemicals (EDCs) need to be addressed in toys. As EDCs are currently neglected in the TSD, we call for the implementation of a suitable Comitology procedure (which is not limited to toys intended for use by children under 36 months, or toys intended to be placed in the mouth) by changing the Directive. Even if in the future a classification for EDCs and horizontal criteria will be developed, a product specific approach to tackle EDCs in toys is urgently needed.
- Persistent, bio-accumulative and toxic chemicals (PBT), as well as very toxic and very bio-accumulative (vPvB) chemicals, need to be banned. Again this would be possible only by changing the Directive for all kinds of toys.
- Chemicals falling in other classes of dangerous substances such as “very toxic”, “toxic”, “harmful”, “corrosive”, “irritant” or non-classified (or not yet classified) substances which pose health hazards must be addressed.
- Sufficient resources must be made available by the Commission and the Member States to systematically identify, assess and regulate chemicals in toys.
- The TSD must be made fit for purpose by introducing a Comitology allowing the adoption or modification of limits for all kinds of toys and all kinds of substances in a fast and flexible way.

5. Conclusions

After 2 years of operation of the European Commission subgroup on chemicals in toys, we have to conclude that the subgroup has failed its mission. Very little progress was made and it is unlikely that things will change to the better.

From the date of its full implementation in July 2013, the revised Toy Safety Directive will still permit the use of many dangerous chemicals, such as carcinogenic, allergenic and hormonal disrupting substances, despite the potential risks to children’s health.

From the work done by the Commission subgroup, it has become clear that the significant shortcomings of the Directive, like the lack of adequate provisions to generally exclude any exposure to CMR substances, particularly in toys intended for use by children under 36 months or in mouth actuated toys, can be solved only by a fundamental revision of the chemical requirements of the Directive, rather than by using the limited Comitology procedure. Such revision is unavoidable as it is unacceptable that the health of children should be ‘played’ with further.

ANEC and BEUC consider the approach on chemicals in toys deeply flawed and insist that fundamental changes are needed to protect children adequately from exposure to chemicals in toys. ANEC and BEUC calls upon policy makers to take the health of the youngest and most vulnerable of consumers more seriously, and to significantly strengthen the chemical requirements in the Toy Safety Directive.

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- ANEC position on SCHER opinion: “Risk from organic CMR substances in Toys. See [ANEC-CHILD-2010-G-092](#).
- ANEC position on SCHER opinion: “Evaluation of the migration limits for chemical elements in toys”. See [ANEC-CHILD-2010-G-093](#).
- ANEC proposal for the coverage of organic CMR substances in toys for children below 36 months and for mouth actuated toys. See [ANEC-CHILD-2011-002](#).
- ANEC proposal on a barium limit value for toys. See [ANEC-CHILD-2011-015](#).
- ANEC/BEUC position paper: flame retardant TCEP should be banned from all toys. See [ANEC-CHILD-2012-G-004final](#).
- ANEC/BEUC position on reducing children's exposure to lead from toys. See [ANEC-CHILD-2012-G-081](#).

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